

From: s22
To: Minister Butler DLO; MPS
Cc: SYME, Sarah; BEDFORD, Chris; MPS; GILMOUR-WALSH, Bridget; EDLINGTON, Mandy; LAWLER, Tony; s22
Subject: RE: Waiver request [SEC=OFFICIAL]
Date: Friday, 7 June 2024 12:49:38 PM
Attachments: image002.png
image003.png

Thanks s22

Critical date has been updated and approved waiver uploaded to the PDR.

Cheers,

s22

s22

s22

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
📧: s22 | 💻: s22 @health.gov.au

This email comes to you from Ngunnawal Country
Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Friday, June 7, 2024 12:31 PM
To: s22 @health.gov.au; MPS <MPS@health.gov.au>
Cc: SYME, Sarah <Sarah.Syme@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; MPS <MPS@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au;
s22 @Health.gov.au; s22
s22 @health.gov.au; s22 @health.gov.au; s22
s22 @Health.gov.au
Subject: RE: Waiver request [SEC=OFFICIAL]

Yes, happy to support the waiver.

Thank you!

s22

From: s22 @health.gov.au>
Sent: Friday, June 7, 2024 12:26 PM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>; MPS <MPS@health.gov.au>
Cc: SYME, Sarah <Sarah.Syme@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>;
 MPS <MPS@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; LAWLER,
 Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>;
 s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: Re: Waiver request [SEC=OFFICIAL]
Importance: High

Thanks s22

We will amend the critical date to 11 June. Are you ok to then grant the waiver on this basis?

@MPS can you please change this for us I. The system as I am unable to.

Cheers,

s22

Get Outlook for iOS

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Friday, June 7, 2024 12:12:35 PM
To: s22 @health.gov.au>
Cc: SYME, Sarah <Sarah.Syme@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>;
 MPS <MPS@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; LAWLER,
 Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>;
 s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: Waiver request [SEC=OFFICIAL]

Hi all

I've spoken with s22 and the preference is for the submission to be progressed today with a critical date of Tuesday 11 June as the Minister will have discussions with colleagues upon receiving advice in the submission today and will then confirm a decision to then seek PM authority for amendments early next week.

Happy to discuss if any concerns.

Thanks

s22

s22 (he/him)
Departmental Liaison Officer
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
T: s22 M: s22
E: Minister.Butler.DLO@health.gov.au
Suite MG.50 | PO Box 6022
Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @health.gov.au>
Sent: Friday, June 7, 2024 11:55 AM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: SYME, Sarah <Sarah.Syme@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; MPS <MPS@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; LAWLER, Tony <Anthony.LAWLER@Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: Waiver request [SEC=OFFICIAL]
Importance: High

Dear DLOs,

Please find below waiver request.

Please let us know if you require anything further,

Cheers,

s22

MS number	MS24-000724
Subject	Vaping Scheduling Information - Comparison of Regulatory Models
Critical date	Tuesday, 11 June 2024
Brief summary of submission	The submission provides information for the Minister to support discussions on the Vaping Bill with both parliamentary and jurisdictional colleagues.
Why is a waiver to the 5 day critical date rule required?	A waiver is required to enable these discussions before the

Note – this must include why the critical date can not be extended to allow the Minister’s Office more than 5 days to consider the submission.

Bill is further debated in the Senate, so that the proposed Government amendments can be progressed, if required, to facilitate passage of the Bill through the Parliament prior to the proposed commencement date of 1 July 2024.

What is the risk to the Minister/Department or Agency if the critical date is not met?

If the critical date of Friday 7 June 2024 is not met there is a risk that the Government Amendments to the Bill may not be expeditiously progressed for introduction in the Senate to support passage of the Bill prior to the proposed commencement date of 1 July 2024.

What is preventing/has prevented the Department/Agency providing this Ministerial Submission at an earlier date?

On 6 June 2024 the Minister’s chief advisor discussed the proposed amendments with Professor Lawler and Dr Gilmour-Walsh, and requested detailed information on them be provided at the earliest possible date.

When will the Ministerial Submission be provided to the Minister’s Office?

Bu COB Friday 7 June 2024

Note – if this date is not met, a new waiver must be requested

Waiver approved by

s22

Cheers,

s22

s22

s22

Health Products Regulation Group
Australian Government, Department of Health and Aged Care
: s22 | : s22 @health.gov.au

This email comes to you from Ngunnawal Country
Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: EDLINGTON, Mandy
To: Minister Butler DLO; s22
Cc: GILMOUR-WALSH, Bridget; BEDFORD, Chris; GOODCHILD, Tiali; s22 ; MCLAY, Nicole; s22
Subject: FW: CIRCULATED - 2R - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]
Date: Monday, 24 June 2024 6:09:00 PM
Attachments: image001.jpg
 image002.png
 2676 2R Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 Roberts.docx
 image004.png
 image003.png
Importance: High

Dear s22

Please find **below** proposed talking points in response to the 2RA from Senator Roberts, which have been prepared in conjunction with s22 and cleared by BGW.

The Government does not support the second reading amendment moved by Senator Roberts.

Confiscation of vapes in schools by teachers is a matter for state and territory education departments.

The Government's reforms are not intended to penalise individual users, particularly not young persons who need our support.

The Department of Health and Aged Care is cooperating with state and territory health departments about the use of vapes by students.

The Department has engaged with the Department of Education to inform schools about:

- the vaping reforms that are being implemented throughout 2024;
- the resources available to support student education about vapes in their jurisdictions; and
- available guidance on cessation support for students who are using vapes and having trouble quitting.

Joint letters from the Commonwealth, state and territory governments were distributed to school principals informing them about these matters and the importance of the reforms to protect students from this public health threat.

The Department is working with the state and territory health departments on the options for the surrender and disposal of vapes.

With thanks

Mandy Edlington

General Counsel (Acting)

Vaping Legislative Reform Branch
 Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 2910 | E: mandy.edlington@health.gov.au
 PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>

Sent: Monday, June 24, 2024 5:22 PM

To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; BEDFORD, Chris <Chris.Bedford@health.gov.au>; s22
s22 @health.gov.au>

Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; legislation <legislation@health.gov.au>

Subject: FW: CIRCULATED - 2R - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]

Hi all

Please see attached second reading amendment to be moved by Senator Roberts. The MO position is to **oppose**.

Could we please have a short set of TPs to support debate? We will need these by **6pm tonight**.

Thanks

s22

Departmental Liaison Officer

Office of the Hon Mark Butler MP

Minister for Health and Aged Care

T: s22 | M: s22

E: Minister.Butler.DLO@health.gov.au

Suite MG.50 | PO Box 6022

Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Senate Parliamentary Liaison Office <SenatePLO@pmc.gov.au>

Sent: Monday, June 24, 2024 5:09 PM

To: s22 @Health.gov.au>; s22 @health.gov.au>;

Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>; s22

s22 @health.gov.au>; s22 @pmc.gov.au>; legislation

<legislation@health.gov.au>

Cc: s22 (Sen P. Wong) s22 @aph.gov.au>;

s22 @aph.gov.au' s22 @aph.gov.au>;

chieflaborwhip.senate@aph.gov.au>; s22 @pm.gov.au>; s22

s22 @finance.gov.au>; Senate Parliamentary Liaison Office

<SenatePLO@pmc.gov.au>; s22 (Sen A. Urquhart) s22 @aph.gov.au>;

s22 @finance.gov.au>; s22 @pm.gov.au>

Subject: CIRCULATED - 2R - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]

OFFICIAL

Please find attached a second reading amendment to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, to be moved by Senator Roberts on behalf of the Pauline Hanson's One Nation Party:

2676

Kind regards,

Mark

Mark McCormack

Assistant Secretary | Parliamentary Liaison Officer to the Senate

Department of the Prime Minister & Cabinet

SG89 Parliament House, Canberra

p. (02) 6277 7597 | m. s22

Ngunnawal Country, One National Circuit, Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600

e. mark.mccormack@pmc.gov.au w. pmc.gov.au

The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

2676

2022-2024

The Parliament of the
Commonwealth of Australia

THE SENATE

Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

(Second reading amendment to be moved by Senator Roberts, on behalf of Pauline Hanson's One Nation)

At the end of the motion, add “, but the Senate:

- (a) notes that there is significant uncertainty in relation to power of teachers to confiscate and destroy vapes found in the possession of students on school grounds; and
- (b) calls on the Government to work with state and territory governments to establish a regime authorising teachers to confiscate and destroy vapes found in the possession of students on school grounds”.

From: EDLINGTON, Mandy
To: s22
Cc: GILMOUR, WA, SH, Bridget; s22
s22
s22
DUTAY, Nicole; s22
REBEKA, Avi; s22
GOODCHILD, Tjia; s22
@health.gov.au;
Subject: RE: For urgent action - ODC TPs - Due by 9.30am [SEC=OFFICIAL]
Date: Monday, 24 June 2024 10:11:00 AM
Attachments: Talking points (import licences and permits and applicable standards).docx
image001.png
image005.png

Dear s22

Please find **attached** talking points on importation requirements and applicable standards cleared by BGW.

With thanks

Mandy Edlington

General Counsel (Acting)

Vaping Legislative Reform Branch
Regulatory Legal Services Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: 02 6289 2910 | E: mandy.edlington@health.gov.au
PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 [mailto:s22@health.gov.au]

Sent: Monday, June 24, 2024 7:18 AM

To: s22 [REDACTED]@Health.gov.au>

Cc: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>.

[REDACTED]@Health.gov.au>; GOODCHILD, Tiali <Tiali.Goodchild@health.gov.au>; [REDACTED]
s22 [REDACTED]@health.gov.au>; Minister Butler DLO
<Minister.Butler.DLO@Health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.Gil.MOUR-WALSH@Health.gov.au>

Subject: RE: ODC TPs [SEC=OFFICIAL]

Good morning

Acknowledging I've seen your email and will confirm someone is actioning.

Thanks

s22 (she/her)

Regulatory Legal Services Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: [REDACTED] | E: [REDACTED]@health.gov.au
Location: Gulana, Fairbairn ACT, 2N.454
PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [mailto:s22@Health.gov.au]

Sent: Monday, June 24, 2024 7:14 AM

To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>

Cc: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>:

Tiali.Goodchild@health.gov.au; GOODCHILD, Tiali <Tiali.Goodchild@health.gov.au>

s22 @health.gov.au>; Minister Butler DLO

<Minister.Butler.DLO@Health.gov.au>

Subject: ODC TPs [SEC=OFFICIAL]

Morning,

Can we please have some very brief TPs on the Office of Drug Control and regulations/ standards for vapes under this model.

Can these be with us by 9.30am.

Best,

s22

s22

Office of the Hon Mark Butler

Minister for Health and Aged Care

M: s22

E: s22 @health.gov.au

PO Box 6022, Parliament House, Canberra ACT 2600, Australia

I acknowledge the Traditional Custodians of the land on which I work and their continued connection to land, sea and community. I pay my respects to all Elders past and present.

Talking points – import requirements and standards for vapes

- Under customs regulations, vaping goods can only be imported into Australia if the goods are therapeutic vaping goods and the importer has a licence and permission to import the vaping goods.
- There are a small number of exceptions, including for travellers who can import a small quantity of vaping goods for their own treatment or the treatment of a person under their care.
- Licences and permissions are processed and issued by the Office of Drug Control (ODC) within the Department of Health and Aged Care.
- To obtain a permission to import a vaping good, an importer must have notified the TGA that the vaping goods comply with TGA standards. These are:
 - the TGA standard *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110); or
 - the applicable essential principles (these are standards for medical devices), set out in the *Therapeutic Goods (Medical Devices) Regulations 2002* (MD Regulations);
- A notification to the TGA is also required for a person to lawfully manufacture or supply vaping goods in Australia, under the applicable exemptions for unapproved therapeutic vaping goods.
- Between 1 January 2024 and 19 June 2024, the TGA received 795 valid notifications for nicotine vapes (including vaping substances, vaping accessories and vaping devices) that may be supplied in pharmacies for smoking cessation or the management of nicotine dependence.
- In the same period, ODC granted 45 import licences and 329 import permissions for vapes that can be supplied in Australia, under the new border controls.
- TGO 110 includes requirements designed to ensure the safety of therapeutic vaping goods, by prohibiting the use of known dangerous ingredients, requiring the amount of nicotine in the vaping good to be within specified limits, specifying child-resistant packaging requirements and limiting flavours to mint or menthol, or tobacco.
- The essential principles set out benchmarks for the safety and performance of medical devices, including that a medical device must not compromise the clinical condition or safety of a patient and must perform in the way intended by the manufacturer.
- Sponsors of vaping devices that were excluded from the therapeutic goods regulatory framework prior to 1 January 2024 may demonstrate compliance with the essential principles by complying with a new medical device standard for vaping devices. The medical device standard can be complied with by meeting certain international standards. Sponsors and manufacturers are familiar with these standards as key international benchmarks for quality management of product design and manufacture.
- The TGA is continuing to consult industry, health representative bodies and other stakeholders to further strengthen both TGO 110 and the standard for vaping devices. Further amendments are expected to be made in the near future to strengthen the regulatory requirements.

From: EDLINGTON, Mandy
To: s22
Cc: HENDERSON, Nick; GILMOUR-WALSH, Bridget; s22
Subject: Amendment regulation package (soft copies) [SEC=OFFICIAL]
Date: Sunday, 23 June 2024 12:20:00 PM
Attachments: MS24-000781.docx
Attachment A - Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.docx
Attachment B - Minute paper - Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.docx
Attachment C - Explanatory memorandum - Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.docx
Attachment D - Explanatory statement - Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.docx
image001.png
Importance: High

Dear s22

Confirming that the regulation amendment package **attached** has been cleared by BGW and Nick Henderson (Acting Deputy Secretary) and submitted through PDMS today.

With thanks

Mandy Edlington

General Counsel (Acting)

Vaping Legislative Reform Branch
Regulatory Legal Services Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: 02 6289 2910 | E: mandy.edlington@health.gov.au
PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.



Australian Government

Department of Health and Aged Care

Ministerial Submission – Standard

MS24-000781

Version (1)

Date sent to MO: 23 June 2024

To: Minister Butler

cc:

Subject: Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Critical date: 8:00AM Monday 24 June 2024 so that the regulation package to be provided to Department of the Prime Minister and Cabinet by 9:00AM on Monday 24 June 2024 to enable the Governor-General's consideration at the special Executive Council meeting on Friday 28 June 2024. If this critical time and date is not met, we have been advised that the proposed regulations will likely not progress to the special meeting.

Recommendations – that you:

1. APPROVE the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (Attachment A)	1. Approved/Not approved/Please discuss
2. SIGN (BUT NOT DATE) the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (Attachment A)	2. Signed/Not signed/Please discuss
3. SIGN (BUT NOT DATE) the Executive Council Minute for the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (Attachment B)	3. Signed/Not signed/Please discuss
4. INITIAL EACH PAGE of the explanatory memorandum for the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (Attachment C)	4. Initialled/Not initialled/Please discuss
5. APPROVE the explanatory statement for the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (Attachment D)	5. Approved/Not approved/Please discuss

Signature

Date: / /

Comments:

Contact	Dr Bridget	Principal Legal and Policy Adviser,	Ph: (02) 6289 4290
Officer:	Gilmour-Walsh	Health Products Regulation Group	Mobile: s22
Clearance	Nick Henderson	Acting Deputy Secretary, Health	Ph: (02) 6289 4270
Officer:		Products Regulation Group	Mobile: s22

Issues:

- On 4 June 2024, you approved the preparation of amendments to the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to support key elements of the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) and to make a number of minor, consequential amendments to reflect the reforms introduced by the Bill. s34
[REDACTED], your policy approval was obtained for the remaining proposed regulation amendments (MS24-000575).
- Principally, the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 (the proposed regulations) would:
 - prescribe the quantities of vaping goods that would amount to a commercial quantity for the purposes of the offences and civil penalty provisions for possessing such quantities of vaping goods;
 - prescribe units of vaping goods for the purposes of the new civil penalty provisions introduced by the Bill for importing, manufacturing, supplying or possessing vaping goods, with the effect that a person who contravenes those civil penalty provisions will do so in respect of each such unit imported, manufactured, supplied or possessed, as part of ensuring that the reforms effectively deter dealings in unlawful vaping goods;
 - prescribe the quantities of vaping goods that would amount to a permitted quantity for the purposes of an exception to the offence and civil penalty provision for possessing less than a commercial quantity in retail premises;
 - make minor modifications to update existing exemptions for therapeutic vaping goods to ensure consistency with the Bill;
 - introduce transitional arrangements for certain therapeutic goods that would otherwise be unlawful upon the Bill's commencement; and
 - extend the definition of 'protected persons' to state and territory officials to whom certain powers and functions are proposed to be delegated under the Act.
- Separately, you provided your policy approval on 28 May 2024 to the preparation of regulation amendments to recognise Western Australia's recent *Therapeutic Goods Law Application Act 2024* (WA) as a corresponding state law under the *Therapeutic Goods Act 1989* (MS24-000583). The proposed regulations would also implement this measure.

Attachments:

- A:** Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.
- B:** Executive Council minute paper for the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.
- C:** Explanatory memorandum for the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.
- D:** Explanatory statement for the proposed Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024.

Sensitivities:

The proposed reforms continue to generate interest in the community and criticism from some importers, manufacturers, retailers and consumers of non-therapeutic vapes. There is, however, clear and public support from health professionals, academia, professional representative organisations, educators and parent representative groups.

Negotiations with the Greens about commercial quantities continue. If the quantities change following those negotiations, urgent instructions will need to be provided to the Office of Parliamentary Counsel to amend the proposed regulations, and updates will need to be made to the explanatory material, and approved by you, to reflect the new numbers. The Executive Council Secretariat would need to be advised so that the papers may be withdrawn, amended and resubmitted.

The making of the regulations is anticipated to occur at a special meeting of the Federal Executive Council on Friday 28 June 2024. The Bill will need to be passed both houses this week and receive Royal Assent from the Governor-General before the proposed regulations may be made.

Consultations:

The department has been consulting a range of stakeholders on the proposed amendments to the Regulations, including jurisdictional health departments, to ensure that they are fit for purpose.

Regulatory Burden Implications and/or Deregulation Opportunities:

An impact analysis (IA) was prepared on the proposed vaping reforms to support the policy approval. The Office of Impact Analysis (OIA) considered the impact analysis to demonstrate *good practice*, consistent with Australian Government best practice regulation requirements (OIA23-03933). The IA is published on the OIA's website.

Minister	Minister Butler
PDR Number	MS24-000781
Subject	Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024 and Replacement Explanatory Memorandum for the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024
Critical Date	Sunday, 23 June 2024
Contact Officer	Dr Bridget Gilmour-Walsh Ph: (02) 6289 4290 Mobile: s22
Clearance Officer	Nick Henderson Ph: (02) 6289 4270 Mobile: s22
Division/Branch	Health Products Regulation Regulatory Legal Services Unit
Has Budget Branch been consulted if there are financial implications?	Not Applicable
Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Please complete

Quality Assurance Check (completed by line area)	Mandy Edlington, Acting Assistant Secretary, Vaping Legislative Reform Branch, Health Products Regulation Group Mobile: s22

Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

I, General the Honourable David Hurley AC CVO DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 2024

David Hurley
Governor-General

By His Excellency's Command

Mark Butler
Minister for Health and Aged Care

Contents

1	Name.....	1
2	Commencement	1
3	Authority.....	1
4	Schedules	2
Schedule 1—Main amendments		3
Part 1—Amendments		3
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		3
<i>Therapeutic Goods Regulations 1990</i>		6
Part 2—Transitional provisions		11
<i>Therapeutic Goods (Medical Devices) Regulations 2002</i>		11
<i>Therapeutic Goods Regulations 1990</i>		12
Schedule 2—Commercial quantities		14
<i>Therapeutic Goods Regulations 1990</i>		14
Schedule 3—Other amendments		15
<i>Therapeutic Goods Regulations 1990</i>		15

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	At the same time as Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence.	
2. Schedule 1	At the same time as Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence.	
3. Schedule 2	The day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i> commence.	
4. Schedule 3	The later of: (a) immediately after the commencement of Parts 1 to 3 of Schedule 1 to the <i>Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024</i>; and (b) immediately after the commencement of Part 2 of the <i>Therapeutic Goods Law Application Act 2024</i> (WA). However, the provisions do not commence at all if the event mentioned in paragraph (b) does not occur.	
Note:	This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.	
(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.		

3 Authority

This instrument is made under the *Therapeutic Goods Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Main amendments

Part 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

1 Paragraph 10.6(2)(a)

Omit “registered in a State or internal Territory and”.

2 Part 1 of Schedule 4 (table item 1.1, column headed “Kinds of medical devices”, paragraph (d))

Omit “registered under a law of a State or Territory”.

3 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraph (b))

Repeal the paragraph, substitute:

(b) The sponsor notice must be given as follows:

- (i) for a device imported into Australia on or after 1 March 2024—before the device is imported;
- (ii) for a device imported into Australia before 1 March 2024—before the earlier of the time the device is supplied to the ultimate consumer and the end of the period of 2 months beginning on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences;
- (iii) for a device manufactured in Australia on or after 1 March 2024—before the device is first supplied in Australia;
- (iv) for a device manufactured in Australia before 1 March 2024—before the earlier of the time the device is supplied to the ultimate consumer and the end of the period of 2 months beginning on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences.

4 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, paragraph (g))

Repeal the paragraph, substitute:

(fa) The sponsor must:

- (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the device; and
- (ii) do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary’s request is made).

(fb) The sponsor must allow an authorised officer:

- (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the device; and
- (ii) while on those premises, to inspect those premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on those premises that relates to the device; and
- (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises.

(fc) The sponsor must, if requested to do so by an authorised officer, produce to the authorised officer such documents relating to the device as the authorised officer requires and allow the authorised officer to copy the documents.

(fd) If the sponsor is not the manufacturer of the device, the sponsor must have procedures in place to ensure that the manufacturer of the device allows an authorised officer:

Schedule 1 Main amendments**Part 1 Amendments**

- (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the manufacturer or any other person deals with the device; and
 - (ii) while on those premises, to inspect those premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on those premises that relates to the device; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises.
- (fe) If the sponsor is not the manufacturer of the device, the sponsor must have procedures in place to ensure that the manufacturer of the device, if the manufacturer is requested to do so by an authorised officer, produces to the authorised officer such documents relating to the device as the authorised officer requires and allow the authorised officer to copy the documents.
- (g) The device may be supplied to a person who is not the ultimate consumer of the device only if:
- (i) the person (the **recipient**) to whom the device is supplied is the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of vaping goods; or
 - (ii) the recipient is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed; or
 - (iii) the Secretary has given the recipient a consent under subsection 41RC(1) of the Act to supply the device; or
 - (iv) in the case of a device that is covered by a determination made by the Minister under section 41R of the Act—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to the device.

5 Part 2 of Schedule 4 (table item 2.17, column headed “Conditions”, subparagraph (h)(ii))

Repeal the subparagraph, substitute:

- (ii) the supply is by a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed; and

6 Part 2 of Schedule 4 (table item 2.18, column headed “Kinds of medical devices”, paragraphs (a) and (b))

Repeal the paragraphs, substitute:

- (a) a therapeutic vaping device; or
- (b) a therapeutic vaping device accessory; or
- (c) a therapeutic cannabis vaping good

7 Part 2 of Schedule 4 (table item 2.18, column headed “Conditions”, paragraph (a))

Omit “or a therapeutic vaping device accessory”, substitute “, a therapeutic vaping device accessory or a therapeutic cannabis vaping good”.

8 Part 2 of Schedule 4 (table item 2.18, column headed “Conditions”, after paragraph (b))

Insert:

- (ba) The sponsor must:
 - (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the device; and
 - (ii) do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary’s request is made).

9 Dictionary (paragraph (a) of the definition of *health professional*)

Before “a dentist”, insert “or”.

10 Dictionary (definition of *medical practitioner*)

Repeal the definition.

11 Dictionary (paragraphs (a) and (b) of the definition of *serious*)

Before “dentist”, insert “or a”.

12 Dictionary (paragraphs (a) and (b) of the definition of *therapeutic cannabis vaping device*)

Repeal the paragraphs, substitute:

- (a) is a vaping device, other than:
 - (i) a disposable therapeutic vape (within the meaning of the *Therapeutic Goods Regulations 1990*); or
 - (ii) a component or article imported for use in the manufacture of a therapeutic cannabis vaping device; and
- (b) is intended, by the person under whose name the device is or is to be supplied, to be used only to administer medicinal cannabis products (within the meaning of that instrument) or medicines containing synthetic cannabis.

13 Dictionary (definition of *therapeutic cannabis vaping device accessory*)

Repeal the definition, substitute:

therapeutic cannabis vaping device accessory means a therapeutic good that is an unfilled cartridge, capsule, pod or other vessel:

- (a) that is designed or intended only for use in, or with, a therapeutic cannabis vaping device; and
- (b) that is designed or intended to contain a therapeutic vaping substance; and
- (c) whether or not the cartridge, capsule, pod or other vessel is designed or intended to be refilled.

14 Dictionary (definition of *therapeutic vaping device*)

Repeal the definition, substitute:

therapeutic vaping device means a therapeutic good that is a vaping device, other than:

- (a) a disposable therapeutic vape (within the meaning of the *Therapeutic Goods Regulations 1990*); or
- (b) a therapeutic cannabis vaping device.

15 Dictionary (definition of *therapeutic vaping device accessory*)

Repeal the definition, substitute:

therapeutic vaping device accessory means a therapeutic good that is an unfilled cartridge, capsule, pod or other vessel:

- (a) that is designed or intended for use in, or with, a therapeutic vaping device; and

Schedule 1 Main amendments
Part 1 Amendments

- (b) that is designed or intended to contain a therapeutic vaping substance; and
 - (c) whether or not the cartridge, capsule, pod or other vessel is designed or intended to be refilled;
- but does not include a therapeutic cannabis vaping device accessory.

Therapeutic Goods Regulations 1990

16 Regulation 2 (paragraph (a) of the definition of *disposable therapeutic vape*)

Omit “this regulation”, substitute “subsection 41P(1) of the Act”.

17 Regulation 2 (definition of *therapeutic vaping pack*)

Repeal the definition, substitute:

therapeutic vaping pack means a primary pack that:

- (a) contains at least one therapeutic vaping substance or therapeutic vaping substance accessory; and
- (b) contains at least one therapeutic vaping device or therapeutic vaping device accessory; and
- (c) does not contain any other therapeutic goods.

18 Regulation 2 (definition of *therapeutic vaping substance accessory*)

Repeal the definition, substitute:

therapeutic vaping substance accessory means a vaping accessory that:

- (a) is designed or intended for use in, or with, a therapeutic vaping device; and
- (b) contains a therapeutic vaping substance.

19 Regulation 2 (definition of *vaping device*)

Repeal the definition.

20 After Part 2E

Insert:

Part 2F—Vaping goods

10N Commercial quantity of vaping goods

For the purposes of the definition of ***commercial quantity*** in subsection 3(1) of the Act, the commercial quantity of a kind of vaping goods specified in column 1 of an item in the following table is the quantity of that kind of vaping goods specified in column 2 of the item.

Commercial quantity of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Quantity
1	Vaping device	9
2	Vaping accessory	90

Commercial quantity of vaping goods

	Column 1	Column 2
Item	Kind of vaping goods	Quantity
3	Vaping substance that is a liquid	300 ml

10P Unit of vaping goods

For the purposes of the definition of ***unit*** in subsection 3(1) of the Act, a ***unit*** of vaping goods means the quantity of the vaping goods specified in column 2 of an item in the following table for the kind of vaping goods specified in column 1 of the item.

Unit of vaping goods

	Column 1	Column 2
Item	Kind of vaping goods	Unit of vaping goods
1	Vaping device	1
2	Vaping accessory	10
3	Vaping substance that is a liquid	60 ml

10Q Permitted quantity

For the purposes of the definition of ***permitted quantity*** in subsection 41QD(10) of the Act, the prescribed quantity of a kind of vaping goods specified in column 1 of an item in the following table is the quantity specified in column 2 of the item.

Permitted quantity of vaping goods

	Column 1	Column 2
Item	Kind of vaping goods	Permitted quantity of vaping goods
1	Vaping device	1
2	Vaping accessory	3
3	Vaping substance that is a liquid	30 ml

21 After regulation 12B

Insert:

12BA Authorities for certain uses—therapeutic vaping substances that are not medicines

- (1) For the purposes of paragraph 19(6)(a) of the Act, in relation to therapeutic vaping substances that are not medicines (***authorised vaping substances***), medical practitioners engaged in clinical practice in or outside a hospital are a prescribed class of medical practitioners.
- (2) For the purposes of subsection 19(6) of the Act, paragraph 19(6)(aa) of the Act does not apply if the supply is of an authorised vaping substance by a medical practitioner to a patient of that practitioner, where:
 - (a) the authorised vaping substance is to be administered by inhalation; and

Schedule 1 Main amendments**Part 1 Amendments**

- (b) the supply is for the indication of the treatment of smoking cessation or management of nicotine dependence.
- (3) The class of recipients prescribed for the purposes of paragraph 19(6)(b) of the Act is the class of recipients consisting of persons each of whom is seeking treatment for smoking cessation or the management of nicotine dependence.
- (4) For the purposes of subsection 19(7) of the Act, the prescribed circumstances in which an authorised vaping substance, or a class of authorised vaping substances, may be supplied in accordance with an authority under subsection 19(5) of the Act are that the supplier of the authorised vaping substance or class of authorised vaping substances complies with the treatment directions (if any) mentioned in the authority for the authorised vaping substance or class of authorised vaping substances.

22 After regulation 46A

Insert:

46B Protected persons

For the purposes of paragraph (b) of the definition of *protected person* in subsection 62(3) of the Act, a person to whom powers or functions are delegated under subsection 57(1A) of the Act is prescribed.

23 Paragraph 47A(2)(a)

Omit “registered in a State or Territory and”.

24 After regulation 47B

Insert:

47C Enforceable directions

For the purposes of paragraph 42YT(2)(e) of the Act, the following things are prescribed:

- (a) quarantine the goods;
- (b) store the goods in a secure manner;
- (c) not supply the goods.

25 Schedule 5 (table item 1, column 2, paragraph (d))

Omit “registered under a law of a State or Territory”.

26 Schedule 5A (table item 15, column 2, paragraph d))

Omit “the sponsor”, substitute “for goods other than therapeutic vaping devices, or therapeutic vaping device accessories, in a therapeutic vaping pack—the sponsor”.

27 Schedule 5A (table item 15, column 3, paragraph (b))

Repeal the paragraph, substitute:

- (b) the sponsor notice must be given as follows:
 - (i) for goods imported into Australia on or after 1 March 2024—before the goods are imported;
 - (ii) for goods imported into Australia before 1 March 2024—before the earlier of the time the goods are supplied to the ultimate consumer and the end of the period of 2 months beginning

- on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences; and
- (iii) for goods manufactured in Australia on or after 1 March 2024—before the goods are first supplied in Australia; and
 - (iv) for goods manufactured in Australia before 1 March 2024—before the earlier of the time the goods are supplied to the ultimate consumer and the end of the period of 2 months beginning on the day Schedule 1 to the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* commences; and

28 Schedule 5A (table item 15, column 3, paragraphs (g) and (h))

Repeal the paragraphs, substitute:

- (fa) the sponsor must:
 - (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the goods; and
 - (ii) do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary's request is made); and
- (fb) the sponsor must allow an authorised officer:
 - (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the goods; and
 - (ii) while on those premises, to inspect those premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on those premises that relates to the goods; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
- (fc) the sponsor must, if requested to do so by an authorised officer, produce to the authorised officer such documents relating to the goods as the authorised officer requires and allow the authorised officer to copy the documents; and
- (fd) if the sponsor is not the manufacturer of the goods, the sponsor must have procedures in place to ensure that the manufacturer of the goods allows an authorised officer:
 - (i) to enter, at any reasonable time, any premises (including premises outside Australia) at which the manufacturer or any other person deals with the goods; and
 - (ii) while on those premises, to inspect those premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on those premises that relates to the goods; and
 - (iii) while on those premises, to make any still or moving image or any recording of those premises or any thing on those premises; and
- (fe) if the sponsor is not the manufacturer of the goods, the sponsor must have procedures in place to ensure that the manufacturer of the goods, if the manufacturer is requested to do so by an authorised officer, produces to the authorised officer such documents relating to the goods as the authorised officer requires and allow the authorised officer to copy the documents; and
- (g) for goods manufactured in Australia—either of the following apply:
 - (i) the goods are manufactured by a person who is the holder of a licence in force under Part 3-3 of the Act that authorises the manufacture of the goods, or the carrying out of the step in the manufacture of the goods, at the manufacturing site where the manufacture, or the step, is carried out;
 - (ii) the goods are manufactured by a person who is exempt in accordance with subsection 34(2) of the Act from the operation of Part 3-3 of the Act in relation to the manufacture of the goods and the Secretary has given the person a consent under subsection 41RC(1) of the Act to manufacture the goods, or carry out the step in the manufacture of the goods, and the manufacture, or the step, is carried out in accordance with the consent; and
- (h) the goods may be supplied to a person who is not the ultimate consumer of the goods only if:
 - (i) the person (the **recipient**) to whom the goods are supplied is the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods; or
 - (ii) the recipient is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in

Schedule 1 Main amendments**Part 1** Amendments

- Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed; or
- (iii) the Secretary has given the recipient a consent under subsection 41RC(1) of the Act to supply the goods; or
 - (iv) in the case of goods that are covered by a determination made by the Minister under section 41R of the Act—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods; and

29 Schedule 5A (table item 15, column 3, subparagraph (i)(ii))

Repeal the subparagraph, substitute:

- (ii) the supply is by a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed; and

30 Schedule 5A (table item 15, column 3, subparagraph (i)(iii))

Omit “the supply”, substitute “for goods other than therapeutic vaping devices, or therapeutic vaping device accessories, in a therapeutic vaping pack—the supply”.

31 Schedule 5A (table item 16, column 3, after paragraph (b))

Insert:

- (ba) the sponsor must:
 - (i) if requested by the Secretary, give the Secretary a reasonable number of samples of the goods; and
 - (ii) do so within the period requested by the Secretary (which must be at least 5 working days starting on the day on which the Secretary’s request is made); and

32 Schedule 7 (table items 22 and 23, column 2, subparagraph (a)(iii))

Omit “registered under a law of a State or Territory”.

Part 2—Transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

33 Regulation 11.73

Omit “on or after”, substitute “before, on or after”.

34 In the appropriate position in Part 11

Insert:

Division 11.22—Application provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

11.79 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

11.80 Application of amendments

- (1) The amendment made by item 3 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule.
- (2) The amendments made by items 4 and 5 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule.
- (3) The amendments made by items 6 and 7 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported on or after 1 October 2024.
- (4) The amendment made by item 8 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule.
- (5) The amendment made by item 12 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after 1 October 2024.

11.81 Transitional vaping devices—exemption from Division 3 of Part 4-11 of the Act

- (1) For the purposes of this regulation, medical devices that are exported from Australia are *transitional vaping devices* if:
 - (a) the devices are therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods; and
 - (b) the devices were imported into, or manufactured in, Australia before the commencement of Schedule 1 to the amending regulations; and

Schedule 1 Main amendments**Part 2** Transitional provisions

- (c) as at that commencement, the importation or manufacture, or any supply, of the devices was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

Exemption

- (2) For the purposes of paragraph 41HA(1)(b) of the Act, transitional vaping devices are exempt from the operation of Division 3 of Part 4-11 of the Act.

When exemption ceases

- (3) Subregulation (2) ceases to have effect at the end of the period of 6 months starting on the day Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* commence.

Therapeutic Goods Regulations 1990**35 Subregulation 96(5)**

Omit “on or after”, substitute “before, on or after”.

36 In the appropriate position in Part 9

Insert:

**Division 26—Application and transitional provisions relating to the
Therapeutic Goods Legislation Amendment (Vaping
Reforms) Regulations 2024**

104 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

105 Authorities for therapeutic vaping substances that are not medicines

Regulation 12BA, as inserted by Schedule 1 to the amending regulations, applies in relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Schedule.

106 Therapeutic vaping packs

The amendment made by item 17 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured on or after 1 October 2024.

107 Exempt goods

- (1) The amendment made by item 27 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule.

- (2) The amendments made by items 26 and 28 to 30 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule.
- (3) The amendment made by item 31 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule.

108 Transitional vaping goods—exemption from Part 3-2 of the Act

- (1) For the purposes of this regulation, therapeutic goods that are exported from Australia are *transitional vaping goods* if:
 - (a) the goods are therapeutic vaping goods; and
 - (b) the goods were imported into, or manufactured in, Australia before the commencement of Schedule 1 to the amending regulations; and
 - (c) as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

Exemption

- (2) For the purposes of subsection 18(1) of the Act, transitional vaping goods are exempt from the operation of Part 3-2 of the Act (except sections 30EA, 31A and 31C to 31F).

When exemption ceases

- (3) Subregulation (2) ceases to have effect at the end of the period of 6 months starting on the day Parts 1 to 3 of Schedule 1 to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* commence.

Schedule 2—Commercial quantities

Therapeutic Goods Regulations 1990

1 Regulation 10N (table)

Repeal the table, substitute:

Unit of vaping goods		
	Column 1	Column 2
Item	Kind of vaping goods	Unit of vaping goods
1	Vaping device	3
2	Vaping accessory	30
3	Vaping substance that is a liquid	100 ml

Schedule 3—Other amendments

Therapeutic Goods Regulations 1990

1 After paragraph 3(3)(bab)

Insert:

(bac) the *Therapeutic Goods Law Application Act 2024* (WA);

MINISTER FOR HEALTH AND AGED CARE

Departmental No.222 of 2024

Minute Paper for the Executive Council

Subject

Executive Council
Meeting No.

Therapeutic Goods Act 1989

*Therapeutic Goods Legislation Amendment (Vaping Reforms)
Regulations 2024*

Approved in Council

Recommended for the approval of His Excellency the
Governor-General in Council that he make Regulations in
the attached form.

.....
David Hurley
Governor-General

.....
Mark Butler
Minister for Health and Aged
Care

.....
Filed in the Records
of the Council

.....
Secretary to the Executive Council

EXPLANATORY MEMORANDUM

Minute No. 222 of 2024 - Minister for Health and Aged Care

Subject - *Therapeutic Goods Act 1989*

Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

The proposed instrument would support the *Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024* (the Amendment Act), which implements national vaping reforms, including by specifying the quantities of vaping goods that would constitute a commercial quantity for offences and civil penalties in the Amendment Act for possessing such quantities.

The *Therapeutic Goods Act 1989* (the Act) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods used in, whether produced in Australia or elsewhere, or exported from, Australia. Subsection 63(1) of the Act provides for the making of regulations not inconsistent with the Act, prescribing matters required or permitted by the Act, or necessary or convenient to be prescribed for carrying out or giving effect to the Act.

The *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the proposed Regulations) would amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to support the *Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024* (the Amendment Act). The Amendment Act implements the national vaping reforms to restrict the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods (particularly non-therapeutic and disposable vaping goods).

In particular, the proposed Regulations would support the Amendment Act by specifying commercial quantities and units of vaping goods for the purposes of new offences and civil penalty provisions introduced by the Amendment Act for possessing vaping goods as part of a suite of measures designed to address and deter illicit trade.

The proposed Regulations would also provide transitional arrangements under which certain therapeutic vaping goods that would otherwise be unlawful upon commencement of the Amendment Act could be dealt with, and make a small number of minor consequential amendments. The proposed Regulations would also allow for the supply or export of compliant vaping goods that were imported or manufactured prior to 1 March 2024, as part of transitional arrangements to assist sponsors to comply with the reforms.

The proposed Regulations would also make a small number of related amendments, including to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law for the purpose of the Act, and to update a small number of definitions and exemptions to ensure consistency between the Act and the TG Regulations and MD Regulations in relation to key terms.

The Therapeutic Goods Administration (TGA) has conducted two significant consultations in relation to these reforms largely implemented by the Amendment Act. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on proposed amendments to the regulation of nicotine vaping products in Australia. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communiqué of 1 September 2023, which conveyed Ministers' collective commitment to enhancing the regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding several webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for the Department of Health and Aged Care on regulatory measures to be implemented, including those that are implemented in these proposed Regulations.

In recent months, the TGA has undertaken extensive consultation with the states and territories on the commercial quantities of vaping goods prescribed in the Amendment Regulations, principally through the National E-Cigarette Working Group. The TGA also engaged with key stakeholders concerning the commercial quantities of vaping goods through the TGA Consultative Committee and TGA Industry Forum held on 17 May 2024. An impact analysis has been published on website of the Office of Impact Analysis at: oia.pmc.gov.au.

The Act specifies no conditions that need to be satisfied before the power to make the proposed Regulations may be exercised. The proposed Regulations would be a legislative instrument for the purposes of the *Legislation Act 2003*. The proposed Regulations would be made between enactment and commencement of the Amendment Act. Section 4 of the *Acts Interpretation Act 1901* confers upon the Governor-General the power to make regulations prior to the commencement of the Amendment Act. The Amendment Act received Royal Assent at the meeting of the Federal Executive Council on 28 June 2024, prior to consideration of the proposed Regulations.

Details of the proposed Regulations are set out in the Attachment.

The Minute recommends that the proposed Regulations be made in the form proposed.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT

Details of the proposed *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*

Section 1 – Name

This section would provide that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations).

Section 2 – Commencement

This section would provide for the commencement of the main amendments in Schedule 1 of the Amendment Regulations on the commencement of Parts 1 to 3 of Schedule 1 to the Amendment Act.

Schedule 2 repeals and replaces the commercial quantities specified in Schedule 1, and commences on the day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the Amendment Act commence. The delayed commencement of Schedule 2 is intended to provide a 3-month transition period to allow quantities of vaping goods that are below the commercial quantities specified in Schedule 1 to be depleted or disposed of as appropriate by persons who are not excepted from the offence and civil penalty provisions in the Act that apply to the possession of vaping goods in an amount equal to or exceeding the commercial quantity.

Schedule 3 commences on the later of the date that is immediately after the commencement of Parts 1 to 3 of Schedule 1 to the Amendment Act, or immediately after the commencement of Part 2 of the *Therapeutic Goods Law Application Act 2024* (WA). However, Schedule 3 does not commence at all if Part 2 of the *Therapeutic Goods Law Application Act 2024* (WA) does not commence.

Section 3 – Authority

This section would provide that the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations) would be made under the *Therapeutic Goods Act 1989*.

Section 4 – Schedules

This section would provide that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Main Amendments

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are still emerging.

The Government's vaping reforms are being implemented in stages over 2024. The Amendment Act is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms included amendments to the *Customs(Prohibited Imports) Regulations 1956*, the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.
- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an

import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.

- since 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standards.

The Amendment Regulations would support the Amendment Act to implement measures that are necessary to give effect to the second stage of reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. The primary intent is to prohibit the importation, domestic manufacture and supply vapes in Australia unless certain requirements under the Act are met. The reforms implemented in the Amendment Regulations align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Summary

Schedule 1 of the Amendment Regulations would principally amend the TG Regulations and the MD Regulations (collectively, the Principal Regulations) to refine the exemptions that facilitate the importation, domestic manufacture and supply in Australia of legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence; to prescribe commercial quantities that apply for a 3 month transitional period following the commencement of the Amendment Regulations; and to extend the definition of 'protected persons' for the purpose of subsection 62(3) of the Act to state and territory officials in certain circumstances.

Specifically, Schedule 1 would amend the TG Regulations and MD Regulations by:

- repealing the definitions of 'medical practitioner' and 'vaping device' and amending references to these terms throughout the Principal Regulations to reflect the application of the definitions of these terms inserted into the Act by the Amendment Act;
- extending the exemptions for notified therapeutic vaping goods, which are currently limited to therapeutic vaping goods that were imported or manufactured or after 1 March 2024, to therapeutic vaping goods that were imported or manufactured before 1 March 2024 where they meet current quality requirements;
- imposing new conditions on the exemptions for notified therapeutic vaping goods to require sponsors to provide a reasonable number of samples on request and to allow authorised officers to enter and inspect premises where sponsors or any other persons deal with therapeutic vaping goods;
- limiting persons that may supply therapeutic vaping goods to ultimate consumers under the exemptions for notified therapeutic vaping goods to pharmacists, medical practitioners and nurse practitioners that are authorised under state or territory law to supply prescription medicines;
- extending the list of persons in the exemptions that may supply and receive therapeutic vaping goods to include persons in relation to whom a consent is granted under section 41RC of the Act and persons specified in a determination under section 41R of the Act;
- extending the notice provisions for articles or components of therapeutic vaping devices and therapeutic vaping device accessories to therapeutic cannabis vaping goods;
- amending the definitions of therapeutic vaping device accessory and therapeutic cannabis vaping device accessory so they are not required to be refillable;

- clarifying that a ‘therapeutic vaping pack’ must include at least one therapeutic vaping substance or therapeutic vaping substance accessory;
- prescribing matters to facilitate the granting of authorities under subsection 19(5) of the Act without ethics committee approval in relation to therapeutic vaping substances that do not contain nicotine or any other active ingredient;
- clarifying that supply to the ultimate consumer under the special access scheme or the authorised prescriber scheme is not required in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack;
- prescribing things that may be required in an enforceable direction;
- prescribing commercial quantities, units and permitted quantities of vaping devices, vaping accessories, and vaping substances that are liquids;
- extending the definition of ‘protected persons’ under subsection 62(3) of the Act to state and territory officials to whom certain powers and functions are delegated under the Act;
- creating a time-limited exemption (for a period of 6 months following commencement of Schedule 1) to permit the export the therapeutic vaping goods and therapeutic cannabis vaping goods that comply with all Commonwealth and state or territory laws before commencement of Parts 1-3 of Schedule 1 to the Amendment Act; and
- including relevant transitional provisions.

Schedule 2 would amend the TG Regulations by repealing the commercial quantities prescribed in Schedule 1 and replacing them with lower commercial quantities. Schedule 2 commences on the day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the Amendment Act commence.

Schedule 3 would amend the TG Regulations to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law.

Part 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Paragraph 10.6(2)(a)

Item 1 would amend the reference to a ‘medical practitioner registered in a State or internal Territory’ in paragraph 10.6(2)(a) to omit the words ‘registered in a State or internal Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that already refers to registration in a State or Territory. Consequently, the words that are proposed to be omitted are redundant when referring to a medical practitioner in the Principal Regulations and therefore not required.

Item [2] – Table item 1.1 of Part 1 of Schedule 4, column headed “Kinds of medical devices”, paragraph (d))

Item 2 would similarly amend the reference to a ‘medical practitioner registered under a law of a State or Territory’ in table item 1.1 of Part 1 of Schedule 4 to omit the words ‘registered under a law of a State of internal Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that already refers to registration in a State or Territory, and consequently these words are redundant when referring to a medical practitioner in the Principal Regulations.

Item [3] – Table item 2.17 of Part 2 of Schedule 4, column headed ‘Conditions’, paragraph (b)

Item 3 would repeal paragraph (b) of the column headed ‘Conditions’ in table item 2.17 of Part 2 of Schedule 4 and insert a new paragraph that includes the existing reference to goods imported or manufactured on or after 1 March 2024, and a new reference to goods that were imported or manufactured before 1 March 2024. A sponsor notice in relation to the latter category of goods must be provided before the device is supplied to the ultimate consumer and no later than 2 months after Schedule 1 to the Amendments Regulations commences.

The effect of this amendment, together with item 33, is to extend the operation of the exemption in item 2.17 so that goods that were imported or manufactured before 1 March 2024 and comply with the essential principles are eligible to be supplied to the ultimate consumer, provided that a sponsor notice is given by the sponsor to the Secretary within 2 months of the commencement of Schedule 1 to the Amendment Regulations. This will create a pathway for the supply of compliant stock that existed prior to the commencement of the application of the exemption on 1 March 2024.

The 2-month timeframe for the giving of a sponsor notice is intended to provide a sufficient period during which compliant stock may be identified and sponsors may make the necessary notification. A time limited period is required so that, at the conclusion of the period, there is certainty as to the goods that can be supplied under the exemption.

Item [4] – Table item 2.17 of Part 2 of Schedule 4, column headed ‘Conditions’, paragraph (g)

Item 4 would insert new conditions of exemption in paragraphs (fa), (fb), (fc), (fd) and (fe), and amend the wording in paragraph (g) in item 2.17.

Medical devices listed in an item in Part 2 of Schedule 4 are exempt from the need to be included in the Register, subject to the specified conditions in the relevant item. Item 2.17 in Part 2 of Schedule 4 provides for the exemption of specific devices subject to compliance with specified conditions. Item 2.17 allows for the lawful importation, manufacture and supply of unregistered therapeutic vaping devices and therapeutic vaping device accessories subject to conditions.

Paragraph (fa) would require the sponsor to provide a reasonable number of samples of a device to the Secretary on request, and to do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the essential principles may be undertaken efficiently.

Paragraph (fb) would require the sponsor to allow an authorised officer to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the device. While on those premises, the sponsor must allow the authorised officer to inspect the premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on the premises that relate to the device. The authorised officer must also be allowed to make any still or moving image or any recording of the premises or any thing on the premises.

Paragraph (fc) would require the sponsor, if requested to do so by an authorised officer, to produce to the authorised officer such documents relating to the device as the authorised person requires and to allow the authorised officer to copy the documents.

Paragraph (fd) would require a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device allows an authorised officer to do the things referred to in paragraph (fb).

Paragraph (fe) would require a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the device as the authorised officer requires and to allow the authorised officer to copy the documents.

The conditions in paragraphs (fb) to (fe) are necessary to ensure that the TGA can obtain information to determine whether therapeutic vaping devices and therapeutic vaping device accessories that have been notified as complying with the essential principles do in fact comply. This may be particularly useful in relation to therapeutic vaping devices and therapeutic vaping device accessories to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* applies, as that standard includes a range of requirements that apply to manufacturing processes, and the ability to enter manufacturing premises will assist in this regard.

Paragraph (g) would specify the persons to whom goods may be supplied by wholesale (persons who are not the ultimate consumer).

Subparagraph (g)(i) would refer to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods. This amendment is made to align the language with that used in section 41QB(8)(a) of the Act, as inserted by the Amendment Act, when referring to the same person. The meaning of this provision would not change.

Subparagraph (g)(ii) would specify a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

Subparagraph (g)(ii) is being amended to align with the description of persons to whom vaping goods may be lawfully supplied by wholesale in section 41QB(8)(b), as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in the analogous subparagraph (g)(iv), which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice could extend to health professionals, such as dentists and optometrists. This amendment would ensure that the exemption applies only in relation to goods supplied by wholesale to a wholesaler, pharmacist, medical practitioner or nurse practitioner that is authorised under the law of a State or Territory, and would be consistent with the exception in section 41QB(10) of the Amendment Act, which applies only to the supply of vaping goods by wholesale to these persons.

Subparagraph (g)(iii) would specify a recipient to whom a consent under subsection 41RC(1) of the Act to supply the device has been given. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient to whom a consent is granted under section 41RC(1) of the Act.

Subparagraph (g)(iv) would specify, in relation to a device that is covered by a determination made by the Minister under section 41R of the Act, a recipient who is not the ultimate consumer specified in the determination, or included in a class of persons specified in the determination. This amendment is necessary to ensure consistency with the amendments under the Amendment Act that allow for goods to be supplied by wholesale to a recipient specified in a determination made by the Minister under section 41R of the Act.

Item [5] – Table item 2.17 of Part 2 of Schedule 4, column headed ‘Conditions’, paragraph (h)(ii)

Item 5 would repeal paragraph (h)(ii) and would insert a new paragraph specifying supply to the ultimate consumer may only be by a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

This subparagraph is being amended to align with the description of persons who may supply vaping goods to ultimate consumers in section 41QB(10) of the Act, as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in subparagraph (h)(ii) of item 2.17, which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice could extend to health professionals, such as dentists and optometrists.

This amendment would ensure that the exemption applies only in relation to goods supplied to the ultimate consumer by a pharmacist, medical practitioner or nurse practitioner, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amendment Act, which applies only to the supply of vaping goods to the ultimate consumer by these persons.

Item [6] and [7] – Table item 2.18 of Part 2 of Schedule 4, column headed “Kinds of medical devices”, paragraphs (a) and (b) and column headed “Conditions”, paragraph (a)

Item 6 would insert a reference to a component or article imported for use in the manufacture of a therapeutic cannabis vaping good in the column that specifies the goods to which the exemption in item 2.18 applies. Item 7 would insert a reference to a therapeutic cannabis vaping good in the description of the sponsor notice that must be provided as a condition of this exemption.

Current item 2.18 in Part 2 of Schedule 4 to the MD Regulations allows for the lawful importation of a component or article imported for use in the manufacture of a therapeutic vaping device and a therapeutic vaping device accessory (which would not include a therapeutic cannabis vaping device or therapeutic cannabis vaping device accessory). The exemption is subject to conditions.

The effect of these amendments is that the notification requirements under subregulation 5A(13) of the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations) and under Part 2 of Schedule 4 to the MD Regulations will change for an article or component for use in the manufacture of a therapeutic cannabis vaping good. Specifically, an importer of such a good will be required to give a notice stating that the goods are for use in the manufacture, in accordance with the requirements of the *Therapeutic Goods Act 1989*, of a therapeutic cannabis vaping good by a manufacturer who holds all relevant licences and approvals required under the law of the relevant State or Territory. This notice requirement currently applies to importers of articles or components for use in the manufacture of therapeutic vaping devices and therapeutic vaping device accessories. These amendments will have the effect that the notification requirements for articles or components imported for use in manufacture, rather than as finished goods, will be the same whether those articles or components are for use in the manufacture of therapeutic vaping devices, therapeutic vaping device accessories, or therapeutic cannabis vaping goods.

A person seeking to import an article or component for use in the manufacture of a therapeutic cannabis vaping good must meet the notification requirements under subregulation 5A(13) of the CPI Regulations. Paragraph 5A(13)(a) of the CPI Regulations applies to a therapeutic cannabis vaping good, including an article or component to be imported for use in manufacture, and requires a statement that the goods comply with the essential principles or are imported with the consent of the Secretary. Paragraph 5A(13)(b) of CPI Regulations applies to goods that are not therapeutic cannabis vaping goods, and includes at subparagraph (ii) the option of giving a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations. By extending the application of item 2.18 of Part 2 of Schedule 4 to the MD Regulations to an article or component for use in the manufacture of a therapeutic cannabis vaping good, these amendments have the effect that a sponsor of these goods will meet the notification requirements under subregulation 5A(13) of the CPI Regulations by giving a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations, rather than needing to meet the more onerous notice requirement under paragraph 5A(13)(a) of CPI Regulations.

Item [8] – Part 2 of Schedule 4 (table item 2.18, column headed ‘Conditions’, after paragraph (b))

Item 8 would insert a new requirement as a condition of the exemption under item 2.18 that the sponsor must provide a reasonable number of samples of a device to the Secretary on request, and must do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the essential principles can be undertaken efficiently.

Items [9], [10] and [11] – Dictionary (paragraph (a) of the definition of ‘health professional’, definition of ‘medical practitioner’, and paragraphs (a) and (b) of ‘serious’)

Item 10 would repeal the definition of ‘medical practitioner’ because the term is defined in the Act, as inserted by the Amendment Act. Items 9 and 11 would amend the references to ‘medical practitioner’ in the definitions of ‘health professional’, and ‘serious’ to reflect the new definition of ‘medical practitioner’ in the Act, as inserted by the Amendment Act.

Item [12] – Dictionary (paragraphs (a) and (b) of the definition of therapeutic cannabis vaping device)

Item 12 would amend the definition of ‘therapeutic cannabis vaping device’ to substitute the term ‘vaping device’ that is defined in the Act, as inserted by the Amendment Act, to ensure consistency with the definition under the Act.

Item 12 would also add subparagraph (a)(ii) to exclude from the definition of ‘therapeutic cannabis vaping device’ a component or article imported for use in the manufacture of a therapeutic cannabis vaping device. The exclusion of a component or article imported for use in the manufacture of a therapeutic cannabis vaping device from the definition of a ‘therapeutic cannabis vaping device’ has the effect that a component or article is not regarded as a ‘therapeutic cannabis vaping device’, and consequently a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations is required instead of a notice under paragraph 5A(13)(a) of the *Customs (Prohibited Imports) Regulations 1956* in order to meet the notification requirements under the subregulation 5A(13) of those regulations.

Item [13] – Dictionary (definition of therapeutic cannabis vaping device accessory)

Item 13 would repeal the definition of therapeutic cannabis vaping device accessory and would replace it with a definition that changes the order of paragraphs (a) and (b) to align with the ordering of those requirements in the definition of ‘vaping accessory’ in the Amending Act. Item 13 would also remove the requirement in paragraph (c) that the good must be designed or intended to be refillable. The only change to the meaning of this definition is that a good can be a ‘therapeutic cannabis vaping device accessory’ whether or not it is intended or designed to be refillable.

Item [14] – Dictionary (definition of therapeutic vaping device)

Item 14 would repeal the definition of therapeutic vaping device and would replace it with a definition that references the term ‘vaping device’ as inserted into the Act by the Amendment Act. In effect, there would be no change to the operation of this term.

Item [15] – Dictionary (definition of therapeutic vaping device accessory)

Item 15 would repeal the definition of therapeutic vaping device accessory and would replace it with a definition that include the words ‘designed or intended’ in paragraphs of (a) and (b) rather than the chapeau of the definition, and would remove the requirement in paragraph (c) that the good must be designed or intended to be refillable. The only change to the meaning of this definition is that a good can be a ‘therapeutic vaping device accessory’ whether or not it is intended or designed to be refillable.

Therapeutic Goods Regulations 1990

Item [16] – Regulation 2 (paragraph (a) of the definition of disposable therapeutic vape)

Item 16 would amend paragraph (a) of the definition of disposable therapeutic vape in the TG Regulations to substitute the reference to ‘vaping device’ defined in the TG Regulations with

the defined term in the Act as inserted by the Amendment Act. In effect, there is no change to the operation of this term.

Item [17] – Regulation 2 (definition of therapeutic vaping pack)

Item 17 would repeal the definition of therapeutic vaping pack and would replace it with a new definition that retains the elements of the current definition in the Act (that it must contain at least one therapeutic vaping device or therapeutic vaping device accessory and not contain any other therapeutic goods). Item 17 would also supplement the definition with a new requirement that a therapeutic vaping pack must also contain at least one therapeutic vaping substance or therapeutic vaping substance accessory.

This amendment would clarify that a therapeutic vaping device or therapeutic vaping device accessory is only to be regulated as part of a therapeutic vaping pack, and consequently subject to the requirements of Chapter 3 of the Act, if the pack also contains a therapeutic vaping substance or therapeutic vaping substance, being goods that are regulated under Chapter 3 of the Act. This amendment would ensure that a pack that contains only a therapeutic vaping device and/or a therapeutic vaping device accessory, being goods that would ordinarily be subject to the requirements of Chapter 4 of the Act if not part of a therapeutic vaping pack, would not be regulated under Chapter 3 of the Act unless the pack of which they are a part also contains goods that are regulated under Chapter 3 of the Act.

Item [18] – Regulation 2 (definition of therapeutic vaping substance accessory)

Item 18 would repeal the definition of therapeutic vaping substance accessory to substitute the description of a vaping device with a reference to the defined term ‘vaping device’ inserted into the Act by the Amendment Act. It also changes the order of paragraphs (a) and (b) to align with the ordering of the definition of ‘vaping accessory’ in the Amendment Act. In effect, there is no operational change to the meaning of this term.

Item [19] – Regulation 2 (definition of vaping device)

Item 19 would repeal the definition of ‘vaping device’, which is defined in the Act, as inserted by the Amendment Act, and accordingly a definition is no longer required in the Principal Regulations.

The definition in the Act, as inserted by the Amendment Act, is the same as that in the current TG Regulations, with the exception of the omission of note 2 in the definition in these Regulations. That note states that, to avoid doubt, therapeutic vaping substances accessories and therapeutic vaping device accessories are not devices to which paragraph (b) of the definition applies (being the paragraph that applies to temporarily inoperable, incomplete, damaged and unfinished devices). The note is not necessary because the definitions of ‘therapeutic vaping substance accessory’ and ‘therapeutic vaping device accessory’ refer to goods that are ‘designed or intended for use in, or with, a therapeutic vaping device’ and it is therefore clear that these items are for use *in or with* a therapeutic vaping device (being a therapeutic good that is a vaping device) rather than amounting to vaping devices in and of themselves.

Item [20] – After Part 2E, insertion of new Part 2F – Vaping goods - commercial quantities units and permitted quantities of vaping goods

Commercial quantity

Item 20 would insert Part 2F, titled ‘Vaping goods’ into the TG Regulations. New regulations 10N, 10P and 10Q would form part of new Part 2F.

New regulation 10N would prescribe commercial quantities of vaping goods for the purpose of the definition of ‘commercial quantity’ in subsection 3(1) of the Act, as inserted by the Amendment Act. Commercial quantities are required because the possession offences and civil penalty provisions in sections 41QC of the Act, as inserted by the Amendment Act, apply in relation to the possession of a commercial quantity of vaping goods other than in circumstances where the exceptions in sections 41QC applies. The exceptions provide for the possession of legitimate therapeutic vapes by specified persons in the supply chain, and by other persons specified in an instrument under section 41R or to whom consent is granted under section 41RC. Consequently, a contravention of section 41QC will only arise, and the commercial quantity is only relevant, in relation to vaping goods that are not legitimate therapeutic vapes and are not specified under section 41R or are goods in relation to which a consent has been granted under section 41RC.

The commercial quantities of vaping goods that are prescribed therefore seek to penalise the possession of illicit vaping goods for commercial purposes and to ensure that legitimate therapeutic use is not penalised.

Regulation 10N would prescribe 9 vaping devices, 90 vaping accessories, and 300 ml of vaping substances that is a liquid. These quantities will apply for a period of 3 months after Schedule 1 to the Amendment Act commences, after which these quantities would be repealed and replaced with the quantities prescribed in amending item 1 of Schedule 2 to the Amendment Regulations, being 3 vaping devices, 30 vaping accessories, and 100 ml of vaping substances that is a liquid.

The higher quantities that would be prescribed for the first 3 months will effectively provide a transition period during which quantities of vaping goods that exceed the commercial quantities that will apply at the conclusion of that 3-month period can be depleted.

Units of vaping goods

New regulation 10P would prescribe quantities of vaping goods for the purpose of the definition of ‘unit’ in subsection 3(1) of the Act, as inserted by the Amendment Act. The civil penalty provisions inserted into the Act by the Amendment Act relevantly provide that a person who contravenes the provisions commits a separate contravention in respect of each unit of vaping goods.

The quantities that would be prescribed as amounting to one unit are one vaping device, 60mL of vaping substance that is a liquid, and 10 vaping accessories. These quantities are based on quantities that may be supplied to an individual as a starter pack.

Permitted quantities

New regulation 10Q would prescribe quantities of vaping goods for the purpose of the definition of ‘permitted quantity’ in subsection 41QD(10) of the Act, as inserted by the Amendment Act. Section 41QD is an offence and civil penalty provision that applies to the possession, in a retail premises, of less than a commercial quantity of vaping goods. An exception is provided in subsection 41QD(9) in relation to the possession of a quantity of a kind of vaping goods by a person if the vaping goods are for use by the person personally, and the quantity is no more than the ‘permitted quantity’ of that kind of vaping goods.

The purpose of the exception in subsection 41QD(9) is to ensure that the personal possession of a small quantity of vaping goods required for personal use (whether legitimate therapeutic use or otherwise) is not penalised simply because it occurs in retail premises. A separate exception in subsections 41QD(7) and (8) applies in relation to possession by authorised persons in the supply chain of vaping goods for legitimate therapeutic use.

The quantities prescribed are 1 vaping device, 3 vaping accessories, and 30mL of vaping substance that is a liquid. The modest quantities that are prescribed are necessary to confine the exception to the possession of quantities that would generally support personal use over the course of a single day. It is necessary to limit the permitted quantities to a single day’s use, so that the exception does not apply to the possession of small quantities intended for commercial supply that could theoretically be for personal use over a longer period such as a month or three months.

Item [21] – After regulation 12B, insertion of new regulation 12BA – authorised prescriber authorities for therapeutic vaping substances that are not medicines

The Act provides a number of avenues that allow access to therapeutic goods that are not included in the Register. The authorised prescriber scheme under subsection 19(5) of the Act allows authorised medical practitioners to lawfully supply a specified ‘unapproved’ therapeutic good (or class of ‘unapproved’ therapeutic goods) to a class of patients with a particular medical condition. Ordinarily, there is requirement for ethics committee approval or specialist college endorsement for a medical practitioner to be given an authority to supply specified therapeutic goods (refer to subsection 19(6)(aa) of the Act). This requirement does not apply in the circumstances (if any) prescribed by the regulations for the purposes of this subsection. The current regulation 12B prescribes the medical practitioners, specified class of goods and circumstances where the requirement for approval by an ethics committee under paragraph 19(6)(aa) are not required.

Item 21 would insert new regulation 12BA into the Principal Regulations relating to authority that may be granted under subsection 19(5) of the Act (the authorised prescriber scheme) to a medical practitioner for the supply of unapproved therapeutic vaping substances that are not medicines. In addition, new regulation 12BA would allow for a specified medical practitioner to be granted authorisation to prescribe and supply unapproved therapeutic vaping substances that do not contain nicotine without having to apply for ethics committee approval. The effect of regulation 12BA would be to ensure that therapeutic vaping substances that do not contain nicotine are treated the same way under the authorised prescriber scheme as therapeutic vaping substances that contain nicotine or any other active ingredient under regulation 12B.

Regulation 12B currently prescribes matters necessary for an authority to be granted under the authorised prescriber scheme in relation to medicines that are therapeutic vaping substances and that contain nicotine. Regulation 12B does not apply to therapeutic vaping substances that do not contain nicotine or any other active ingredient because regulation 12B is limited to medicines and these goods do not meet the definition of ‘medicine’. This amendment prescribes matters necessary for an authority to be granted under the authorised prescriber scheme in relation to therapeutic vaping substances that are not medicines.

The class of persons that would be prescribed in subregulation 12BA(2) for the purposes of paragraph 19(6)(a) of the Act is the same class as that prescribed under regulation 12B, being medical practitioners engaged in clinical practice in or outside a hospital are a prescribed class of medical practitioners.

Subregulation 12BA(2) would prescribe therapeutic vaping substances that are not medicines where they are to be administered by inhalation and the supply is for the treatment of smoking cessation or the management of nicotine dependence for the purpose of subsection 19(6) of the Act. The effect of this is that an authorised prescriber authority can be granted for these goods without requiring approval from an ethics committee, as is the case under regulation 12B for therapeutic vaping substances that contain nicotine where the supply is for the treatment of smoking cessation or the management of nicotine dependence.

Subregulation 12BA(3) would prescribe the class of recipients for the purposes of paragraph 19(6)(b) of the Act as the class of persons each of whom is seeking treatment for smoking cessation or the management of nicotine dependence.

Subregulation 12BA(4) would prescribe the circumstances in which therapeutic vaping substances may be authorised for supply under the authorised prescriber scheme as being that the supplier of the authorised vaping substance or class of authorised vaping substances complies with the treatment directions (if any) mentioned in the authority for the authorised vaping substance or class of authorised vaping substances. These are the same circumstances prescribed under regulation 12B for therapeutic vaping substances that contain nicotine.

Item [22] – After regulation 47B, insertion of new section 47C - Protected persons

Item 22 would insert new regulation 46B into the TG Regulations to prescribe a person for the purpose of the definition of ‘protected person’ in the new subsection 62(3) of the Act, as inserted by the Amendment Act. The person prescribed is a person to whom powers or functions are delegated under the new subsection 57(1A) of the Act, as inserted by the Amendment Act, which provides for the Secretary to delegate all or any of the powers and functions under Chapter 5A (enforcement), section 52AAA (forfeiture of things seized under search warrant), or section 52AAB (return or retention of thing declared not to be forfeited) to an officer of a Department of State, a Department or administrative unit of the Public Service of a Territory, or an authority of a State or of a Territory, being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement.

The effect of this amendment is that state and territory officers that are delegated powers or functions under subsection 57(1A) of the Act will be ‘protected persons’ for the purpose of section 62 of the Act and accordingly will be protected from criminal responsibility in accordance with section 62. That section protects certain persons from criminal responsibility for offences under a law of the Commonwealth or a State law, in circumstances relating to

obtaining, possessing, or conveying goods in connection with finding out whether the Act or Principal Regulations have been complied with. This amendment will ensure that state and territory officers can undertake compliance and enforcement activities without such activities amounting to contraventions of the Act.

Item [23] – paragraph 47A(2)(a)

Item 23 would amend the reference to a ‘medical practitioner registered in a State or Territory’ in paragraph 47A(2)(a) to omit the words ‘registered in a State or Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that incorporates registration in a State or Territory, and consequently these words are redundant when referring to a medical practitioner in the Principal Regulations.

Item [24] – After regulation 47B, insertion of new regulation 47C - Enforceable directions

This item would insert a new regulation 47C that prescribes, for the purpose of paragraph 42YT(2)(e) of the Act, a requirement to quarantine goods, store goods in a secure manner, and not supply goods, as things that may be the subject of an enforceable direction under section 42YT of the Act. The power to require these things to be done is necessary to ensure the supply of therapeutic goods can be prevented where the Secretary believes, on reasonable grounds, that therapeutic goods do not comply with the Act and the direction is necessary to protect the health and safety of humans.

Item [25] – Schedule 5 (table item 1, column 2, paragraph (d))

Item 25 would amend the reference to a ‘medical practitioner registered under a law of a State or Territory’ in item 1 of Schedule 5 to omit the words ‘registered under a law of a State or Territory’. The Amendment Act defines a ‘medical practitioner’ by reference to registration in a State or Territory and therefore these words are redundant when describing a medical practitioner in the Principal Regulations.

Item [26] – Schedule 5A (table item 15, column 2, paragraph d))

Item 26 would amend item 15 to clarify that the requirement that a wholesaler must intend the goods to be supplied to the ultimate consumer of the goods in accordance with an approval or authority under section 19 of the Act (being the special access and authorised prescriber schemes) does not apply in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack.

Unlike therapeutic vaping substances and therapeutic vaping substance accessories, which may only be supplied to the ultimate consumer pursuant to the special access scheme or the authorised prescriber scheme, therapeutic vaping devices or therapeutic vaping device accessories that are regulated under Chapter 4 of the Act are not presently required to be supplied to the ultimate consumer pursuant to the special access or authorised prescriber schemes. This amendment clarifies that therapeutic vaping devices and therapeutic vaping device accessories are to be treated in the same way when part of a therapeutic vaping pack.

Item [27] – Schedule 5A (table item 15, column 3, paragraph (b))

Item 27 would repeal paragraph (b) of column 3 in table item 15 of Schedule 5A and would insert a new paragraph that would extend the scope of the notification requirement in relation to vaping goods that have been imported into Australia or manufactured in Australia before 1 March 2024. The current notification requirements only apply where the goods are imported into Australia, or manufactured in Australia on or after 1 March 2024. This item would permit sponsor notices to be given in relation to vaping goods that were imported into Australia before 1 March 2024 and manufactured in Australia before 1 March 2024 provided the notice is given no later than 2 months after Schedule 1 to the Amendment Regulations commences. Note however that despite allowing for the supply of these goods, supply of these goods would be limited to pharmacists and other persons specified in subparagraph (i)(ii) (also refer to item 29).

Item 15 of Schedule 5A provides the lawful basis for allowing therapeutic vaping goods to be imported, manufactured and supplied in Australia, despite these goods not being included in the Register, subject to specified conditions being met.

The effect of this amendment, together with amending item 35, is to extend the operation of the exemption in item 15 so that goods that were imported or manufactured before 1 March 2024 and comply with applicable standards are eligible to be supplied to the ultimate consumer under item 15, provided that they are notified within two months of the commencement of Schedule 1 to the Amendment Regulations. This will create a pathway for the supply of compliant stock that existed prior to the commencement of the application of the exemption on 1 March 2024.

The imposition of the 2-month timeframe, beginning on the day these amendments come into force, for the giving of a sponsor notice is intended to provide a sufficient period during which compliant stock may be identified and sponsors may make the necessary notification.

Item [28] – Schedule 5A (table item 15, column 3, paragraphs (g) and (h))

Item 25 would repeal paragraphs (g) and (h) of item 15 and would insert new paragraphs (fa), (fb), (fc), (fd), (fe), (g) and (h).

Paragraph (fa) would require the sponsor to provide a reasonable number of samples of the goods to the Secretary on request, and to do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the relevant standards can be undertaken efficiently.

Paragraph (fb) would require the sponsor to allow an authorised officer to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the goods. While on those premises, the authorised officer must be allowed to inspect the premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on the premises that relates to the goods. The authorised officer must also be allowed to make any still or moving image or any recording of the premises or any thing on the premises.

Paragraph (fc) would require the sponsor, if requested to do so by an authorised officer, to produce to the authorised person such documents relating to the goods as the authorised person requires and allow the authorised person to copy the documents.

Paragraph (fd) would require a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the goods allows an authorised officer to do the things referred to in paragraph (fb).

Paragraph (fe) would require a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the goods as the authorised person requires and allow the authorised person to copy the documents.

The conditions in paragraphs (fb) to (fe) are necessary to ensure that the TGA can obtain information to determine whether therapeutic vaping goods that have been notified as complying with standards do in fact comply with those standards.

Paragraph (g) would specify the persons who may lawfully manufacture the goods in Australia.

Subparagraph (g)(i) would refer to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods. This amendment is made to align the language with that is used in section 41QA(5)(b)(i) of the Act, as inserted by the Amendment Act, when referring to the same person. The intent of this provision has not changed.

Subparagraph (g)(ii) would refer to a person to whom the Secretary has given consent in accordance with subsection 41RC(1) of the Act, as inserted by the Amendment Act, to manufacture the goods and the manufacture of the goods is in accordance with that consent.

Paragraph (h) would specify the persons to whom goods may be supplied by wholesale (persons who are not the ultimate consumers of the goods).

Subparagraph (h)(i) would refer to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the device. This amendment is made to align the subparagraph with language used in section 41QB(8)(a) of the Act, as inserted by the Amendment Act, when referring to the same person. The intent of this provision would not change.

Subparagraph (h)(ii) would be amended to align with the description of persons to whom vaping goods may be lawfully supplied by wholesale in section 41QB(8)(b) of the Act, as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in the analogous subparagraph (h)(ii), which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice extends to health professionals such as dentists and optometrists. This amendment would ensure that the exemption applies only in relation to goods supplied by wholesale to a wholesaler, pharmacist, medical practitioner or nurse practitioner that is authorised under the law of a State or Territory, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amendment Act, which applies only to the supply of vaping goods by wholesale to these persons.

Subparagraph (h)(iii) would refer to a recipient to whom a consent under subsection 41RC(1) of the Act to supply the goods has been given. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient to whom a consent is granted under section 41RC(1) of the Act.

Subparagraph (h)(iv) would specify, in relation to a good that is covered by a determination made by the Minister under section 41R of the Act, a recipient specified in the determination, or included in a class of persons specified in the determination. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient specified in a determination made by the Minister under section 41R of the Act.

Item [29] – Schedule 5A (table item 15, column 3, subparagraph (i)(ii))

Item 29 would amend the description of the persons in subparagraph (i)(ii) of item 15 who may supply goods to the ultimate consumer, to specify a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

This subparagraph would need to be amended to align with the description of persons who may supply vaping goods to the ultimate consumer in section 41QB(10) of the Act, as inserted by the Amending Act. This class of persons is narrower than the class of persons currently specified in subparagraph (i)(ii) of item 15, which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the Poisons Standard, and in practice extends to health professionals such as dentists and optometrists.

This amendment would ensure that the exemption applies only in relation to goods supplied to the ultimate consumer by a pharmacist, medical practitioner or nurse practitioner, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amending Act which applies only to the supply of vaping goods to the ultimate consumer by these persons.

Item [30] – Schedule 5A (table item 15, column 3, subparagraph (i)(iii))

Item 30 would amend item 15 to clarify that the requirement that the ultimate supply to a consumer must be in accordance with such an approval or authority under section 19 of the Act (being the special access scheme or the authorised prescriber scheme) does not apply in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack.

Unlike therapeutic vaping substances and therapeutic vaping substance accessories, which may only be supplied to the ultimate consumer pursuant to the special access scheme or the authorised prescriber scheme, therapeutic vaping devices or therapeutic vaping device accessories that are regulated under Chapter 4 of the Act are not required to be supplied to the ultimate consumer pursuant to the special access or authorised prescriber schemes. This amendment would make it clear that therapeutic vaping devices and therapeutic vaping device accessories are to be treated in the same way when part of a therapeutic vaping pack.

Item [31] – Schedule 5A (table item 16, column 3, after paragraph (b))

Item 31 would insert a new condition in item 16 of Schedule 5A that the sponsor must provide a reasonable number of samples of a good to the Secretary on request, and must do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post notification testing to assess compliance with the standards can be undertaken efficiently.

Item [32] – Schedule 7 (table items 22 and 23, column 2, subparagraph (a)(iii))

Item 32 would amend references to a ‘medical practitioner registered under a law of a State or Territory’ to omit the words ‘registered under a law of a State or Territory’. The Amendment Act defines a ‘medical practitioner’ by reference to registration in a State or Territory and these words are therefore redundant when describing a medical practitioner in the Principal Regulations.

Part 2—Transitional provisions**Item [33] – regulation 11.73**

Regulation 11.73 currently states that the amendments made by Part 1 of Schedule 2 to the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (other than the amendments of the Dictionary) apply to therapeutic goods imported or manufactured on or after 1 March 2024.

Item 33 would replace the reference in regulation 11.73 to therapeutic goods imported or manufactured on or after 1 March 2024 with a reference to therapeutic goods imported or manufactured before, on or after 1 March 2024. This amendment is necessary because the Amendment Regulations amend item 2.17 of Part 2 of Schedule 4 to the MD Regulations so that it applies to therapeutic goods imported or manufactured before 1 March 2024.

This amendment, together with amending item 3, would have the effect that therapeutic goods imported or manufactured before 1 March 2024 are eligible to meet the requirements of the exemption in item 2.17. It does not have retrospective effect because the exemption requires prospective meeting of those requirements, including the giving of a sponsor notice, in order for the exemption to apply.

This amendment would have the effect that items 1.5 and 1.6 of Part 2 of Schedule 4 to the MD Regulations, which were repealed by the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* in relation to therapeutic goods imported or manufactured on or after 1 March 2024, is now also repealed in relation to therapeutic goods imported or manufactured before 1 March 2024. This is consistent with the amendments to the Act made by the Amendment Act, under which the new offence and civil penalty provisions relating to vaping goods in the Act apply to vaping goods unless an exemption applies under which ‘the sponsor has given a notice in compliance with the exemption’. The exemptions in items 1.5 and 1.6 of Part 2 of Schedule 4 do not require a notice to be given and consequently goods that are exempt under those items cannot meet this requirement, and therefore are prohibited to be supplied.

Item [34] – Part 11, Application provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Item 34 would insert a new Division 11.22 into Part 11 of the MD Regulations. Division 11.22 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions.

Clause 11.79 – Definitions

Clause 11.79 would provide a definition for the term “amending regulations” in the new Division 11.22. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

Clause 11.80 – Application of amendments

Clause 11.80 would provide that the amendment made by item 3 of Schedule 1 applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule. This has the effect that therapeutic goods imported or manufactured before, on or after the commencement of the Schedule will be eligible to provide a sponsor notice and meet the requirements of the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations.

Clause 11.80 would also provide that the amendments made by items 4 and 5 of Schedule 1 apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule. This has the effect that the new conditions of the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations requiring the provision of a reasonable number of samples on request and allowing authorised officers to enter and inspect premises, and the description of the persons who may supply goods to the ultimate consumer, do not apply in relation to goods imported or manufactured before the commencement of that Schedule.

Clause 11.80 would also provide that the amendments made by item 6, 7 and 12 of Schedule 1 to the amending regulations would apply in relation to therapeutic goods imported on or after 1 October 2024. This has the effect that articles or components for use in the manufacture of therapeutic cannabis vaping goods that are imported on or after 1 October 2024 will be excluded from the definition of “therapeutic cannabis vaping device “ and accordingly will be required to give a notice under section 2.18 of Part 2 of Schedule 4 to the MD Regulations.

Clause 11.80 would also provide that item 8 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule. It also has the effect that the new condition requiring the provision, on request, of a reasonable number of samples of goods imported under item 2.18, does not apply to in relation to therapeutic goods imported before the commencement of that Schedule.

Clause 11.81 – Transitional vaping devices—exemption from Division 3 of Part 4-11 of the Act

Clause 11.81 would provide a transition provision for transitional vaping devices in relation to the exemption from Division 3 of Part 4-11 of the Act.

Subclause (1) provides that medical devices that are exported from Australia are *transitional vaping devices* if the devices are therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods, and were imported, manufactured or supplied before the commencement of Schedule 1 to the Amendment Regulations, and as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

In effect, clause 11.81 allows a sponsor to export therapeutic vaping goods that complied with all relevant laws that were applicable at the time the goods were imported, manufactured or supplied (as applicable), without requiring the goods to be included in the Register. The clause would reduce regulatory burden associated with exporting such goods, allowing sponsors to potentially minimise the financial impact where such goods can no longer be lawfully supplied in Australia.

Pursuant to subclause (3), this exemption from the operation of Part Division 3 of Part 4-11 the Act ceases to have effect at the end of the period of 6 months starting on the day Schedule 1 to the Amendment Regulations commence. After this date, these goods will be required to be included in the Australian Register of Therapeutic Goods to be lawfully exported.

Item [35] – subregulation 96(5)

Subregulation 96(5) would provide that item 15 of the table in Schedule 5A to the TG Regulations, as inserted by Schedule 1 to the amending regulations, applies in relation to therapeutic goods imported or manufactured on or after 1 March 2024.

Item 35 would replace the reference in subregulation 96(5) to therapeutic goods imported or manufactured on or after 1 March 2024 with a reference to therapeutic goods imported or manufactured before, on or after 1 March 2024. This amendment is necessary because amending item 3 amends item 15 in Schedule 5A to the TG Regulations so that it applies to therapeutic goods that were imported or manufactured before 1 March 2024.

This amendment, together with amending item 3, would have the effect that therapeutic goods imported or manufactured before 1 March 2024 are eligible to meet the requirements of the exemption in item 15 of Schedule 5A to the TG Regulations. It does not have retrospective effect because the exemption requires prospective meeting of those requirements, including the giving of a sponsor notice, in order for the exemption to apply.

Item [36] – Part 9 , Division 26 - Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Item 36 would insert a new Division 26 into Part 9 of the TG Regulations. Division 26 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions.

Clause 104 – Definitions

Clause 104 would provide a definition for the term “amending regulations” in the new Division 26. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

Clause 105 – Authorities for therapeutic vaping substances that are not medicines

Clause 105 would provide that the amendment to regulation 12BA applies in relation to an authority given under subsection 19(5) of the Act on or after the commencement of Schedule 1 to the amending regulations. This has the effect that authorities under the authorised prescriber scheme can be granted in the absence of ethics committee approval for therapeutic vaping substances that do not contain nicotine or any other active ingredient upon commencement of that Schedule.

Clause 106 – Therapeutic vaping packs

Clause 106 would provide that the amendment made by item 17 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured on or after 1 October 2024.

This has the effect that a primary pack that is imported or manufactured before 1 October 2024 and consists only of therapeutic vaping devices and/or therapeutic vaping device accessories will continue to be regarded as a therapeutic vaping pack, whereas a primary pack that is imported or manufactured on or after 1 October 2024 will only be regarded as a therapeutic vaping pack if it also contains at least one therapeutic vaping substance and/or therapeutic vaping substance accessory.

Clause 107 – Exempt goods

Clause 107 would provide that the amendment made by item 27 of Schedule 1 applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule. This has the effect that therapeutic goods imported or manufactured before, on or after the commencement of the Schedule will be eligible to provide a sponsor notice and meet the requirements of the exemption in item 15 of Schedule 5A to the TG Regulations.

Clause 107 would also provide that the amendments made by items 26 and 28 to 30 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule. This has the effect that the new conditions of the exemption in item 15 of Schedule 5A to the TG Regulations requiring the provision of a reasonable number of samples upon request and allowing authorised officers to enter and inspect premises, and the description of the persons who may supply goods to the ultimate consumer, do not apply in relation to goods imported or manufactured before the commencement of that Schedule. It also has the effect that the amendment to clarify that a special access scheme or authorised prescriber approval is not required for devices that are a part of a therapeutic vaping pack applies from the commencement of Schedule 1.

Clause 107 would provide that the amendments made by item 31 of Schedule 1 applies in relation to therapeutic goods imported on or after the commencement of that Schedule. This has the effect that the new condition requiring the provision, on request, of a reasonable number of samples of goods imported under item 16 of Schedule 5A to the TG Regulations does not apply to in relation to therapeutic goods imported before the commencement of that Schedule.

Clause 108 – Transitional vaping goods—exemption from Division 3 of Part 4-11 of the Act

Clause 108 would provide a transition provision for transitional vaping goods in relation to the exemption from Division 3 of Part 4-11 of the Act.

Subclause (1) defines ***transitional vaping goods*** as therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods that are exported and that were imported, manufactured or supplied before the commencement of Schedule 1 to the Amendment Regulations, and as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

In effect, clause 108 allows a sponsor to export therapeutic vaping goods that complied with all relevant laws that were applicable at the time the goods were imported, manufactured or supplied (as applicable), without requiring the goods to be included in the Australian Register of Therapeutic Goods. The clause would reduce regulatory burden associated with exporting such goods, allowing sponsors to potentially minimise the financial impact where such goods can no longer be lawfully supplied in Australia.

Pursuant to subclause (3), this exemption from the operation of Part 3-2 of the Act ceases to have effect at the end of the period of 6 months starting on the day Schedule 1 to the Amendment Regulations commence. After this date, these goods will be required to be included in the Australian Register of Therapeutic Goods to be lawfully exported.

Schedule 2 – Commercial quantities

Item [1] – Regulation 10N (table)

Schedule 2 would commence on the day after the end of the period of 3 months beginning on the day Schedule 1 to the Amendment Regulations commences. Item 1 would repeal the table in regulation 10N and replaces it with lower commercial quantities of 3 vaping devices, 30 vaping device accessories, and 100 ml of vaping substance that is a liquid.

Schedule 3 – Other matters

Item [1]– After paragraph 3(3)(bab)

Item 1 would insert a reference to the *Therapeutic Goods Law Application Act 2024* (WA) in subregulation 3(3), with the effect that the *Therapeutic Goods Law Application Act 2024* (WA) is declared to be a corresponding State law for the definition of ‘corresponding State law’ in subsection 3(1) of the Act. This item would commence on the later of the commencement of Schedule 1 to the Amending Act and immediately after the commencement of Part 2 of *Therapeutic Goods Law Application Act 2024* (WA). However, it does not commence at all if Part 2 of *Therapeutic Goods Law Application Act 2024* (WA) does not commence.

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

The *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations) amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) to support the *Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024* (the Amendment Act). The Amendment Act implements the national vaping reforms to restrict the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods (particularly non-therapeutic and disposable vaping goods).

In particular, the Amendment Regulations support the Amendment Act by specifying commercial quantities and units of vaping goods for the purposes of new offences and civil penalty provisions introduced by the Amendment Act for possessing vaping goods as part of a suite of measures designed to address and deter illicit trade.

The Amendment Regulations also provide transitional arrangements under which certain therapeutic vaping goods that would otherwise be unlawful upon commencement of the Amendment Act can be dealt with, and make a small number of minor consequential amendments. The Amendment Regulations also allow for the supply or export of compliant vaping goods that were imported or manufactured prior to 1 March 2024, as part of transitional arrangements to assist sponsors to comply with the reforms.

The Amendment Regulations also make a small number of related amendments, including to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law for the purpose of the Act, and to update a small number of definitions and exemptions to ensure consistency between the Act and the TG Regulations and MD Regulations in relation to key terms.

Details of the Amendment Regulations are set out in the Attachment.

The Amendment Regulations are compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in Attachment B.

Consultation

The Therapeutic Goods Administration (TGA) conducted two significant consultations in relation to these reforms largely implemented by the Amendment Act. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on proposed amendments to the regulation of nicotine vaping products in Australia. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique of 1 September 2023, which conveyed Ministers' collective commitment to enhancing the regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding several webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for the Department of Health and Aged Care on regulatory measures to be implemented, including those that are implemented in these Amendment Regulations.

In recent months, the TGA has undertaken extensive consultation with the states and territories on the commercial quantities of vaping goods prescribed in the Amendment Regulations, principally through the National E-Cigarette Working Group. The TGA also engaged with key stakeholders concerning the commercial quantities of vaping goods through the TGA Consultative Committee and TGA Industry Forum held on 17 May 2024. An impact analysis has been published on website of the Office of Impact Analysis at: oia.pmc.gov.au.

The Amendment Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*. The Amendment Regulations are made between enactment and commencement of the Amendment Act. Section 4 of the *Acts Interpretation Act 1901* confers upon the Governor-General the power to make regulations prior to the commencement of the Amendment Act. The Amendment Act received Royal Assent at the meeting of the Federal Executive Council on 28 June 2024, prior to consideration of the proposed Regulations.

Details of the Amendment Regulations are set out in the Attachment.

Authority: Subsection 63(1) of the *Therapeutic Goods Act 1989*

ATTACHMENT A**Details of the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*****Section 1 – Name**

This section provides that the title of the Regulations is the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations).

Section 2 – Commencement

This section provides for the commencement of the main amendments in Schedule 1 of the Amendment Regulations on the commencement of Parts 1 to 3 of Schedule 1 to the Amendment Act.

Schedule 2 repeals and replaces the commercial quantities specified in Schedule 1, and commences on the day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the Amendment Act commence. The delayed commencement of Schedule 2 is intended to provide a 3-month transition period to allow quantities of vaping goods that are below the commercial quantities specified in Schedule 1 to be depleted or disposed of as appropriate by persons who are not excepted from the offence and civil penalty provisions in the Act that apply to the possession of vaping goods in an amount equal to or exceeding the commercial quantity.

Schedule 3 commences on the later of the date that is immediately after the commencement of Parts 1 to 3 of Schedule 1 to the Amendment Act, or immediately after the commencement of Part 2 of the *Therapeutic Goods Law Application Act 2024* (WA). However, Schedule 3 does not commence at all if Part 2 of the *Therapeutic Goods Law Application Act 2024* (WA) does not commence.

Section 3 – Authority

This section provides that the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations) are made under the *Therapeutic Goods Act 1989*.

Section 4 – Schedules

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Main Amendments

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are still emerging.

The Government's vaping reforms are being implemented in stages over 2024. The Amendment Act is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms included amendments to the *Customs(Prohibited Imports) Regulations 1956*, the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.
- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an

import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.

- since 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standards.

The Amendment Regulations support the Amendment Act to implement measures that are necessary to give effect to the second stage of reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. The primary intent is to prohibit the importation, domestic manufacture and supply vapes in Australia unless certain requirements under the Act are met. The reforms implemented in the Amendment Regulations align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Summary

Schedule 1 of the Amendment Regulations principally amends the TG Regulations and the MD Regulations (collectively, the Principal Regulations) to refine the exemptions that facilitate the importation, domestic manufacture and supply in Australia of legitimate therapeutic vapes for smoking cessation and the management of nicotine dependence; to prescribe commercial quantities that apply for a 3 month transitional period following the commencement of the Amendment Regulations; and to extend the definition of 'protected persons' for the purpose of subsection 62(3) of the Act to state and territory officials in certain circumstances.

Specifically, Schedule 1 amends the TG Regulations and MD Regulations by:

- repealing the definitions of 'medical practitioner' and 'vaping device' and amending references to these terms throughout the Principal Regulations to reflect the application of the definitions of these terms inserted into the Act by the Amendment Act;
- extending the exemptions for notified therapeutic vaping goods, which are currently limited to therapeutic vaping goods that were imported or manufactured or after 1 March 2024, to therapeutic vaping goods that were imported or manufactured before 1 March 2024 where they meet current quality requirements;
- imposing new conditions on the exemptions for notified therapeutic vaping goods to require sponsors to provide a reasonable number of samples on request and to allow authorised officers to enter and inspect premises where sponsors or any other persons deal with therapeutic vaping goods;
- limiting persons that may supply therapeutic vaping goods to ultimate consumers under the exemptions for notified therapeutic vaping goods to pharmacists, medical practitioners and nurse practitioners that are authorised under state or territory law to supply prescription medicines;
- extending the list of persons in the exemptions that may supply and receive therapeutic vaping goods to include persons in relation to whom a consent is granted under section 41RC of the Act and persons specified in a determination under section 41R of the Act;
- extending the notice provisions for articles or components of therapeutic vaping devices and therapeutic vaping device accessories to therapeutic cannabis vaping goods;
- amending the definitions of therapeutic vaping device accessory and therapeutic cannabis vaping device accessory so they are not required to be refillable;

- clarifying that a ‘therapeutic vaping pack’ must include at least one therapeutic vaping substance or therapeutic vaping substance accessory;
- prescribing matters to facilitate the granting of authorities under subsection 19(5) of the Act without ethics committee approval in relation to therapeutic vaping substances that do not contain nicotine or any other active ingredient;
- clarifying that supply to the ultimate consumer under the special access scheme or the authorised prescriber scheme is not required in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack;
- prescribing things that may be required in an enforceable direction;
- prescribing commercial quantities, units and permitted quantities of vaping devices, vaping accessories, and vaping substances that are liquids;
- extending the definition of ‘protected persons’ under subsection 62(3) of the Act to state and territory officials to whom certain powers and functions are delegated under the Act;
- creating a time-limited exemption (for a period of 6 months following commencement of Schedule 1) to permit the export the therapeutic vaping goods and therapeutic cannabis vaping goods that comply with all Commonwealth and state or territory laws before commencement of Parts 1-3 of Schedule 1 to the Amendment Act; and
- including relevant transitional provisions.

Schedule 2 amends the TG Regulations by repealing the commercial quantities prescribed in Schedule 1 and replacing them with lower commercial quantities. Schedule 2 commences on the day after the end of the period of 3 months beginning on the day Parts 1 to 3 of Schedule 1 to the Amendment Act commence.

Schedule 3 amends the TG Regulations to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law.

Part 1—Amendments

Therapeutic Goods (Medical Devices) Regulations 2002

Item [1] – Paragraph 10.6(2)(a)

Item 1 amends the reference to a ‘medical practitioner registered in a State or internal Territory’ in paragraph 10.6(2)(a) to omit the words ‘registered in a State or internal Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that already refers to registration in a State or Territory. Consequently, the words that are omitted are redundant when referring to a medical practitioner in the Principal Regulations and therefore not required.

Item [2] – Table item 1.1 of Part 1 of Schedule 4, column headed “Kinds of medical devices”, paragraph (d))

Item 2 similarly amends the reference to a ‘medical practitioner registered under a law of a State or Territory’ in table item 1.1 of Part 1 of Schedule 4 to omit the words ‘registered under a law of a State of internal Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that already refers to registration in a State or Territory, and consequently these words are redundant when referring to a medical practitioner in the Principal Regulations.

Item [3] – Table item 2.17 of Part 2 of Schedule 4, column headed ‘Conditions’, paragraph (b)

Item 3 repeals paragraph (b) of the column headed ‘Conditions’ in table item 2.17 of Part 2 of Schedule 4 and insert a new paragraph that includes the existing reference to goods imported or manufactured on or after 1 March 2024, and a new reference to goods that were imported or manufactured before 1 March 2024. A sponsor notice in relation to the latter category of goods must be provided before the device is supplied to the ultimate consumer and no later than 2 months after Schedule 1 to the Amendments Regulations commences.

The effect of this amendment, together with item 33, is to extend the operation of the exemption in item 2.17 so that goods that were imported or manufactured before 1 March 2024 and comply with the essential principles are eligible to be supplied to the ultimate consumer, provided that a sponsor notice is given by the sponsor to the Secretary within 2 months of the commencement of Schedule 1 to the Amendment Regulations. This will create a pathway for the supply of compliant stock that existed prior to the commencement of the application of the exemption on 1 March 2024.

The 2-month timeframe for the giving of a sponsor notice is intended to provide a sufficient period during which compliant stock may be identified and sponsors may make the necessary notification. A time limited period is required so that, at the conclusion of the period, there is certainty as to the goods that can be supplied under the exemption.

Item [4] – Table item 2.17 of Part 2 of Schedule 4, column headed ‘Conditions’, paragraph (g)

Item 4 inserts new conditions of exemption in paragraphs (fa), (fb), (fc), (fd) and (fe), and amend the wording in paragraph (g) in item 2.17.

Medical devices listed in an item in Part 2 of Schedule 4 are exempt from the need to be included in the Register, subject to the specified conditions in the relevant item. Item 2.17 in Part 2 of Schedule 4 provides for the exemption of specific devices subject to compliance with specified conditions. Item 2.17 allows for the lawful importation, manufacture and supply of unregistered therapeutic vaping devices and therapeutic vaping device accessories subject to conditions.

Paragraph (fa) requires the sponsor to provide a reasonable number of samples of a device to the Secretary on request, and to do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the essential principles may be undertaken efficiently.

Paragraph (fb) requires the sponsor to allow an authorised officer to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the device. While on those premises, the sponsor must allow the authorised officer to inspect the premises and the device and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the device or any thing on the premises that relate to the device. The authorised officer must also be allowed to make any still or moving image or any recording of the premises or any thing on the premises.

Paragraph (fc) requires the sponsor, if requested to do so by an authorised officer, to produce to the authorised officer such documents relating to the device as the authorised person requires and to allow the authorised officer to copy the documents.

Paragraph (fd) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device allows an authorised officer to do the things referred to in paragraph (fb).

Paragraph (fe) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the device as the authorised officer requires and to allow the authorised officer to copy the documents.

The conditions in paragraphs (fb) to (fe) are necessary to ensure that the TGA can obtain information to determine whether therapeutic vaping devices and therapeutic vaping device accessories that have been notified as complying with the essential principles do in fact comply. This may be particularly useful in relation to therapeutic vaping devices and therapeutic vaping device accessories to which the *Therapeutic Goods (Medical Device Standard—Therapeutic Vaping Devices) Order 2023* applies, as that standard includes a range of requirements that apply to manufacturing processes, and the ability to enter manufacturing premises will assist in this regard.

Paragraph (g) specifies the persons to whom goods may be supplied by wholesale (persons who are not the ultimate consumer).

Subparagraph (g)(i) refers to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods. This amendment is made to align the language with that used in section 41QB(8)(a) of the Act, as inserted by the Amendment Act, when referring to the same person. The meaning of this provision is not changed.

Subparagraph (g)(ii) specifies a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

Subparagraph (g)(ii) is amended to align with the description of persons to whom vaping goods may be lawfully supplied by wholesale in section 41QB(8)(b), as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in the analogous subparagraph (g)(iv), which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice could extend to health professionals, such as dentists and optometrists. This amendment ensures that the exemption applies only in relation to goods supplied by wholesale to a wholesaler, pharmacist, medical practitioner or nurse practitioner that is authorised under the law of a State or Territory, and is consistent with the exception in section 41QB(10) of the Amendment Act, which applies only to the supply of vaping goods by wholesale to these persons.

Subparagraph (g)(iii) specifies a recipient to whom a consent under subsection 41RC(1) of the Act to supply the device has been given. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient to whom a consent is granted under section 41RC(1) of the Act.

Subparagraph (g)(iv) specifies, in relation to a device that is covered by a determination made by the Minister under section 41R of the Act, a recipient who is not the ultimate consumer specified in the determination, or included in a class of persons specified in the determination. This amendment is necessary to ensure consistency with the amendments under the Amendment Act that allow for goods to be supplied by wholesale to a recipient specified in a determination made by the Minister under section 41R of the Act.

Item [5] – Table item 2.17 of Part 2 of Schedule 4, column headed ‘Conditions’, paragraph (h)(ii)

Item 5 repeals paragraph (h)(ii) and inserts a new paragraph specifying supply to the ultimate consumer may only be by a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

This subparagraph is amended to align with the description of persons who may supply vaping goods to ultimate consumers in section 41QB(10) of the Act, as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in subparagraph (h)(ii) of item 2.17, which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice could extend to health professionals, such as dentists and optometrists.

This amendment ensures that the exemption applies only in relation to goods supplied to the ultimate consumer by a pharmacist, medical practitioner or nurse practitioner, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amendment Act, which applies only to the supply of vaping goods to the ultimate consumer by these persons.

Item [6] and [7] – Table item 2.18 of Part 2 of Schedule 4, column headed “Kinds of medical devices”, paragraphs (a) and (b) and column headed “Conditions”, paragraph (a)

Item 6 inserts a reference to a component or article imported for use in the manufacture of a therapeutic cannabis vaping good in the column that specifies the goods to which the exemption in item 2.18 applies. Item 7 inserts a reference to a therapeutic cannabis vaping good in the description of the sponsor notice that must be provided as a condition of this exemption.

Current item 2.18 in Part 2 of Schedule 4 to the MD Regulations allows for the lawful importation of a component or article imported for use in the manufacture of a therapeutic vaping device and a therapeutic vaping device accessory (which does not include a therapeutic cannabis vaping device or therapeutic cannabis vaping device accessory). The exemption is subject to conditions.

The effect of these amendments is that the notification requirements under subregulation 5A(13) of the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations) and under Part 2 of Schedule 4 to the MD Regulations will change for an article or component for use in the manufacture of a therapeutic cannabis vaping good. Specifically, an importer of such a good will be required to give a notice stating that the goods are for use in the manufacture, in accordance with the requirements of the *Therapeutic Goods Act 1989*, of a therapeutic cannabis vaping good by a manufacturer who holds all relevant licences and approvals required under the law of the relevant State or Territory. This notice requirement currently applies to importers of articles or components for use in the manufacture of therapeutic vaping devices and therapeutic vaping device accessories. These amendments will have the effect that the notification requirements for articles or components imported for use in manufacture, rather than as finished goods, will be the same whether those articles or components are for use in the manufacture of therapeutic vaping devices, therapeutic vaping device accessories, or therapeutic cannabis vaping goods.

A person seeking to import an article or component for use in the manufacture of a therapeutic cannabis vaping good must meet the notification requirements under subregulation 5A(13) of the CPI Regulations. Paragraph 5A(13)(a) of the CPI Regulations applies to a therapeutic cannabis vaping good, including an article or component to be imported for use in manufacture, and requires a statement that the goods comply with the essential principles or are imported with the consent of the Secretary. Paragraph 5A(13)(b) of CPI Regulations applies to goods that are not therapeutic cannabis vaping goods, and includes at subparagraph (ii) the option of giving a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations. By extending the application of item 2.18 of Part 2 of Schedule 4 to the MD Regulations to an article or component for use in the manufacture of a therapeutic cannabis vaping good, these amendments have the effect that a sponsor of these goods will meet the notification requirements under subregulation 5A(13) of the CPI Regulations by giving a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations, rather than needing to meet the more onerous notice requirement under paragraph 5A(13)(a) of CPI Regulations.

Item [8] – Part 2 of Schedule 4 (table item 2.18, column headed ‘Conditions’, after paragraph (b))

Item 8 inserts a new requirement as a condition of the exemption under item 2.18 that the sponsor must provide a reasonable number of samples of a device to the Secretary on request, and must do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the essential principles can be undertaken efficiently.

Items [9], [10] and [11] – Dictionary (paragraph (a) of the definition of ‘health professional’, definition of ‘medical practitioner’, and paragraphs (a) and (b) of ‘serious’)

Item 10 repeals the definition of ‘medical practitioner’ because the term is defined in the Act, as inserted by the Amendment Act. Items 9 and 11 amends the references to ‘medical practitioner’ in the definitions of ‘health professional’, and ‘serious’ to reflect the new definition of ‘medical practitioner’ in the Act, as inserted by the Amendment Act.

Item [12] – Dictionary (paragraphs (a) and (b) of the definition of therapeutic cannabis vaping device)

Item 12 amends the definition of ‘therapeutic cannabis vaping device’ to substitute the term ‘vaping device’ that is defined in the Act, as inserted by the Amendment Act, to ensure consistency with the definition under the Act.

Item 12 also adds subparagraph (a)(ii) to exclude from the definition of ‘therapeutic cannabis vaping device’ a component or article imported for use in the manufacture of a therapeutic cannabis vaping device. The exclusion of a component or article imported for use in the manufacture of a therapeutic cannabis vaping device from the definition of a ‘therapeutic cannabis vaping device’ has the effect that a component or article is not regarded as a ‘therapeutic cannabis vaping device’, and consequently a notice under item 2.18 of Part 2 of Schedule 4 to the MD Regulations is required instead of a notice under paragraph 5A(13)(a) of the *Customs (Prohibited Imports) Regulations 1956* in order to meet the notification requirements under the subregulation 5A(13) of those regulations.

Item [13] – Dictionary (definition of therapeutic cannabis vaping device accessory)

Item 13 repeals the definition of therapeutic cannabis vaping device accessory and replaces it with a definition that changes the order of paragraphs (a) and (b) to align with the ordering of those requirements in the definition of ‘vaping accessory’ in the Amending Act. Item 13 also removes the requirement in paragraph (c) that the good must be designed or intended to be refillable. The only change to the meaning of this definition is that a good can be a ‘therapeutic cannabis vaping device accessory’ whether or not it is intended or designed to be refillable.

Item [14] – Dictionary (definition of therapeutic vaping device)

Item 14 repeals the definition of therapeutic vaping device and replaces it with a definition that references the term ‘vaping device’ as inserted into the Act by the Amendment Act. In effect, there is no change to the operation of this term.

Item [15] – Dictionary (definition of therapeutic vaping device accessory)

Item 15 repeals the definition of therapeutic vaping device accessory and replaces it with a definition that include the words ‘designed or intended’ in paragraphs of (a) and (b) rather than the chapeau of the definition, and removes the requirement in paragraph (c) that the good must be designed or intended to be refillable. The only change to the meaning of this definition is that a good can be a ‘therapeutic vaping device accessory’ whether or not it is intended or designed to be refillable.

Therapeutic Goods Regulations 1990

Item [16] – Regulation 2 (paragraph (a) of the definition of disposable therapeutic vape)

Item 16 amends paragraph (a) of the definition of disposable therapeutic vape in the TG Regulations to substitute the reference to ‘vaping device’ defined in the TG Regulations with

the defined term in the Act as inserted by the Amendment Act. In effect, there is no change to the operation of this term.

Item [17] – Regulation 2 (definition of therapeutic vaping pack)

Item 17 repeals the definition of therapeutic vaping pack and replaces it with a new definition that retains the elements of the current definition in the Act (that it must contain at least one therapeutic vaping device or therapeutic vaping device accessory and not contain any other therapeutic goods). Item 17 also supplements the definition with a new requirement that a therapeutic vaping pack must also contain at least one therapeutic vaping substance or therapeutic vaping substance accessory.

This amendment clarifies that a therapeutic vaping device or therapeutic vaping device accessory is only to be regulated as part of a therapeutic vaping pack, and consequently subject to the requirements of Chapter 3 of the Act, if the pack also contains a therapeutic vaping substance or therapeutic vaping substance, being goods that are regulated under Chapter 3 of the Act. This amendment ensures that a pack that contains only a therapeutic vaping device and/or a therapeutic vaping device accessory, being goods that are ordinarily subject to the requirements of Chapter 4 of the Act if not part of a therapeutic vaping pack, are not regulated under Chapter 3 of the Act unless the pack of which they are a part also contains goods that are regulated under Chapter 3 of the Act.

Item [18] – Regulation 2 (definition of therapeutic vaping substance accessory)

Item 18 repeals the definition of therapeutic vaping substance accessory to substitute the description of a vaping device with a reference to the defined term ‘vaping device’ inserted into the Act by the Amendment Act. It also changes the order of paragraphs (a) and (b) to align with the ordering of the definition of ‘vaping accessory’ in the Amendment Act. In effect, there is no operational change to the meaning of this term.

Item [19] – Regulation 2 (definition of vaping device)

Item 19 repeals the definition of ‘vaping device’, which is defined in the Act, as inserted by the Amendment Act, and accordingly a definition is no longer required in the Principal Regulations.

The definition in the Act, as inserted by the Amendment Act, is the same as that in the current TG Regulations, with the exception of the omission of note 2 in the definition in these Regulations. That note states that, to avoid doubt, therapeutic vaping substances accessories and therapeutic vaping device accessories are not devices to which paragraph (b) of the definition applies (being the paragraph that applies to temporarily inoperable, incomplete, damaged and unfinished devices). The note is not necessary because the definitions of ‘therapeutic vaping substance accessory’ and ‘therapeutic vaping device accessory’ refer to goods that are ‘designed or intended for use in, or with, a therapeutic vaping device’ and it is therefore clear that these items are for use *in or with* a therapeutic vaping device (being a therapeutic good that is a vaping device) rather than amounting to vaping devices in and of themselves.

Item [20] – After Part 2E, insertion of new Part 2F – Vaping goods - commercial quantities units and permitted quantities of vaping goods

Commercial quantity

Item 20 inserts Part 2F, titled ‘Vaping goods’ into the TG Regulations. New regulations 10N, 10P and 10Q form part of new Part 2F.

New regulation 10N prescribes commercial quantities of vaping goods for the purpose of the definition of ‘commercial quantity’ in subsection 3(1) of the Act, as inserted by the Amendment Act. Commercial quantities are required because the possession offences and civil penalty provisions in sections 41QC of the Act, as inserted by the Amendment Act, apply in relation to the possession of a commercial quantity of vaping goods other than in circumstances where the exceptions in sections 41QC applies. The exceptions provide for the possession of legitimate therapeutic vapes by specified persons in the supply chain, and by other persons specified in an instrument under section 41R or to whom consent is granted under section 41RC. Consequently, a contravention of section 41QC will only arise, and the commercial quantity is only relevant, in relation to vaping goods that are not legitimate therapeutic vapes and are not specified under section 41R or are goods in relation to which a consent has been granted under section 41RC.

The commercial quantities of vaping goods that are prescribed therefore seek to penalise the possession of illicit vaping goods for commercial purposes and to ensure that legitimate therapeutic use is not penalised.

Regulation 10N prescribes 9 vaping devices, 90 vaping accessories, and 300 ml of vaping substances that is a liquid. These quantities will apply for a period of 3 months after Schedule 1 to the Amendment Act commences, after which these quantities are repealed and replaced with the quantities prescribed in amending item 1 of Schedule 2 to the Amendment Regulations, being 3 vaping devices, 30 vaping accessories, and 100 ml of vaping substances that is a liquid.

The higher quantities that are prescribed for the first 3 months will effectively provide a transition period during which quantities of vaping goods that exceed the commercial quantities that will apply at the conclusion of that 3-month period can be depleted.

Units of vaping goods

New regulation 10P prescribes quantities of vaping goods for the purpose of the definition of ‘unit’ in subsection 3(1) of the Act, as inserted by the Amendment Act. The civil penalty provisions inserted into the Act by the Amendment Act relevantly provide that a person who contravenes the provisions commits a separate contravention in respect of each unit of vaping goods.

The quantities that are prescribed amount to one unit are one vaping device, 60mL of vaping substance that is a liquid, and 10 vaping accessories. These quantities are based on quantities that may be supplied to an individual as a starter pack.

Permitted quantities

New regulation 10Q prescribes quantities of vaping goods for the purpose of the definition of ‘permitted quantity’ in subsection 41QD(10) of the Act, as inserted by the Amendment Act. Section 41QD is an offence and civil penalty provision that applies to the possession, in a retail premises, of less than a commercial quantity of vaping goods. An exception is provided in subsection 41QD(9) in relation to the possession of a quantity of a kind of vaping goods by a person if the vaping goods are for use by the person personally, and the quantity is no more than the ‘permitted quantity’ of that kind of vaping goods.

The purpose of the exception in subsection 41QD(9) is to ensure that the personal possession of a small quantity of vaping goods required for personal use (whether legitimate therapeutic use or otherwise) is not penalised simply because it occurs in retail premises. A separate exception in subsections 41QD(7) and (8) applies in relation to possession by authorised persons in the supply chain of vaping goods for legitimate therapeutic use.

The quantities prescribed are 1 vaping device, 3 vaping accessories, and 30mL of vaping substance that is a liquid. The modest quantities that are prescribed are necessary to confine the exception to the possession of quantities that generally support personal use over the course of a single day. It is necessary to limit the permitted quantities to a single day’s use, so that the exception does not apply to the possession of small quantities intended for commercial supply that could theoretically be for personal use over a longer period such as a month or three months.

Item [21] – After regulation 12B, insertion of new regulation 12BA – authorised prescriber authorities for therapeutic vaping substances that are not medicines

The Act provides a number of avenues that allow access to therapeutic goods that are not included in the Register. The authorised prescriber scheme under subsection 19(5) of the Act allows authorised medical practitioners to lawfully supply a specified ‘unapproved’ therapeutic good (or class of ‘unapproved’ therapeutic goods) to a class of patients with a particular medical condition. Ordinarily, there is requirement for ethics committee approval or specialist college endorsement for a medical practitioner to be given an authority to supply specified therapeutic goods (refer to subsection 19(6)(aa) of the Act). This requirement does not apply in the circumstances (if any) prescribed by the regulations for the purposes of this subsection. The current regulation 12B prescribes the medical practitioners, specified class of goods and circumstances where the requirement for approval by an ethics committee under paragraph 19(6)(aa) are not required.

Item 21 inserts new regulation 12BA into the Principal Regulations relating to authority that may be granted under subsection 19(5) of the Act (the authorised prescriber scheme) to a medical practitioner for the supply of unapproved therapeutic vaping substances that are not medicines. In addition, new regulation 12BA allows for a specified medical practitioner to be granted authorisation to prescribe and supply unapproved therapeutic vaping substances that do not contain nicotine without having to apply for ethics committee approval. The effect of regulation 12BA is to ensure that therapeutic vaping substances that do not contain nicotine are treated the same way under the authorised prescriber scheme as therapeutic vaping substances that contain nicotine or any other active ingredient under regulation 12B.

Regulation 12B currently prescribes matters necessary for an authority to be granted under the authorised prescriber scheme in relation to medicines that are therapeutic vaping substances and that contain nicotine. Regulation 12B does not apply to therapeutic vaping substances that do not contain nicotine or any other active ingredient because regulation 12B is limited to medicines and these goods do not meet the definition of ‘medicine’. This amendment prescribes matters necessary for an authority to be granted under the authorised prescriber scheme in relation to therapeutic vaping substances that are not medicines.

The class of persons that is prescribed in subregulation 12BA(2) for the purposes of paragraph 19(6)(a) of the Act is the same class as that prescribed under regulation 12B, being medical practitioners engaged in clinical practice in or outside a hospital are a prescribed class of medical practitioners.

Subregulation 12BA(2) prescribes therapeutic vaping substances that are not medicines where they are to be administered by inhalation and the supply is for the treatment of smoking cessation or the management of nicotine dependence for the purpose of subsection 19(6) of the Act. The effect of this is that an authorised prescriber authority can be granted for these goods without requiring approval from an ethics committee, as is the case under regulation 12B for therapeutic vaping substances that contain nicotine where the supply is for the treatment of smoking cessation or the management of nicotine dependence.

Subregulation 12BA(3) prescribes the class of recipients for the purposes of paragraph 19(6)(b) of the Act as the class of persons each of whom is seeking treatment for smoking cessation or the management of nicotine dependence.

Subregulation 12BA(4) prescribe the circumstances in which therapeutic vaping substances may be authorised for supply under the authorised prescriber scheme as being that the supplier of the authorised vaping substance or class of authorised vaping substances complies with the treatment directions (if any) mentioned in the authority for the authorised vaping substance or class of authorised vaping substances. These are the same circumstances prescribed under regulation 12B for therapeutic vaping substances that contain nicotine.

Item [22] – After regulation 47B, insertion of new section 47C - Protected persons

Item 22 inserts new regulation 46B into the TG Regulations to prescribe a person for the purpose of the definition of ‘protected person’ in the new subsection 62(3) of the Act, as inserted by the Amendment Act. The person prescribed is a person to whom powers or functions are delegated under the new subsection 57(1A) of the Act, as inserted by the Amendment Act, which provides for the Secretary to delegate all or any of the powers and functions under Chapter 5A (enforcement), section 52AAA (forfeiture of things seized under search warrant), or section 52AAB (return or retention of thing declared not to be forfeited) to an officer of a Department of State, a Department or administrative unit of the Public Service of a Territory, or an authority of a State or of a Territory, being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement.

The effect of this amendment is that state and territory officers that are delegated powers or functions under subsection 57(1A) of the Act will be ‘protected persons’ for the purpose of section 62 of the Act and accordingly will be protected from criminal responsibility in accordance with section 62. That section protects certain persons from criminal responsibility for offences under a law of the Commonwealth or a State law, in circumstances relating to

obtaining, possessing, or conveying goods in connection with finding out whether the Act or Principal Regulations have been complied with. This amendment will ensure that state and territory officers can undertake compliance and enforcement activities without such activities amounting to contraventions of the Act.

Item [23] – paragraph 47A(2)(a)

Item 23 amends the reference to a ‘medical practitioner registered in a State or Territory’ in paragraph 47A(2)(a) to omit the words ‘registered in a State or Territory’. The Amendment Act inserts a definition of ‘medical practitioner’ into the Act that incorporates registration in a State or Territory, and consequently these words are redundant when referring to a medical practitioner in the Principal Regulations.

Item [24] – After regulation 47B, insertion of new regulation 47C - Enforceable directions

This item inserts a new regulation 47C that prescribes, for the purpose of paragraph 42YT(2)(e) of the Act, a requirement to quarantine goods, store goods in a secure manner, and not supply goods, as things that may be the subject of an enforceable direction under section 42YT of the Act. The power to require these things to be done is necessary to ensure the supply of therapeutic goods can be prevented where the Secretary believes, on reasonable grounds, that therapeutic goods do not comply with the Act and the direction is necessary to protect the health and safety of humans.

Item [25] – Schedule 5 (table item 1, column 2, paragraph (d))

Item 25 amends the reference to a ‘medical practitioner registered under a law of a State or Territory’ in item 1 of Schedule 5 to omit the words ‘registered under a law of a State or Territory’. The Amendment Act defines a ‘medical practitioner’ by reference to registration in a State or Territory and therefore these words are redundant when describing a medical practitioner in the Principal Regulations.

Item [26] – Schedule 5A (table item 15, column 2, paragraph d))

Item 26 amends item 15 to clarify that the requirement that a wholesaler must intend the goods to be supplied to the ultimate consumer of the goods in accordance with an approval or authority under section 19 of the Act (being the special access and authorised prescriber schemes) does not apply in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack.

Unlike therapeutic vaping substances and therapeutic vaping substance accessories, which may only be supplied to the ultimate consumer pursuant to the special access scheme or the authorised prescriber scheme, therapeutic vaping devices or therapeutic vaping device accessories that are regulated under Chapter 4 of the Act are not presently required to be supplied to the ultimate consumer pursuant to the special access or authorised prescriber schemes. This amendment clarifies that therapeutic vaping devices and therapeutic vaping device accessories are to be treated in the same way when part of a therapeutic vaping pack.

Item [27] – Schedule 5A (table item 15, column 3, paragraph (b))

Item 27 repeals paragraph (b) of column 3 in table item 15 of Schedule 5A and inserts a new paragraph that extends the scope of the notification requirement in relation to vaping goods that have been imported into Australia or manufactured in Australia before 1 March 2024. The current notification requirements only apply where the goods are imported into Australia, or manufactured in Australia on or after 1 March 2024. This item permit sponsor notices to be given in relation to vaping goods that were imported into Australia before 1 March 2024 and manufactured in Australia before 1 March 2024 provided the notice is given no later than 2 months after Schedule 1 to the Amendment Regulations commences. Note however that despite allowing for the supply of these goods, supply of these goods is limited to pharmacists and other persons specified in subparagraph (i)(ii) (also refer to item 29).

Item 15 of Schedule 5A provides the lawful basis for allowing therapeutic vaping goods to be imported, manufactured and supplied in Australia, despite these goods not being included in the Register, subject to specified conditions being met.

The effect of this amendment, together with amending item 35, is to extend the operation of the exemption in item 15 so that goods that were imported or manufactured before 1 March 2024 and comply with applicable standards are eligible to be supplied to the ultimate consumer under item 15, provided that they are notified within two months of the commencement of Schedule 1 to the Amendment Regulations. This will create a pathway for the supply of compliant stock that existed prior to the commencement of the application of the exemption on 1 March 2024.

The imposition of the 2-month timeframe, beginning on the day these amendments come into force, for the giving of a sponsor notice is intended to provide a sufficient period during which compliant stock may be identified and sponsors may make the necessary notification.

Item [28] – Schedule 5A (table item 15, column 3, paragraphs (g) and (h))

Item 25 repeals paragraphs (g) and (h) of item 15 and inserts new paragraphs (fa), (fb), (fc), (fd), (fe), (g) and (h).

Paragraph (fa) requires the sponsor to provide a reasonable number of samples of the goods to the Secretary on request, and to do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post-notification testing to assess compliance with the relevant standards can be undertaken efficiently.

Paragraph (fb) requires the sponsor to allow an authorised officer to enter, at any reasonable time, any premises (including premises outside Australia) at which the sponsor or any other person deals with the goods. While on those premises, the authorised officer must be allowed to inspect the premises and the goods and to examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of the goods or any thing on the premises that relates to the goods. The authorised officer must also be allowed to make any still or moving image or any recording of the premises or any thing on the premises.

Paragraph (fc) requires the sponsor, if requested to do so by an authorised officer, to produce to the authorised person such documents relating to the goods as the authorised person requires and allow the authorised person to copy the documents.

Paragraph (fd) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the goods allows an authorised officer to do the things referred to in paragraph (fb).

Paragraph (fe) requires a sponsor that is not the manufacturer to have procedures in place to ensure that the manufacturer of the device, if requested to do so by an authorised officer, produces to the authorised officer such documents relating to the goods as the authorised person requires and allow the authorised person to copy the documents.

The conditions in paragraphs (fb) to (fe) are necessary to ensure that the TGA can obtain information to determine whether therapeutic vaping goods that have been notified as complying with standards do in fact comply with those standards.

Paragraph (g) specifies the persons who may lawfully manufacture the goods in Australia.

Subparagraph (g)(i) refers to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the goods. This amendment is made to align the language with that is used in section 41QA(5)(b)(i) of the Act, as inserted by the Amendment Act, when referring to the same person. The intent of this provision has not changed.

Subparagraph (g)(ii) refers to a person to whom the Secretary has given consent in accordance with subsection 41RC(1) of the Act, as inserted by the Amendment Act, to manufacture the goods and the manufacture of the goods is in accordance with that consent.

Paragraph (h) specifies the persons to whom goods may be supplied by wholesale (persons who are not the ultimate consumers of the goods).

Subparagraph (h)(i) refers to the holder of a licence in force under Part 3-3 of the Act that authorises a step in the manufacture of the device. This amendment is made to align the subparagraph with language used in section 41QB(8)(a) of the Act, as inserted by the Amendment Act, when referring to the same person. The intent of this provision does not change.

Subparagraph (h)(ii) is amended to align with the description of persons to whom vaping goods may be lawfully supplied by wholesale in section 41QB(8)(b) of the Act, as inserted by the Amendment Act. This class of persons is narrower than the class of persons currently specified in the analogous subparagraph (h)(ii), which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the current Poisons Standard, and in practice extends to health professionals such as dentists and optometrists. This amendment ensures that the exemption applies only in relation to goods supplied by wholesale to a wholesaler, pharmacist, medical practitioner or nurse practitioner that is authorised under the law of a State or Territory, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amendment Act, which applies only to the supply of vaping goods by wholesale to these persons.

Subparagraph (h)(iii) refers to a recipient to whom a consent under subsection 41RC(1) of the Act to supply the goods has been given. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient to whom a consent is granted under section 41RC(1) of the Act.

Subparagraph (h)(iv) specifies, in relation to a good that is covered by a determination made by the Minister under section 41R of the Act, a recipient specified in the determination, or included in a class of persons specified in the determination. This amendment is necessary to ensure that the exemption applies to goods supplied by wholesale to a recipient specified in a determination made by the Minister under section 41R of the Act.

Item [29] – Schedule 5A (table item 15, column 3, subparagraph (i)(ii))

Item 29 amends the description of the persons in subparagraph (i)(ii) of item 15 who may supply goods to the ultimate consumer, to specify a pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the State or Territory in which the recipient carries on a business, practises or is employed.

This subparagraph is amended to align with the description of persons who may supply vaping goods to the ultimate consumer in section 41QB(10) of the Act, as inserted by the Amending Act. This class of persons is narrower than the class of persons currently specified in subparagraph (i)(ii) of item 15, which refers to any person who is authorised under the law of a State or Territory to deal with one or more substances included in Schedule 4 to the Poisons Standard, and in practice extends to health professionals such as dentists and optometrists.

This amendment ensures that the exemption applies only in relation to goods supplied to the ultimate consumer by a pharmacist, medical practitioner or nurse practitioner, and is consistent with the exception in section 41QB(10) of the Act, as inserted by the Amending Act, which applies only to the supply of vaping goods to the ultimate consumer by these persons.

Item [30] – Schedule 5A (table item 15, column 3, subparagraph (i)(iii))

Item 30 amends item 15 to clarify that the requirement that the ultimate supply to a consumer must be in accordance with such an approval or authority under section 19 of the Act (being the special access scheme or the authorised prescriber scheme) does not apply in relation to therapeutic vaping devices or therapeutic vaping device accessories that are part of a therapeutic vaping pack.

Unlike therapeutic vaping substances and therapeutic vaping substance accessories, which may only be supplied to the ultimate consumer pursuant to the special access scheme or the authorised prescriber scheme, therapeutic vaping devices or therapeutic vaping device accessories that are regulated under Chapter 4 of the Act are not required to be supplied to the ultimate consumer pursuant to the special access or authorised prescriber schemes. This amendment makes it clear that therapeutic vaping devices and therapeutic vaping device accessories are to be treated in the same way when part of a therapeutic vaping pack.

Item [31] – Schedule 5A (table item 16, column 3, after paragraph (b))

Item 31 inserts a new condition in item 16 of Schedule 5A that the sponsor must provide a reasonable number of samples of a good to the Secretary on request, and must do so within the period specified by the Secretary, which must be at least 5 working days. Obtaining samples in a timely manner is necessary to ensure that post notification testing to assess compliance with the standards can be undertaken efficiently.

Item [32] – Schedule 7 – (table items 22 and 23, column 2, subparagraph (a)(iii))

Item 32 amends references to a ‘medical practitioner registered under a law of a State or Territory’ to omit the words ‘registered under a law of a State or Territory’. The Amendment Act defines a ‘medical practitioner’ by reference to registration in a State or Territory and these words are therefore redundant when describing a medical practitioner in the Principal Regulations.

Part 2—Transitional provisions**Item [33] – regulation 11.73**

Regulation 11.73 currently states that the amendments made by Part 1 of Schedule 2 to the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* (other than the amendments of the Dictionary) apply to therapeutic goods imported or manufactured on or after 1 March 2024.

Item 33 replaces the reference in regulation 11.73 to therapeutic goods imported or manufactured on or after 1 March 2024 with a reference to therapeutic goods imported or manufactured before, on or after 1 March 2024. This amendment is necessary because the Amendment Regulations amend item 2.17 of Part 2 of Schedule 4 to the MD Regulations so that it applies to therapeutic goods imported or manufactured before 1 March 2024.

This amendment, together with amending item 3, has the effect that therapeutic goods imported or manufactured before 1 March 2024 are eligible to meet the requirements of the exemption in item 2.17. It does not have retrospective effect because the exemption requires prospective meeting of those requirements, including the giving of a sponsor notice, in order for the exemption to apply.

This amendment has the effect that items 1.5 and 1.6 of Part 2 of Schedule 4 to the MD Regulations, which were repealed by the *Therapeutic Goods Legislation Amendment (Vaping) Regulations 2023* in relation to therapeutic goods imported or manufactured on or after 1 March 2024, are now also repealed in relation to therapeutic goods imported or manufactured before 1 March 2024. This is consistent with the amendments to the Act made by the Amendment Act, under which the new offence and civil penalty provisions relating to vaping goods in the Act apply to vaping goods unless an exemption applies under which ‘the sponsor has given a notice in compliance with the exemption’. The exemptions in items 1.5 and 1.6 of Part 2 of Schedule 4 do not require a notice to be given and consequently goods that are exempt under those items cannot meet this requirement, and therefore are prohibited to be supplied.

Item [34] – Part 11, Application provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Item 34 insert a new Division 11.22 into Part 11 of the MD Regulations. Division 11.22 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions.

Clause 11.79 – Definitions

Clause 11.79 provides a definition for the term “amending regulations” in the new Division 11.22. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

Clause 11.80 – Application of amendments

Clause 11.80 provides that the amendment made by item 3 of Schedule 1 applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule. This has the effect that therapeutic goods imported or manufactured before, on or after the commencement of the Schedule will be eligible to provide a sponsor notice and meet the requirements of the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations.

Clause 11.80 also provides that the amendments made by items 4 and 5 of Schedule 1 apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule. This has the effect that the new conditions of the exemption in item 2.17 of Part 2 of Schedule 4 to the MD Regulations requiring the provision of a reasonable number of samples on request and allowing authorised officers to enter and inspect premises, and the description of the persons who may supply goods to the ultimate consumer, do not apply in relation to goods imported or manufactured before the commencement of that Schedule.

Clause 11.80 also provides that the amendments made by item 6, 7 and 12 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported on or after 1 October 2024. This has the effect that articles or components for use in the manufacture of therapeutic cannabis vaping goods that are imported on or after 1 October 2024 will be excluded from the definition of “therapeutic cannabis vaping device “ and accordingly will be required to give a notice under section 2.18 of Part 2 of Schedule 4 to the MD Regulations.

Clause 11.80 also provides that item 8 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported on or after the commencement of that Schedule. It also has the effect that the new condition requiring the provision, on request, of a reasonable number of samples of goods imported under item 2.18, does not apply to in relation to therapeutic goods imported before the commencement of that Schedule.

Clause 11.81 – Transitional vaping devices—exemption from Division 3 of Part 4-11 of the Act

Clause 11.81 provides a transition provision for transitional vaping devices in relation to the exemption from Division 3 of Part 4-11 of the Act.

Subclause (1) provides that medical devices that are exported from Australia are *transitional vaping devices* if the devices are therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods, and were imported, manufactured or supplied before the commencement of Schedule 1 to the Amendment Regulations, and as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

In effect, clause 11.81 allows a sponsor to export therapeutic vaping devices, therapeutic vaping device accessories or therapeutic cannabis vaping goods that complied with all relevant laws that were applicable at the time the goods were imported, manufactured or supplied (as applicable), without requiring the goods to be included in the Register. The clause reduces regulatory burden associated with exporting such goods, allowing sponsors to potentially minimise the financial impact where such goods can no longer be lawfully supplied in Australia.

Pursuant to subclause (3), this exemption from the operation of Part Division 3 of Part 4-11 the Act ceases to have effect at the end of the period of 6 months starting on the day Schedule 1 to the Amendment Regulations commence. After this date, these goods will be required to be included in the Australian Register of Therapeutic Goods to be lawfully exported.

Item [35] – subregulation 96(5)

Subregulation 96(5) provides that item 15 of the table in Schedule 5A to the TG Regulations, as inserted by Schedule 1 to the amending regulations, applies in relation to therapeutic goods imported or manufactured on or after 1 March 2024.

Item 35 replaces the reference in subregulation 96(5) to therapeutic goods imported or manufactured on or after 1 March 2024 with a reference to therapeutic goods imported or manufactured before, on or after 1 March 2024. This amendment is necessary because amending item 3 amends item 15 in Schedule 5A to the TG Regulations so that it applies to therapeutic goods that were imported or manufactured before 1 March 2024.

This amendment, together with amending item 3, has the effect that therapeutic goods imported or manufactured before 1 March 2024 are eligible to meet the requirements of the exemption in item 15 of Schedule 5A to the TG Regulations. It does not have retrospective effect because the exemption requires prospective meeting of those requirements, including the giving of a sponsor notice, in order for the exemption to apply.

Item [36] – Part 9, Division 26 - Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

Item 36 inserts a new Division 26 into Part 9 of the TG Regulations. Division 26 houses transitional provisions relating to the measures in the Amendment Regulations. This provides guidance in relation to the date of application of certain provisions.

Clause 104 – Definitions

Clause 104 provides a definition for the term “amending regulations” in the new Division 26. Amending regulations means the *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024*.

Clause 105 – Authorities for therapeutic vaping substances that are not medicines

Clause 105 provides that the amendment to regulation 12BA applies in relation to an authority given under subsection 19(5) of the Act on or after the commencement of Schedule 1 to the amending regulations. This has the effect that authorities under the authorised prescriber scheme can be granted in the absence of ethics committee approval for therapeutic vaping substances that do not contain nicotine or any other active ingredient upon commencement of that Schedule.

Clause 106 – Therapeutic vaping packs

Clause 106 provides that the amendment made by item 17 of Schedule 1 to the amending regulations applies in relation to therapeutic goods imported or manufactured on or after 1 October 2024.

This has the effect that a primary pack that is imported or manufactured before 1 October 2024 and consists only of therapeutic vaping devices and/or therapeutic vaping device accessories will continue to be regarded as a therapeutic vaping pack, whereas a primary pack that is imported or manufactured on or after 1 October 2024 will only be regarded as a therapeutic vaping pack if it also contains at least one therapeutic vaping substance and/or therapeutic vaping substance accessory.

Clause 107 – Exempt goods

Clause 107 provides that the amendment made by item 27 of Schedule 1 applies in relation to therapeutic goods imported or manufactured before, on or after the commencement of that Schedule. This has the effect that therapeutic goods imported or manufactured before, on or after the commencement of the Schedule will be eligible to provide a sponsor notice and meet the requirements of the exemption in item 15 of Schedule 5A to the TG Regulations.

Clause 107 also provides that the amendments made by items 26 and 28 to 30 of Schedule 1 to the amending regulations apply in relation to therapeutic goods imported or manufactured on or after the commencement of that Schedule. This has the effect that the new conditions of the exemption in item 15 of Schedule 5A to the TG Regulations requiring the provision of a reasonable number of samples upon request and allowing authorised officers to enter and inspect premises, and the description of the persons who may supply goods to the ultimate consumer, do not apply in relation to goods imported or manufactured before the commencement of that Schedule. It also has the effect that the amendment to clarify that a special access scheme or authorised prescriber approval is not required for devices that are a part of a therapeutic vaping pack applies from the commencement of Schedule 1.

Clause 107 provides that the amendments made by item 31 of Schedule 1 apply in relation to therapeutic goods imported on or after the commencement of that Schedule. This has the effect that the new condition requiring the provision, on request, of a reasonable number of

samples of goods imported under item 16 of Schedule 5A to the TG Regulations does not apply to in relation to therapeutic goods imported before the commencement of that Schedule.

Clause 108 – Transitional vaping goods—exemption from Part 3-2 of the Act

Clause 108 provides a transition provision for transitional vaping goods in relation to the exemption from Part 3-2 of the Act.

Subclause (1) defines ***transitional vaping goods*** as therapeutic vaping goods that are exported and that were imported, manufactured or supplied before the commencement of Schedule 1 to the Amendment Regulations, and as at that commencement, the importation or manufacture, or any supply, of the goods was done in accordance with any applicable laws of the Commonwealth or of a State or Territory.

In effect, clause 108 allows a sponsor to export therapeutic vaping goods that complied with all relevant laws that were applicable at the time the goods were imported, manufactured or supplied (as applicable), without requiring the goods to be included in the Australian Register of Therapeutic Goods. The clause reduces regulatory burden associated with exporting such goods, allowing sponsors to potentially minimise the financial impact where such goods can no longer be lawfully supplied in Australia.

Pursuant to subclause (3), this exemption from the operation of Part 3-2 of the Act ceases to have effect at the end of the period of 6 months starting on the day Schedule 1 to the Amendment Regulations commence. After this date, these goods will be required to be included in the Australian Register of Therapeutic Goods to be lawfully exported.

Schedule 2 – Commercial quantities

Item [1] – Regulation 10N (table)

Schedule 2 commences on the day after the end of the period of 3 months beginning on the day Schedule 1 to the Amendment Regulations commences. Item 1 would repeal the table in regulation 10N and replaces it with lower commercial quantities of 3 vaping devices, 30 vaping device accessories, and 100 ml of vaping substance that is a liquid.

Schedule 3 – Other matters

Item [1]– After paragraph 3(3)(bab)

Item 1 inserts a reference to the *Therapeutic Goods Law Application Act 2024* (WA) in subregulation 3(3), with the effect that the *Therapeutic Goods Law Application Act 2024* (WA) is declared to be a corresponding State law for the definition of ‘corresponding State law’ in subsection 3(1) of the Act. This item commences on the later of the commencement of Schedule 1 to the Amending Act and immediately after the commencement of Part 2 of *Therapeutic Goods Law Application Act 2024* (WA). However, it does not commence at all if Part 2 of *Therapeutic Goods Law Application Act 2024* (WA) does not commence.

ATTACHMENT B**Statement of Compatibility with Human Rights**

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024

The *Therapeutic Goods Legislation Amendment (Vaping Reforms) Regulations 2024* (the Amendment Regulations) are compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The Amendment Regulations support the *Therapeutic Goods and Other Legislation (Vaping Reforms) Act 2024* (the Amendment Act), which implements reforms to the regulation of all vaping goods. The Amendment Act implements the national vaping reforms to restrict the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods, particularly non-therapeutic and disposable single use vapes.

The Amendment Regulations amend the *Therapeutic Goods Regulations 1990* (the TG Regulations) and *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) (collectively, the Principal Regulations), to prescribe matters and make other consequential amendments necessary to implement the measures in the Amendment Act.

In particular, the Amendment Regulations support the Amendment Act by prescribing commercial quantities, permitted quantities and units of vaping goods for the purposes of the new offence and civil penalty provisions introduced by the Amendment Act relating to the possession of vaping goods as part of a suite of measures designed to address and deter illicit trade in Australia.

The Amendment Regulations provide transitional arrangements under which certain therapeutic vaping goods that would otherwise be unlawful on commencement of the Amendment Act may be dealt with, and make a small number of minor consequential amendments. The Amendment Regulations also allow for the supply or export of compliant vaping goods that were imported or manufactured prior to 1 March 2024, as part of transitional arrangements to assist sponsors to comply with the reforms.

In addition, the Amendment Regulations make a small number of related amendments, including to declare the *Therapeutic Goods Law Application Act 2024* (WA) to be a corresponding state law for the purpose of the Act, and to update a small number of definitions and exemptions to ensure consistency between the Amendment Act and the TG Regulations and MD Regulations in relation to key terms.

The Amendment Regulations support the national vaping reform measures that are intended to address the risks posed by vaping to youth and young adults in Australia, the possible long term adverse health effects of vaping to Australians who use vapes, and the adverse

health effects of toxic chemicals and other ingredients found in vapes. The amendments provide for additional controls for the importation, manufacture and supply of therapeutic vaping goods, including new conditions for exemptions to ensure compliance with applicable standards.

Principally, the Amendment Regulations appropriately and reasonably support objectives to enable legitimate patient access to certain therapeutic vaping goods for smoking cessation and the management of nicotine dependence, where clinically appropriate.

Background

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision.

However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping products that are being accessed by young people.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are still emerging.

The Government's vaping reforms are being implemented in stages over 2024. The Amendment Act is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms included amendments to the *Customs (Prohibited Imports) Regulations 1956*, the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD

Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- since 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply;
- since 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply;
- since 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standards.

The Amendment Regulations would support the Amendment Act to implement measures that are necessary to give effect to the second stage of reforms to the regulation of vapes announced by the Minister for Health and Aged Care in May 2023. The reforms implemented in the Amendment Regulations align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Human rights implications

The Amendment Regulations engage the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (the ICESCR).

The right to health

The Amendment Regulations engage the right to health in Article 12 of the ICESCR. Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health and includes an obligation on state parties to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000)*, the United Nations Committee on Economic, Social and Cultural Rights states that health is a 'fundamental human right indispensable for the exercise of other human rights', and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

Vaping has been associated with a range of short-term health risks and its long-term health effects use are still unknown. Marketing and use of vapes in the community has increased rapidly in recent years, particularly among youth and young adults and poses a major risk to population health and Australia's success in tobacco control.

The Amendment Regulations take positive steps to promote the right to health by supporting the Government's package of regulatory reforms concerning vapes. These reforms bolster and simplify the regulatory framework for the importation, domestic manufacture and supply of therapeutic vapes in Australia, subject to compliance with relevant quality standards applying to those goods, for use in smoking cessation or the management of nicotine dependence. The reforms promote the right to health as the new requirements limit patient access to therapeutic vapes from medical practitioners, nurse practitioners and registered pharmacists.

The benefits of this are twofold. Firstly, the reforms will arrest the increasing uptake of recreational vaping, especially amongst youth and young adults; effectively restricting domestic supply of non-therapeutic vapes while still allowing for legitimate therapeutic use strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to support Australians combating smoking addiction or nicotine dependence.

The reforms also take positive steps to promote the right to health by ensuring that access to therapeutic vapes are only those in appropriate setting and supervision by a health practitioner.

In supporting these reforms, the Amendment Regulations promote and address aspects of the right to health under Article 12 of the ICESCR that relate to recognising the right of everyone to enjoy the highest attainable standard of physical and mental health.

Conclusion

The Amendment Regulations are compatible with human rights because they promote the right to health in Article 12 of the ICESCR.

From: [GILMOUR-WALSH, Bridget](#)
To: s22
Cc: [EDLINGTON, Mandy](#); s22; [HENDERSON, Nick](#)
Subject: Replacement EM [SEC=OFFICIAL]
Date: Friday, 21 June 2024 12:12:28 AM
Attachments: [Vaping Reforms Bill Replacement EM \(June 2024\).docx](#)

Hi s22

Here is the replacement EM.

The main changes are highlighted in yellow – there are 3 sections which largely repeat what we said to the scrutiny of bills committee and promised to incorporate in the EM. There are also a few minor corrections in yellow highlight or track.

As per email yesterday, we need to send this to the printers by 11 am to meet a Monday tabling deadline. Very grateful if you could ensure clearance before then.

Happy to discuss.

Thanks

Bridget

2022-2023-2024

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

**THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT
(VAPING REFORMS) BILL 2024**

REPLACEMENT EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Aged Care,
the Hon Mark Butler MP)

THIS MEMORANDUM REPLACES THE EXPLANATORY MEMORANDUM
PRESENTED TO THE HOUSE OF REPRESENTATIVES ON 21 MARCH 2024
AND RESPONDS TO ISSUES RAISED BY THE SENATE STANDING
COMMITTEE FOR THE SCRUTINY OF BILLS IN SCRUTINY DIGESTS NO. 5
AND 6 OF 2024, DATED 27 MARCH 2024 AND 15 MAY 2024 RESPECTIVELY

THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT (VAPING REFORMS) BILL 2024

OUTLINE

The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) amends the *Therapeutic Goods Act 1989* (the TG Act) to prohibit the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable vaping goods. Therapeutic vaping goods will continue to be available and subject to regulation under the TG Act in line with other medicines and therapeutic goods. This is necessary to address the growing risk posed by vaping in Australia, particularly to youth and young adults, while preserving legitimate patient access to therapeutic vaping goods for smoking cessation and the management of nicotine dependence, where clinically appropriate.

The TG Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods used in, whether produced in Australia or elsewhere, or exported from, Australia. The Bill extends the national system of controls for therapeutic goods under the TG Act to the regulation of vaping goods. The national system is essentially a federal cooperative scheme between the Commonwealth, states and territories. It is achieved through the application of corresponding laws enacted in each state and territory, with Western Australia ~~having recently progressing introduced legislation to the Parliament of Western Australia to enact~~ their own corresponding law.

The Bill provides a single consistent framework that applies nationally to regulate the importation, domestic manufacture, supply, commercial possession and advertisement of all vapes, irrespective of nicotine content or therapeutic claims. The extension of the TG Act to vapes is appropriate and necessary in the circumstances to address the alarming increase of vaping rates in Australia, particularly among youth and young adults, and maintain legitimate patient access to therapeutic vapes where clinically appropriate.

The Government's vaping reforms will be implemented in stages over 2024. The Bill is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms comprised amendments to the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations), the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- From 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.

- From 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.
- From 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standard.

Specifically, the Bill amends the TG Act to implement a new framework for the regulation of vapes, to more readily authorise state and territory officials to undertake enforcement action and other consequential changes. The framework for the regulation of vapes includes certain powers for the Secretary and Minister to determine the scope and coverage of the regulatory scheme for vaping goods.

Importantly, the Bill introduces new offences and civil penalty provisions relating to the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods to support the reforms. Exceptions to the offences and civil penalty provisions specify the circumstances in which importation, domestic manufacture, supply and commercial possession of legitimate therapeutic vaping goods for smoking cessation and the management of nicotine dependence is permitted in Australia.

The intention of the new offences and civil penalty provisions is to deter unlawful conduct, arrest the alarming increase in the use of vapes in Australia, particularly among youth and young adults, and prevent a new generation of persons being exposed to dangerous chemicals, and developing nicotine dependence.

The Bill enhances existing compliance and enforcement powers in the TG Act by:

- enabling state and territory officers to exercise powers and functions, particularly compliance and enforcement powers relating to supply and possession of vaping goods;
- extending the authority of persons able to issue monitoring, offence, and civil penalty related warrants in relation to premises, to court registrars and other officers of a court of a state or territory;
- facilitating information sharing with the states and territories and other compliance and enforcement bodies;
- enabling the publication of information relating to the importation, manufacture, supply and advertisement of vaping goods;

- amending the TG Act to deal more effectively with the seizure of unlawful vaping goods, and create new powers for the forfeiture and destruction of unlawful vaping goods;
- introducing a power to allow enforceable directions to be made to manage unlawful vaping goods and therapeutic goods generally; and
- otherwise facilitating effective enforcement of the new regulatory controls and therapeutic good requirements more generally.

The Bill implements measures that are necessary to give effect to reforms announced by the Minister for Health and Aged Care on 2 May 2023 and 28 November 2023. The reforms support the Government's broader objectives to reduce the prevalence of smoking and vaping in the community and align with the objectives, priorities and targets outlined in the National Tobacco Strategy 2023-2030. All Australian governments are strongly committed to addressing the public health challenge posed by the marketing and use of vaping goods.

Consequential amendments are also included in this Bill to other Commonwealth legislation, namely, the *Customs Act 1901* (the Customs Act), the *Industrial Chemicals Act 2019* and the *Public Health (Tobacco and Other Products) Act 2023*.

The public health problem

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among people aged 14 years and over, current use of vaping nearly tripled between 2019 (2.5%) and 2022–2023 (7.0%). The increase was even more marked among young people, with current use of vaping goods increasing from 5.3% to 21% among people aged 18-24, and from 1.8% to 9.7% among people aged 14-17 during the same period.¹ These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing use and marketing of vaping goods.

Vaping goods are widely marketed, available and accessible to youth and young adults in Australia, and many products have a low purchase price compared to many consumer goods and tobacco products. Advertising occurs across a range of media channels that have broad reach among youth and young adults, including websites, social media, in print and in retail stores. Evidence also suggests that exposure to these advertisements increases the likelihood that youth and young adults will try vaping. Direct exposure to promotional material relating to vaping contributes to decreased risk perceptions for vaping.

Marketing of vaping goods intentionally targets youth and young adults through promotional activities and product features. Vaping goods are aggressively promoted by the vaping industry in online advertising and other youth-focused media channels. Advertising spending is often focused on social media promotion, allowing for lower costs and wider reach, particularly to youth and young adults. Colours and flavours

¹ Australian Institute of Health and Welfare (2024), 'National Drug Strategy Household Survey 2022–2023', AIHW, Australian Government. Available at: <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey/contents/about>

further contribute to the appeal of vaping goods and their uptake among youth and young adults.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision.

However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. The latest findings from the 2022/23 Australian secondary school students alcohol and other drug survey show that 1 in 6 (16%) secondary school students (12 to 17 years) reported [recent vaping in 2022/23](#). ~~recent date in tobacco control.~~

Reforms are therefore needed to address the high levels of uptake of vaping among youth and young adults, the health risks that vapes pose to human health, the impacts of vaping on the initiation, continuation and cessation of tobacco product use, and the practice of dual use with conventional tobacco products. Indeed, there is strong and consistent evidence that youth and young adults who vape are more likely to take up smoking, compared to those who do not,² and the long-term health risks of vaping are not yet known. The highly addictive nature of nicotine, and the fact that vapes are inhaled into the lungs, mean the population-wide health risks of these products can be severe.

Vaping involves inhaling a large mix of chemicals, including listed poisons, heavy metals such as nickel and chromium, and chemical by-products produced during heating such as formaldehyde, nitrosamines, acetone, and acrolein. Acrolein, aldehydes, and polycyclic hydrocarbons are ‘probably carcinogenic’ according to the International Agency for Research on Cancer, while nicotine derivatives (nitrosonornicotine and nitrosamine ketone) are known potent carcinogens in humans. Further, low concentrations of toxic chemicals in vaping substances convert to high concentrations when aerosolised, after heating, and as chemicals combine.³

A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Studies have shown the many damaging impacts of e-cigarette use include addiction, poisoning, acute nicotine toxicity, seizures, burns, lung injury, and increased uptake of cigarette smoking.⁴

² Baenziger ON et al. (2021) ‘E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis,’ *BMJ Open* 11(3). Available at: <https://pubmed.ncbi.nlm.nih.gov/33785493/>

³ Gordon LG and Preston P. (2024) ‘Healthcare costs attributable to e-cigarette use and subsequent uptake of cigarette smoking by Australians who have never smoked’ *Australian Health Review* 48(1), 52-57. doi: doi.org/10.1071/AH23178

⁴ Gordon LG and Preston P. (2024) ‘Healthcare costs attributable to e-cigarette use and subsequent uptake of cigarette smoking by Australians who have never smoked’ *Australian Health Review* 48(1), 52-57. doi: doi.org/10.1071/AH23178

Based on the available evidence to date, numerous studies have highlighted concerns regarding vaping use and their potential effects on adverse pregnancy outcomes, adolescent brain development, cardiovascular disease risks, cancer risks, respiratory disease and oral health. Second-hand exposure to e-cigarette aerosol is also a further area of concern. Emerging research also suggests that use of nicotine e-cigarettes may worsen mental health, and amplify stress, anxiety and depressive symptoms. However, given that vaping goods remain relatively new, the impact of their use on most clinical outcomes remains highly uncertain.⁵⁶⁷⁸

Broader actions to reduce the prevalence of vaping and smoking in Australia

The regulatory reforms included in this Bill complement a wider set of actions being taken by Governments in Australia in line with the National Tobacco Strategy 2023-2030 to reduce the rates of use of tobacco and nicotine products. The Australian Government is implementing a comprehensive range of regulatory and non-regulatory measures in parallel with this Bill. The *Public Health (Tobacco and Other Products) Act 2023* commencing from 1 April 2024 streamlines and modernises existing Commonwealth tobacco control laws. It also extends advertising regulations to vaping goods. New tobacco excise measures were announced in May 2023 to further reduce the affordability of tobacco products.

New measures will also provide information and support to people seeking to quit vaping and smoking, and to discourage people from starting or taking it back up. The Government will provide \$29.5 million over 4 years to help Australians quit, including through enhanced nicotine cessation, education and training among health practitioners, scaling up state and territory Quitlines and other quit services, and online quit supports including a national consumer online cessation hub and redeveloping and modernising the My Quitbuddy app. A further \$63.4 million investment in public health information campaigns aims to discourage Australians from taking up vaping and smoking and encourage quitting. The Government will provide \$141.2 million to extend the successful Tackling Indigenous Smoking program to reduce uptake of vaping and reduce smoking among First Nations people.

Australia's international obligations

As a party to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), Australia has legal obligations to develop and implement effective policies not only to prevent and reduce tobacco consumption and exposure, but also to prevent and reduce nicotine addiction.

⁵ Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. (2022) 'Electronic cigarettes and health outcomes: systematic review of global evidence.' Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

⁶ National Health and Medical Research Council (2022) 'CEO Statement: Electronic Cigarettes' National Health and Medical Research Council.

⁷ Obisesan OH, Mirbolouk M, Osei AD, Orimoloye OA, Uddin SMI, Dzaye O, El Shahawy O, Al Rifai M, Bhatnagar A, Stokes A, Benjamin EJ, DeFilippis AP, Blaha MJ. (2019) 'Association Between e-Cigarette Use and Depression in the Behavioral Risk Factor Surveillance System 2016-2017.' JAMA Netw Open. 2;2(12)

⁸ Javed S, Usmani S, Sarfraz Z, Sarfraz A, Hanif A, Firoz A, Baig R, Sharath M, Walia N, Chérrez-Ojeda I, Ahmed S. (2022) 'A Scoping Review of Vaping, E-Cigarettes and Mental Health Impact: Depression and Suicidality'. J Community Hosp Intern Med Perspect. 2;12(3):33-39.

Australia has also committed under Article 5.3 of the WHO FCTC to protect its public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry in accordance with national law. Australia's obligations under Article 5.3 extend to new and emerging products, such as e-cigarettes and heated tobacco products.⁹

CONSULTATION

The TGA conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on reforms to the regulation of nicotine vaping products in Australia. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through the Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communique dated 1 September 2023, which conveyed the Ministers' collective commitment to enhancing regulation of vapes.

A second, targeted consultation was undertaken with stakeholders between 7 September 2023 and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding numerous webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for Health and Aged Care on the regulatory measures to be implemented, including those ~~included~~ in this Bill.

On 28 November 2023, the Minister announced the *Next steps on vaping reforms*, including the commencement of the first stage of the new vaping reforms on 1 January 2024. The TGA engaged in further updates with supply chain stakeholders, including manufacturers, suppliers, pharmacies and pharmaceuticals, healthcare professional and public health organisations, following the Minister's announcement.

On 12 January 2024, the TGA and the Office of Drug Control hosted a webinar to outline the impacts of the reforms to the medicinal cannabis industry. On 17 January 2024, the TGA hosted a further public webinar to outline the reforms. On 22 and 27 February 2024, the TGA held additional webinars with medical practitioners and pharmacists respectively.

On 1 March 2024, the TGA circulated draft provisions of the Bill to members of the National E-Cigarette Working Group, comprising representatives from the

⁹ See Australian Government Department of Health and Aged Care 'Guidance for public officials on interacting with tobacco industry' Available at: <https://www.health.gov.au/sites/default/files/2023-05/guidance-for-public-officials-on-interacting-with-the-tobacco-industry.pdf>

Commonwealth, states and territories for comment. Feedback from the exposure draft informed the final drafting of the Bill.

IMPACT ANALYSIS

An impact analysis was prepared on the proposed reforms to the regulation of vapes, based on the feedback received from stakeholders and the Australian public. The Office of Impact Analysis assessed the impact analysis and determined that it was consistent with good practice and met Australian Government best practice regulation requirements (**OBPR23-03933**).

The impact analysis supports this explanatory memorandum and has also been published on the Office of Impact Analysis website: www.oia.pmc.gov.au/.

FINANCIAL IMPACT STATEMENT

The Government will provide \$82.0 million over four years from 2023–24 to support the vaping reforms, awareness raising and enforcement activities. Funding includes:

- \$56.9 million over two years from 2023–24 to the Therapeutic Goods Administration to support regulatory development activities; and
- \$25.0 million over two years from 2023–24 to support the Australian Border Force’s regulatory and enforcement activities.

This measure builds on the 2023–24 Budget measure titled Vaping Regulation Reform and Smoking Cessation Package. The package committed to ban all vapes, other than therapeutic vapes imported, manufactured or supplied in accordance with the TG Act.

The regulatory reforms are part of the Government’s implementation of the National Tobacco Strategy and related initiatives on vaping and smoking prevention and cessation.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT (VAPING REFORMS) BILL 2024

The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill

The Bill will implement the second stage of the Government's vaping reform measures by amending the *Therapeutic Goods Act 1989* (the TG Act). The first stage of the Government's vaping reform measures comprised amendments to the *Therapeutic Goods Regulations 1990* (the TG Regulations), *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations). These amendments commenced operation on 1 January 2024.

In restricting the availability of, and access to, vaping goods in Australia, the Bill is intended to address the high levels of uptake of vaping among youth and young adults, the health risks that vapes pose to human health, the impacts of vaping on the initiation, continuation and cessation of tobacco product use, and the practice of dual use with conventional tobacco products. Despite the new restrictions and prohibitions applying to the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods, the Bill preserves legitimate patient access to therapeutic vaping goods for smoking cessation and the management of nicotine dependence under appropriate health practitioner supervision. All therapeutic vaping goods, including vaping goods that do not contain nicotine, are to be supplied in Australia, only by registered pharmacists, medical practitioners or nurse practitioners authorised to do so under state or territory law.

The public health problem

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vaping goods.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of

products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration for smoking cessation or tobacco smoking. These changes were intended to prevent youth and young adults from vaping, while allowing current smokers to access therapeutic vaping goods for smoking cessation under appropriate medical supervision.

However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping goods that are being accessed by young people.

The reforms implemented in the Bill align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Objectives

The Bill provides for the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are imported into Australia, manufactured in Australia, supplied in Australia or exported from Australia. This is to address the health risks posed by vaping, while ensuring therapeutic vaping goods remain available, where clinically appropriate, to patients in pharmacy settings.

Human rights implications

The Bill engages the following human rights:

- the *right to health* under Article 12 of the International Covenant on Economic Cultural and Social Rights (ICESCR);
- the *right to life* under Article 6 of the International Covenant on Civil and Political Rights (ICCPR);
- the *obligation to ensure the survival and development of children* under Article 6(2) of the Convention of the Rights of the Child (CRC);
- the *obligation to protect children from illicit use of narcotic drugs and psychotropic substances* under Article 33 of the CRC;
- the *right to privacy* under Article 17 of the ICCPR;
- the *right to freedom of expression* under Article 19(2) of the ICCPR;
- the *right to a fair hearing* under Article 14(1) of the ICCPR;
- the *right to the presumption of innocence* under Article 14(2) of the ICCPR;
- the *right to be free from self-incrimination* under Article 14(3)(g) of the ICCPR;

- the right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted under Article 14(7) of the ICCPR.

The right to health

The Bill engages the right to health in Article 12 of the ICESCR. Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health and includes an obligation on state parties to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000)*, the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

Vaping has been associated with a range of short-term health risks, and its long-term health effects are still unknown. Marketing of vaping goods and use in the community has increased rapidly in recent years, particularly among young people, and pose a major risk to population health and Australia’s success in tobacco control.

The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are not yet known. Importantly, the long-term health effects of vaping are not known, and public health experts are concerned they could be of a similar magnitude to those resulting from smoking tobacco.

The Bill takes positive steps to promote the right to health by restricting access to vaping goods, except where clinically warranted through pharmacy (and medical) settings.

Bans on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods are intended to arrest and reverse the increasing uptake of recreational vaping, especially amongst youth and young adults by banning the domestic supply of vaping goods outside the pharmaceutical supply chain.

Allowing patient access to therapeutic vapes strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to support Australians to quit smoking or manage nicotine dependence.

Ensuring vaping goods are only accessed under appropriate health practitioner supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

In parallel to the introduction of the Bill, cessation services in Australia will be enhanced to ensure support for people who seek assistance to stop vaping.

The Bill promotes ~~and address~~ aspects of the right to health under Article 12 of the ICESCR that relate to recognising the right of everyone to enjoy the highest attainable standard of physical and mental health.

The right to life

By seeking to reduce the incidence of vaping, thereby reducing the associated health risks and controlling access to vapes, the measures contained in the Bill promote the right to life.

Nicotine, which is contained in most vapes and e-liquids, is highly poisonous and intentional or unintentional ingestion can lead to nicotine poisoning or death. An average 2-year-old child would experience potentially lethal effects by ingesting as little as 0.8 ml of a 100 mg/ml nicotine e-liquid.¹⁰

Vape use has been associated with a number of short-term health risks, including death from lung injury. The long terms health consequences of vaping are unknown and public health experts are concerned that those risks could be of a similar magnitude to those resulting from smoking tobacco.

Further, vaping is a strong predictor of future tobacco use for youth and young adults, including for those who would otherwise be unlikely to take up conventional smoking.¹¹ Vaping also mimics behavioural and sensory aspects of smoking, which makes the transition to combustible smoking more likely.¹²

Tobacco use causes more deaths than any other behavioural risk factor. Up to two thirds of deaths in tobacco smokers can be attributed to smoking, and long-term

¹⁰ Morgan J and Kelso C, (2021) 'Nicotine Vaping Product Analysis: Evidence from the University of Wollongong'. Available at: .

¹¹ Department of Health and Aged Care, (2020) 'Notice of final decision to amend the current Poisons Standard – nicotine' Australian Government. Available at: <https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-current-poisons-standard-nicotine#:~:text=Pursuant%20to%20regulation%2042ZCZR%20of,to%20be%20fitted%20in%20liquid>

¹² Baenziger ON et al. (2021) 'E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis,' BMJ Open 11(3). Available at: <https://pubmed.ncbi.nlm.nih.gov/33785493/>

smokers die an average of 10 years earlier than nonsmokers. Exposure to second-hand smoke is also a cause of preventable death and disability in both adults and children. Tobacco use and exposure among pregnant people and their babies is one of the most prevalent preventable causes of infant death and illness and of adverse pregnancy outcomes including preterm birth and still-birth.¹³

Tobacco smoking by youth and young adults has immediate adverse health consequences and accelerates the development of chronic diseases across the full life course. It can lead to nicotine dependence that causes young people to continue smoking for longer, causing increased physical damage. In addition, quitting smoking at any age reduces the risk of premature death and improves quality of life.

The Bill promotes the right to life by implementing measures to prohibit access to vaping goods unless clinically appropriate under health practitioner supervision.

Obligation to ensure the survival and development of children

Article 6(2) of the CRC requires state parties to take measures to ensure the survival and development of children to the greatest extent possible.

Vaping goods pose a particular risk to children. The variability in concentration and toxicity of active ingredients, particularly nicotine, but also other toxic substances, increases the risk that children who consume these ingredients may ingest a fatal dose or suffer severe adverse effects. In addition, vapes contain flavours designed to entice children, and for which the adverse effects are unknown. Although these flavours may be safe when ingested, their safety profile when inhaled directly into the lungs is not established.

Vapes can contain harmful chemicals that are known to cause irreversible lung damage and may also have chronic long-term effects. In addition, it appears that most products on the domestic market contain, or are likely to be used in conjunction with, nicotine. This is the case even where no nicotine is indicated on the label of the product, if any label exists.

Vaping goods are frequently designed to look like other innocuous and ubiquitous objects such as pens, USB devices, lip gloss, toys and sippy cups. The designs use colours, illustrations and cartoons that are deliberately attractive to children and may lead to misconceptions that vaping goods are harmless when this is not the case. To the extent that restricting the importation, domestic manufacture and supply of vaping goods may adversely affect the health of persons (including young persons) who are already addicted to nicotine, the prohibition in this amendment will not extend to those who are legitimately prescribed vaping substances that contain nicotine for the management of that dependence, in accordance with clinical guidelines, under appropriate health practitioner supervision.

In summary, the vaping reform will promote the survival and development of children to the greatest extent possible and where the measure may limit a child's rights, the

¹³ Dietz P, England L, Shapiro-Mendoza C, Tong V, Farr S and Callaghan W (2010) 'Infant morbidity and mortality attributable to prenatal smoking in the US' 39(1): 45–52, Am J Prev Med.

limitation is necessary in order to protect the Australian community, in particular children, from the risks to health that misuse can cause, and is reasonable and proportionate as access to vaping substances is still available where there is a legitimate medical need.

Obligation to protect children from illicit use of narcotic drugs and psychotropic substances

Article 33 of the CRC specifically requires state parties to take appropriate measures to protect children (up to the age of 18) from the illicit use of narcotic drugs and psychotropic substances. Although vapes are not specifically listed in the relevant international treaties banning narcotic drugs and psychotropic substances, the substances in unregulated vapes are not known and on occasion have been found to include a range of drugs. Further, the Committee on the Rights of the Child has recognised that Article 33 has a broad application and may impose obligations on state parties to protect children from the use of substances that are not listed in the Conventions, such as alcohol and tobacco. The Committee therefore urges state parties to regulate or prohibit information on and marketing of substances, such as alcohol and tobacco, particularly when the information or marketing targets children and adolescents.

The new controls on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods will promote the protection of children from exposure and easy access to addictive and unsafe vaping goods. Under the reforms, vaping goods are only intended to be accessed by legitimate patients through limited supply channels involving registered pharmacists, medical practitioners and nurse practitioners authorised under state or territory law to supply prescription medicines. This will reduce the potential for vapes to be supplied unlawfully to children.

The controls placed on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods are therefore an important tool for promoting children's rights to be protected from nicotine dependence and exposure to other dangerous substances, including potentially narcotic drugs and psychotropic substances, in vaping goods. These measures, by restricting the importation, domestic manufacture and supply of untested and potentially dangerous substances contained in vaping goods will assist in preventing their supply to, and access by, youth and young adults.

These measures seek to promote the requirement to protect children from exposure to, and use of, narcotic drugs, psychotropic substances and other harmful substances that may be contained in vaping goods to the greatest extent possible. The limitation is reasonable and proportionate as access to vaping goods is still available where there is a legitimate therapeutic need under appropriate medical supervision.

The right to privacy

The Bill engages the protection against arbitrary or unlawful interference with privacy. Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual's privacy, family, home or correspondence, and protects a person's honour

and reputation from unlawful attacks. The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. For interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the circumstances. The United Nations Human Rights Committee has interpreted the requirement of ‘reasonableness’ as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances.

The Bill provides for the collection, use and disclosure of information, which may include personal information. These provisions engage and may limit the right to privacy. The proposed information gathering, reporting and release measures are reasonable, necessary and proportionate to a legitimate objective of supporting the effective implementation of the vaping reforms for a public health objective.

Consent scheme

The Bill amends the TG Act to introduce a consent scheme under section 41RC to allow persons who do not have a licence or authority under the TG Act or state and territory laws to lawfully manufacture, possess or supply vaping goods. Persons that can be granted consent may include:

- (a) persons transporting vaping goods within a state or from one state to another;
- (b) persons storing vaping goods for supply to a wholesaler or a pharmacist; and
- (c) pharmacists compounding or manufacturing different vaping goods.

A person who has been granted a consent under new section 41RC will be able to lawfully use the consent as a defence to the manufacturing, supply and possession offences or civil penalty contraventions under new Chapter 4A of the TG Act.

These provisions engage and may limit the right to privacy. The proposed information gathering and reporting measures are reasonable, necessary and proportionate to a legitimate objective of supporting the objects of the vaping reform to promote and support public health objectives.

If personal information is provided in a report to the Secretary, the collection, storage, use and disclosure of such personal information would be subject to the requirements and limitations in the *Privacy Act 1988*. The Department of Health takes seriously its obligations and compliance with requirements applying to personal information that it holds and collects under the *Privacy Act 1988*.

Investigations, entry to premises, investigations, seizure and forfeiture

The Bill introduces new offences and civil penalty contraventions in relation to the importation, manufacture, supply, commercial possession and advertisement of vaping goods. In addition, a new section 52AAA is introduced in the Bill in which ~~seized~~ vaping goods seized under a warrant under section 50 of the TG Act in specified circumstances are forfeited to the Commonwealth without any court order, and conviction or contravention of a civil penalty provision being established through court proceedings.

Although new offences and civil penalty contraventions are introduced in the TG Act by the Bill, individuals are protected against arbitrary interference with privacy. In general the entry, search and seizure powers cannot be exercised without the person affected being fully informed, a voluntary consent of the occupier of the premises ~~being~~ provided by the affected person, or the presence of a prior authorisation in the form of a warrant. There are exceptions to these in circumstances where an authorised person exercises entry and seizure powers in the interests of public health ~~in order~~ to avoid an imminent risk of death, serious illness or serious injury (refer to section 46B of the TG Act). The powers of an authorised person under Part 6-2 of the TG Act relating to entry, search and warrant remain unchanged.

The offence and civil penalty related warrants issued under section 50 of the TG Act are only issued by an issuing officer if satisfied, by information on oath that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, in or on the premises evidential material in respect of an offence against the TG Act, in respect of a contravention of a civil penalty provision or in respect of both. An issuing officer must not issue a warrant unless the authorised person or some other person has given to the issuing officer, either orally or by affidavit, such further information as the officer requires concerning the grounds on which the issue of the warrant is being sought (subsection 50(3) refers). Such constraints on this power ensure adequate safeguards against arbitrary limitations on the right to privacy in the issuing of warrants.

If entry is authorised by warrant, the authorised person must provide a copy of the warrant to the occupier of the premises. This provides for the transparent utilisation of the powers and mitigates arbitrariness and risk of abuse.

Part 6-2 of Chapter 6 of the TG provides for constraints on the exercise of the powers by authorised persons and therefore limits the susceptibility to arbitrary use or abuse and ensures that their use is reasonable and proportionate in the circumstances.

Forfeiture of goods seized under specified circumstances for the purposes of section 52AAA will only be those seized under a warrant granted under current section 50 of the TG Act. This provision engages the right to privacy in Article 17 of the ICCPR. To the extent that it may limit this right, the limitation is provided for by law. The forfeiture of specified things or goods are subject to judicial review and can be challenged by the person who owns or possess the goods.

As such, any interference with an individual's privacy that may be said to be enabled under the TG Act to enforce the regulation of the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods would not be an arbitrary inference within the meaning of Article 17 of the ICCPR.

Accordingly, the amendments made in relation to the bans on importation, domestic manufacture, supply, commercial possession and advertisement are reasonable, necessary and proportionate to achieving the legitimate objective of the new regulatory framework applying to vaping goods in Australia.

The right to freedom of expression

Formatted: Indent: Left: 0 cm, Hanging: 0.75 cm, Keep with next

The Bill contains prohibitions on the advertising of vaping goods (new Part 5-1A). Article 19(2) of the ICCPR engages the right to freedom of expression, which extends to any medium, including written and oral communications, the media, public protest, broadcasting and artistic works, and may include commercial advertising.

Article 19(3) of the ICCPR states that public health is a basis on which the right to freedom of expression can be limited. This right may be limited as provided for by law and when necessary for respect of the rights or reputations of others, for the protection of national security, public order, or of public health or morals. Limitations must be prescribed by legislation necessary to achieve the desired purpose and proportionate to the need on which the limitation is predicated.

The Bill contains prohibitions on the advertising of vaping goods in the new Part 5-1A. These prohibitions engage and may limit the right to freedom of expression, which is protected by Article 19(2) of the ICCPR. However, these restrictions are directed to the desired purpose of reducing illegitimate and non-therapeutic vaping and the related health risks. This is a legitimate public health objective and accordingly the prohibition is necessary to achieve the desired purpose and proportionate to the need on which the limitation is predicated.

Legitimate objective: measure is justified under a permitted limitation

The right to freedom of expression is not absolute. It carries special responsibilities and may be restricted on several grounds. Article 19(3) of the ICCPR expressly states that the right to freedom of expression may be subject to limitations necessary for the protection of public health. The limitation (if any) of the right to freedom of expression in the Bill aims to achieve a legitimate objective – the protection of public health – by contributing to efforts to reduce vaping rates and the associated health risks. This is of critical importance in relation to the advertising of vaping goods to youth and young adults by means of retail websites and social media. The Bill aims to achieve this by prohibiting the direct and indirect promotion of vaping goods subject to ~~subject to~~ very limited exceptions, including patient consultations and authorisations given under new section 42DZC.

Reasonable: measure will be effective to achieve the desired ends

The proposed reforms include a comprehensive advertising ban of vaping goods in Australia. The ban would include a broad range of media platforms, extending to social media and other forms of advertising, promotion and sponsorship. It is important that the public's exposure to advertising and promotion of vaping goods, which pose a serious risk to population health, is limited to combat the sale and uptake of vapes.

Proportionate: measure does not impinge on freedom of expression to a greater degree than is necessary

The restrictions are central to achieving the aims and objectives of the advertising measure and are proportionate to the public health risk posed.

Vaping goods are widely marketed, available and accessible to youth and young adults in Australia. Evidence suggests that exposure to these advertisements increases the likelihood that youth and young adults will try vaping. Direct exposure to vaping promotions has contributed to decreased risk perceptions for vaping. Some marketing of vaping goods is also emulating successful tobacco advertising, presenting vaping as an enviable lifestyle choice, aligning the products with celebrities and influencers, and fashionable and youthful places and activities.

Marketing of vaping goods intentionally targets youth and young adults through its promotional activities and product features. Vapes are aggressively promoted via online advertising and other youth-focused media channels. Advertising spending is often focused on social media promotion, allowing for lower costs and wider reach, particularly to youth and young adults. The marketing messages promote perceptions among youth and young adults that vaping goods are fun, cool, healthier and safer than tobacco cigarettes, and often focus on the appeal of flavours.

Despite the general prohibition, advertising would still be allowed to persons involved in the legitimate supply of therapeutic vapes (such as health professionals and pharmaceutical wholesalers) and where advice is given directly to a patient by a health practitioner in the course of treatment. The Secretary is also conferred with a power to permit advertising in specified circumstances.

It is also important to note that the term *advertise* has a limited meaning and does not cover all communications in relation to vapes. The term *advertise* is defined in section 3 of the Act. In effect it provides that to advertise goods means to intend, either directly or indirectly, to promote the use or supply of those goods.

Necessary: no less restrictive means of achieving the desired ends

The prohibition on advertising will contribute to efforts to reduce vaping rates in Australia. Given the widespread impact of advertising vaping goods, particularly in relation to unlawful vaping goods with no therapeutic purpose, restrictions are necessary to arrest the uptake of illegitimate vapes and to protect public health.

Vaping is associated with a range of short-term health risks and the long-term health risk are unknown. Further, there is evidence that vaping is a strong predictor of future tobacco use, particularly among youth and young adults. There is strong and consistent evidence that youths and young adults who vape are up to three times as likely to take up smoking, compared to those who do not. Smoking is the leading cause of preventable disease and death in Australia. Smoking reduces a person's life expectancy and their quality of life and may increase the risk of many conditions and diseases such as lung cancer, chronic obstructive pulmonary disease, heart disease, stroke and cardiovascular disease. Smoking can also cause diabetes, dental problems, hearing and vision loss and fertility problems.

The Bill, however, allows the promotion of therapeutic vaping goods in limited circumstances. A general prohibition on the advertising of vaping goods, with limited, and necessary exceptions, is the only means by to effectively combat the danger that such advertising poses to the Australian community.

Although the advertising measures applying to prohibition of advertising of vaping goods affects and limits, the freedom of expression, they are necessary to achieve the desired public health purpose and are proportionate to the need on which the limitation is predicated.

The right to a fair hearing

The Bill engages the right to a fair hearing under Article 14(1) of the ICCPR. The right to a fair hearing is a fundamental part of the rule of law and the proper administration of justice. The essential right guarantees equality before courts and tribunals, and, in the determination of criminal charges, or any suit at law, the right to a fair and public hearing before a competent, independent and impartial court or tribunals established by law. Those charged with a criminal offence have the rights set out in Articles 14(2) to (7), including the presumption of innocence and the guarantees set out in Article 14(2). The Bill engages this right and at the same time ensures that a defendant is provided with a right to a fair hearing before the relevant court, whether under an offence provision or a civil penalty provision. No provision relating to any of these offences seeks to displace or modify defendants' fair hearing rights under Article 14.

Application of both criminal and civil penalties

The Bill's offence provisions contain both criminal penalties and civil penalties. These include fault-based offences, strict liability offences and civil penalties. The Commonwealth will decide in each case whether to prosecute a person for a fault-based or strict liability offence, or whether to bring proceedings for a civil penalty order. Division 2 of Part 5A-1 of Chapter 5A of the TG Act places restrictions on what kinds of proceedings can be brought against persons who are alleged to have contravened the TG Act. These limitations broadly mirror those seen in Division 3 of Part 4 of the *Regulatory Powers (Standard Provisions) Act 2014*. The provision in the TG Act relating to bringing criminal proceedings after civil penalty orders have been issued against a person is more restrictive than the provision that regulates the same situation in the *Regulatory Powers (Standard Provisions) Act 2014*. The limitations imposed by Division 2 of Part 5A-1 of Chapter 5A of the TG Act will apply to all new offences and civil penalty provisions introduced by the Bill.

Most relevantly:

- section 42YF provides that the Federal Court must not make a pecuniary penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is substantially the same as the conduct constituting the contravention;
- section 42YG operates to stay civil proceedings if criminal proceedings commence or have commenced and relate to the same, or substantially the same, conduct. This is to prevent any information that arises during criminal proceedings prejudicing civil proceedings. If the criminal proceedings result in a conviction, civil proceedings related to the same, or substantially the same,

Formatted: Space After: 6 pt

conduct will be dismissed. Civil proceedings may resume if the person is not convicted of the offence;

- section 42YH prevents criminal proceedings being brought against a person for conduct that is substantially the same as conduct constituting a contravention of a civil penalty provision if a pecuniary penalty order has been made against the person in respect of that conduct; and
- section 42YI provides that evidence given by an individual during proceedings for a civil penalty order cannot be used in any criminal proceedings, against the same individual relating to the same conduct. This ensures that information or documents produced during civil proceedings are not relied upon to support subsequent criminal proceedings, unless they are criminal proceedings relating to falsifying evidence in civil proceedings. While it is appropriate to allow criminal proceedings after civil proceedings have ended, given the overriding importance of the criminal justice system, criminal proceedings not related to falsifying evidence must rely upon evidence gathered during independent investigations, not evidence from prior civil proceedings.

Civil penalties

The Bill introduces, alongside criminal sanctions, civil penalty provisions relating to the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods. A civil penalty is a punitive sanction of a financial nature and provisions imposing civil penalties do not specify aggravating elements and fault elements. The penalties are imposed through civil court proceedings rather than through the criminal prosecution process. A civil penalty takes the form of a monetary penalty only and does not result in any criminal conviction. A criminal prosecution is a more appropriate sanction where a contravention is deliberate, where fraud may be involved, where the conduct demonstrates recklessness, where there is a serious pattern of continuous intentional contraventions, or where conduct has endangered lives or has caused death or serious injury.

A civil penalty is more appropriate to enable responsible persons to be fined for breaches of the TG Act where other sanctions, such as criminal prosecution, may not be as effective or appropriate in the circumstances. The civil penalty regime is also intended to act as a deterrent to behavior that breaches regulatory requirements, and also to act as an incentive for persons to establish systems designed to avoid breaches of regulatory requirements. In these ways, the civil penalty scheme is intended to prevent instances where public health and safety is, or could be, placed in jeopardy.

The focus of a civil penalty scheme is generally on the regulation of commercial activity. The inclusion of a civil penalty regime is proposed to strengthen enforcement options to deter non-compliance with regulatory requirements by persons whose main objective is monetary profit.

The levels of these penalties have been set having regard not just in relation to the significant impact on the health of the users of vaping goods but to the fact that the perpetrators stand to make significant financial gains from unlawful dealings with vaping goods. The potential monetary benefit of unlawful dealings with vaping goods

is significant. The objective is, for the benefit of good health outcomes for consumers, to incentivise those who have the most to gain by breaching the TG Act to comply with regulatory requirements.

Prescribing conduct that is subject to a civil penalty could engage criminal process rights if the imposition of civil penalties is classified as ‘criminal’ under international human rights law.

Guidance Note 2: Offence provisions, civil penalties and human rights (December 2014), which is published by the Parliamentary Joint Committee on Human Rights, states that civil penalty provisions may engage criminal process rights under Articles 14 and 15 of the ICCPR, regardless of the distinction between criminal and civil penalties in domestic law.

When a provision imposes a civil penalty, an assessment is required as to whether it amounts to a ‘criminal’ penalty for the purposes of the ICCPR. Determining whether penalties could be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.

The Bill seeks to create various civil penalty provisions, which will be expressly classified as civil penalties for the purposes of Australian domestic law and will not impose criminal liability. For several reasons, the civil penalty provisions are unlikely to be considered criminal for the purposes of human rights. These provisions are not classified and identified as criminal under the TG Act. Rather, they are alternatives to criminal prosecution and do not carry a sanction for imprisonment for non-payment. Further, a finding of breach will not lead to the creation of a criminal record. The provisions are part of an enforcement regime to incentivise those who would otherwise have much to gain by not complying with regulatory requirements to comply for the benefit of public health thus the high level of penalty. As such, the criminal process rights under Articles 14 and 15 of the ICCPR would be unlikely to apply.

The civil penalty provisions in the Bill are principally intended to provide an effective deterrent to non-compliance, and to reflect the serious potential impact on public health of non-compliance. Prosecution of a person for contravention of a civil penalty provision will generally only be considered after other available compliance measures have been considered. Those measures may include, for example, the giving of an infringement notice.

To provide effective deterrence, the penalties for individuals and bodies corporate are significant ranging from a maximum 5,000 penalty units for individuals to 50,000 penalty units for bodies corporate, to 7,000 penalty units for individuals to 70,000 penalty units for bodies corporate. These high penalties are commensurate to the public health risks associated with the use of vaping goods. The civil penalty contraventions are not directed to members of the public in general but only to those who are importing, manufacturing, supplying, commercially possessing and advertising illegal vaping goods. These penalties are comparable with existing civil penalty provisions under the TG Act and consistent with the penalties for similar conduct in comparable legislation, such as the *Corporations Act 2001* (section 1317G)

and pecuniary penalties under consumer law under *Competition and Consumer Act 2010*.

Thus, the civil penalties are classified as civil penalties and not criminal for the purposes of human rights law.

Further, a person who is the subject of a civil penalty proceeding has a right to a fair hearing before a competent, independent, and impartial court as provided for under the current Part 5A-1 (civil penalties) under Chapter 5A of the TG Act, which supports compatibility with the right to a fair hearing under Article 14(1) of the ICCPR.

The right to the presumption of innocence under Article 14(2)

Article 14(2) of the ICCPR provides that everyone charged with a criminal offence shall have the right to be presumed innocent until proven guilty according to law. The right to presumption of innocence is also a fundamental common law principle.

Strict liability offences

When strict liability applies to an offence, the prosecution is only required to prove the physical elements of an offence, not the fault elements, beyond reasonable doubt for the defendant to be found guilty. The defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the *Criminal Code*).

Strict liability is used in circumstances where there is a public interest in ensuring that regulatory schemes are observed, and it can be reasonably expected that the person was aware of their duties and obligations. Strict liability offences can be considered a limitation of the presumption of innocence because the defendant can be found guilty without the prosecution being required to prove fault.

The inclusion of strict liability offences for a contravention of the TG Act is a purposeful deterrence measure. A requirement for the prosecution to prove the existence of a fault element, such as intention or recklessness, would not adequately protect the public from the supply, and advertising for supply, of vapes, that are non-compliant with requisite regulatory obligations.

Strict liability offences are introduced because of the potential risk to public health arising from vapes, to strike an appropriate balance between deterrence and the right of the individual to be presumed innocent. The conduct involved in these offences is sufficiently serious that, if the defendant were convicted of an equivalent fault-based offence, a much higher penalty could be imposed including, in some cases, a significant term of imprisonment.

The strict liability provisions are compatible with Article 14(2) of the ICCPR, as the provisions pursue a legitimate objective in acting as a deterrent to behaviour that may otherwise represent a risk to public health, in particular, youth and young people, and are reasonable and proportionate in achieving that outcome. Where the prosecution that the defendant is culpable and the relevant fault elements such as intention and recklessness can be established, the normal fault-based offence could be pursued.

Reverse burden of proof

The primary offences in the Bill have offence and civil penalty specific defences, described in the Bill as exceptions. In effect, these defences reverse the burden of proof that would usually apply in an offence or civil penalty contravention, by requiring the defendant to discharge the evidential burden of proof for one or more elements. The reverse onus represents a departure from the ordinary principle of criminal law that a defendant is presumed to be innocent, and that the prosecution must prove every element of an offence relevant to the person's guilt.

The exceptions for relevant offences and civil penalty contraventions are set out in subsection 41Q(5) for importation, subsection 41QA(5) for manufacture, subsections 41QB(6), (7) and (8) operating in conjunction for wholesale supply, subsections 41QB(9), (10) and (11) operating in conjunction for retail supply, subsections 41QC(13) and (14) operating in conjunction for possession of a commercial quantity and subsections 41QD (7) and (8) operating in conjunction for possession of less than a commercial quantity. Under these exceptions, a person charged with the relevant offence will bear the evidential burden – that is, the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist (see subsection 13.3 of the *Criminal Code*). In each case, placing the evidential burden on the defendant is a reasonable and proportionate measure to ensure the effective regulation of vaping goods.

Although counter to the fundamental principle of the presumption of innocence, it is established practice that reversal of burden offences are reasonable and appropriate in circumstances in which relevant matters will ordinarily and peculiarly be within the defendant's knowledge while also be easily adduced by the defendant and where the conduct proscribed by the offence poses a grave danger to public health or safety. The existence of evidence relating to a particular licence, authorisation, approval, permission or exemption in relation to certain vaping goods or conduct is particularly within the knowledge of the defendant.

This approach is well established in Commonwealth and state and territory legislation. The presence of exceptions, for which the defendant must adduce or point to evidence that is peculiarly within their knowledge, can be seen in offence provisions under the TG Act (sections 19B and 41MI), the Criminal Code (sections 137.1 and 137.2), and state legislation such as the *Drug Misuse and Trafficking Act 1985* NSW (section 10).

The Bill introduces offences and civil penalty provisions that prohibit the import, manufacture, advertising, supply and commercial possession of vaping goods, subject to exceptions. Depending on the prohibited conduct, the exceptions include where the person has the appropriate licence, authority, approval or authorisation, the person was granted a consent by the Secretary of the Department to carry out those activities or the goods are supplied within the existing (lawful) pharmaceutical supply chain. The prohibited conduct and supply chain are made up of controls at the Commonwealth or state and territory levels, or both. The enforcement of these prohibitions is to be undertaken by both states and territories, as well as the

Commonwealth. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with one government agency and is very likely to be split across many.

In contrast, the person seeking to rely on the exceptions will likely hold the evidence to substantiate the lawful status of the goods with respect to relevant importation, manufacture, supply or possession activities. The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the efficient regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. The Bill provides a list of the necessary evidence that a defendant needs to produce, such as an authority to prescribe a prescription only medicine in a state or territory or otherwise deal with vaping goods.

Thus, these provisions, despite reversing the evidential burden, are compatible with Article 14(2) of the ICCPR, as they pursue a legitimate objective in acting as a deterrent to behaviour and activities that may otherwise represent a risk to public health, and are reasonable and proportionate in achieving that outcome.

The right to be free from self-incrimination

Article 14(3)(g) of the ICCPR protects the right of an individual to be free from self-incrimination in the determination of a criminal charge by providing that a person cannot be compelled to testify against him or herself or confess guilt. The common law also recognises the privilege against self-incrimination, which applies unless expressly or impliedly overridden by statute. The privilege against self-incrimination may be subject to permissible limits but any such limitations must be for a legitimate objective and be reasonable, necessary and proportionate to that objective.

This Bill limits the right for an individual to be free from self-incrimination where the exercise of this right could seriously undermine the effectiveness of the regulatory scheme and prevent the identification of persons involved in the advertising, and potentially the supply, of vaping goods.

Sections 42DZD and 42DZE provide an offence and civil penalty where a person advertises or causes the advertising of vaping goods without authorisation or in a manner that does not comply with an authorisation that has been given. However, it may not be clear from the outset whether the person responsible for the advertisement was the person apparently responsible or a third party. Sections 42DZF, 42DZG, and 42DZH confer a power to require production, by a person apparently responsible for advertising vaping goods, of specified information relating to advertisements about vaping goods, which could be used to obtain information about the procurement of an advertisement, such as the identity of the procurer.

Without limiting the right to be free from self-incrimination, persons apparently responsible for advertising could withhold pertinent information that would seriously

undermine the Secretary's power to identify persons involved in the advertising, and potentially the supply, of vaping goods.

Section 42DZJ therefore removes the privilege against self-incrimination in relation to the requirement to provide specified information under sections 42DZF.

The abrogation of the privilege is acceptable in the circumstances because the specified information will generally only be within the knowledge of the person concerned and persons who may be acting unlawfully and would be unlikely to identify themselves. Further, the abrogation of the privilege is accompanied by immunity under section 42DCJ from further criminal or civil proceedings against the individual to whom a requirement to produce specified information is directed, other than in a limited number of proceedings. These proceedings are those in relation to an offence for providing information or document in response to a notice and the information or document is false or misleading in a material particular (subsections 42DZG(3) and (4) refer), or a civil penalty contravention proceeding under subsection 42DZH where the person complying with the notice gives information or documents that are false or misleading in a material particular. The proceedings would be justifiable to ensure that the person complying with the notice provides relevant information or documents that are not false or misleading in a material particular.

Criminal offences and civil penalty provisions relating to the importation, manufacture, supply, commercial possession and advertisement of vaping goods, subject to exceptions

The Bill introduces the following offences and civil penalty contraventions, subject to exceptions:

- (a) section 41Q provides a fault-based offence (subsection 41Q(1) refers), an offence of strict liability (subsection 41Q(2) refers), and a civil penalty provision (subsection 41Q(3) refers) relating to the importation of vaping goods in Australia. Subsections 41Q(1), (2) and (3) do not apply if the importation of the vaping goods would not be prohibited under the CPI Regulations under the *Customs Act 1901* (the Customs Act);
- (b) section 41QA provides a fault-based offence, a strict liability offence and a civil penalty provision relating to the manufacture of vaping goods at premises in Australia. These offences and civil penalty contravention do not apply if the vaping goods are therapeutic goods and the person manufacturing the goods:
 - (i) is a holder of a manufacturing licence under Part 3-3 of the TG Act, or
 - ~~(ii) holds a conformity assessment document that applies to the vaping goods;~~
 - ~~or~~
 - ~~(iii) was granted a consent under subsection 41RC(1) to manufacture the vaping goods, or carry out the manufacture of the vaping goods at the premises and the manufacture, or the step was carried out in accordance with the consent; or~~
 - ~~(iv) holds a conformity assessment document that applies to the vaping goods;~~

Formatted: Indent: Left: 2 cm, No bullets or numbering

- (c) section 41QB provides a fault-based offence, a strict liability offence and a civil penalty provision relating to the supply of vaping goods. Exceptions from the application of these provisions apply in relation to legitimate persons involved in the wholesale supply chain and the retail supply chain of therapeutic vapes respectively;
- (d) section 41QC provides fault-based offences, strict liability offences and civil penalty provisions relating to the possession of at least commercial quantities of vaping goods. Exceptions to the application of these provisions apply in relation to legitimate persons involved in the supply chain for therapeutic vapes. Absolute liability applies to the physical element of the fault-based offence in relation to the specified quantity of the kind of vaping goods;
- (e) section 41QD provides a fault-based offence, a strict liability offence and a civil penalty provision relating to the possession of less than a commercial quantity of vaping goods, subject to exceptions. Absolute liability applies to the physical element of the fault-based offence in relation to the quantity being less than a commercial quantity of that kind of vaping goods. Exceptions to the application of these provisions apply in relation to legitimate persons involved in the supply chain for therapeutic vapes. Importantly, there is also an exception if possession is for personal use or if a person possesses vaping goods on behalf of another person for whom the goods have been lawfully supplied;
- (f) section 42DZD provides a fault-based offence and a strict liability offence relating to the advertisement of vaping goods, which is not authorised, or if authorised does not comply with the authorisation;
- (g) section 42DZE provides a civil penalty provision relating to the advertisement of vaping goods, which are not authorised or if authorised does not comply with the authorisation;
- (h) section 42DZG provides fault-based offences and strict liability offences for the failure to comply with a notice under section 42DZF or provision of false or misleading information;
- (i) section 42DZH provides a civil penalty provision in relation to giving false or misleading information or document in compliance with a notice under section 42DZF;
- (j) section 42DZL provides offences for contravening a direction under section 42DZK; and
- (k) section 42DZM provides civil penalty provisions for contravening a direction under section 42DZK.

The right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted

Formatted: Keep with next

Article 14(7) of the ICCPR provides that “no one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country”. This prohibition on double jeopardy is also a fundamental safeguard in the common law of Australia. It means that a person who has been convicted or acquitted of a criminal charge is not to be re-tried for the same or substantially the same offence. This prohibition, as provided in Article 14(7), is limited to proceedings relating to a criminal charge. However, it is noted that whether a proceeding is civil or relates to a criminal charge under Article 14(7) is determined by the substance and the effect of the proceedings themselves, rather than their label under domestic law.

The right not to be twice tried or punished for the same offence may be engaged as the Bill permits both criminal and ‘civil’ proceedings to be brought against a person for the same conduct. However, the commencement and conduct of proceedings brought under the offences and civil penalty provisions introduced by the Bill are subject to the requirements under Division 2 of Part 5A-1 of Chapter 5A of the TG Act. Under Division 2 of Part 5A-1 criminal proceedings may not be commenced against a person after they have been ordered to pay a civil penalty for the same conduct. Similarly, criminal proceedings cannot be brought against a person for conduct that has already been the subject of civil penalty order. Finally, any civil proceedings for the same conduct for which criminal proceedings have commenced are stayed and can only be re-instated if the person is not convicted of the criminal offence.

Absolute liability

The Bill includes absolute liability fault element to specified physical elements set out in paragraphs 41QC(1)(b), 41QC(4)(b), 41QC(7)(b) and 41QD(1)(b) of the fault-based offences.

In relation to paragraph 41QC(1)(b), for example, the absolute liability fault element is proposed because it would be quite challenging and difficult to prove beyond reasonable doubt that a person was reckless that the quantity in their possession was at least a commercial quantity but less than 100 times the commercial quantity.

Similarly, it would be quite challenging for the prosecution to prove beyond reasonable doubt that a person was reckless that the quantity in their possession was at least a commercial quantity but less than 100 times the commercial quantity. Although recklessness is a lower threshold than knowledge or intention, the prosecution would still be required to point to some evidence that suggests the defendant was reckless as to the specific quantity. This includes recklessness as to what a commercial quantity is under the Regulations.

Requiring proof of fault of the relevant element to which strict or absolute liability applies would undermine deterrence in relation to the possession of a commercial quantity of vaping goods, and there are legitimate grounds for penalising persons lacking the necessary fault in respect of that element. The objective is to deter the

possession and subsequent supply of commercial quantities of vaping goods in Australia. At the same time, supply and possession of vaping goods for smoking cessation or the management of nicotine dependence would be permissible. The circumstances where possession of these goods are allowed or acceptable are set out in the exceptions to the offences.

The same reasoning applies to new paragraphs 41QC(4)(b), 41QC(7)(b), and 41QD(1)(b). By way of comparison, for drug offences under the *Criminal Code*, the fault element attached to the physical element relating to quantity (which is circumstance) is absolute liability (see s 6.2 of the Code). As such, there are no fault elements attributed to the physical element that the drugs are of a certain quantity.

An example of this approach can be found in s 307.5 of the Code:

“307.5 Possessing commercial quantities of unlawfully imported border controlled drugs or border controlled plants

- (1) A person commits an offence if:
 - (a) the person possesses a substance; and
 - (b) the substance was unlawfully imported; and
 - (c) the substance is a border controlled drug or border controlled plant; and
 - (d) the quantity possessed is a commercial quantity.

Penalty: Imprisonment for life or 7,500 penalty units, or both.

- (2) Absolute liability applies to paragraphs (1)(b) and (d).
- (3) The fault element for paragraph (1)(c) is recklessness.
- (4) Subsection (1) does not apply if the person proves that he or she did not know that the border controlled drug or border controlled plant was unlawfully imported.

Note: A defendant bears a legal burden in relation to the matter in subsection (4) (see section 13.4).”

The rationale behind this approach is discussed in the Explanatory Memorandum to the Law and Justice Legislation Amendment (Serious Drug Offences and Other Measures) Bill 2005:

“Applying absolute liability to the element of quantity...will markedly improve the enforceability of these offences [drug offences]. This approach was recommended by MCCOC in 2003 as a modification to the model offences originally proposed in its 1998 report and was also endorsed by the Standing Committee of Attorneys-General”.

The MCCOC refers to the Model Criminal Code Officers Committee of the Standing Committee of Attorneys-General, which was involved in the development of a national model criminal code for Australian jurisdictions.

Applying this approach to new draft 41QC(1), provided the prosecution can establish that the quantity is at least a commercial quantity but less than 100 times the commercial quantity, both the physical and fault elements will be satisfied. The same observations can be made for the other possession offences in the Bill. Note, however, that despite the inclusion of the absolute liability fault element, the human rights relating to presumption of innocence, the right to a fair trial and hearing, and the right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted all apply to the defendant.

The human rights identified in Article 14 of the ICCPR, are engaged by the Bill but the Bill does not limit those rights, and if it does there are legitimate reasons for doing so to ensure that access to vaping goods is appropriately restricted. In achieving that objective, any limitation to a particular human right is proportionate to that objective.

Conclusion

The Bill is compatible with human rights because it promotes and supports a number of rights and to the extent that it limits other rights, the limitations are reasonable, necessary and proportionate.

The Bill promotes and supports the following rights:

- the *right to health* under Article 12 of the ICESCR;
- the *right to life* under Article 6 of the International Covenant on Civil and Political Rights (ICCPR);
- the *obligation to ensure the survival and development of children* under Article 6(2) of the Convention of the Rights of the Child (CRC);
- the *obligation to protect children from illicit use of narcotic drugs and psychotropic substances* under Article 33 of the CRC.

The Bill engages a number of other rights, being:

- the *right to privacy* under Article 17 of the ICCPR;
- the *right to freedom of expression* under Article 19(2) of the ICCPR;
- the *right to a fair hearing* under Article 14(1) of the ICCPR;
- the *right to the presumption of innocence* under Article 14(2) of the ICCPR;
- the *right to be free from self-incrimination* under Article 14(3)(g) of the ICCPR;
- the *right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted* under Article 14(7) of the ICCPR.

However, to the extent that the Bill limits any of these rights the limitations are reasonable, necessary and proportionate to achieving the aim of protecting public health by limiting access to harmful vaping goods.

The Hon Mark Butler MP, Minister for Health and Aged Care

THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT (VAPING REFORMS) BILL 2024

NOTES ON CLAUSES

Clause 1 – Short Title

The clause provides for the short title of the TG Act, once enacted, to be the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*.

Clause 2 – Commencement

This clause provides the timetable for the commencement of various provisions contained in the Bill as follows:

- Sections 1 to 3 commence on the day that the Bill receives the Royal Assent;
- Schedule 1 commences the later of 1 July 2024 and the day after the Bill receives Royal Assent;
- Schedule 2 commences the day after the Bill receives the Royal Assent; and
- Schedule 3 commences at the same time as Schedule 1.

Clause 3 – Schedules

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms.

This is a technical provision which gives operational effect to the amendments contained in the Schedules.

Schedule 1 amends the *Therapeutic Goods Act 1989* (the TG Act).

Schedule 2 amends the *Customs Act 1901* (the Customs Act).

Schedule 3 amends other Acts, including the *Industrial Chemicals Act 2019* and the *Public Health (Tobacco and Other Products) Act 2023*.

SCHEDULE 1 — Amendment of the *Therapeutic Goods Act 1989*

Background

On 2 May 2023, the Minister for Health and Aged Care announced the Government's intention to address the significant generational harms posed by vaping in Australia by implementing a ban on all vaping goods, except vaping goods imported, manufactured, or supplied in accordance with the TG Act, and to strengthen the controls for therapeutic vapes, including by requiring therapeutic vapes to be supplied to patients through pharmacy settings.

At a general level, a 'therapeutic vape' is a shorthand expression for therapeutic vaping goods which are 'therapeutic goods' within the meaning of the TG Act and supplied within the existing (lawful) pharmaceutical supply chain.

The amendments in this Schedule will implement these measures by expanding the TG Act to regulate vaping goods that are not simply 'therapeutic goods'. This is intended to achieve a comprehensive, and nationally consistent, approach to the regulation of vapes by relying on the federal cooperative scheme for therapeutic goods. All states and territories have enacted corresponding laws to adopt the Commonwealth TG Act as amended from time, ~~with except for~~ Western Australia recently progressing its own corresponding law. The corresponding laws are designed to fill the gap in the Commonwealth's constitutional power to ensure appropriate coverage for the regulation of therapeutic goods.

Specifically, the measures in this Schedule are intended to:

- introduce key definitions, and related powers including the power for the Minister to, by legislative instrument, determine that specified goods are therapeutic goods, including when used, advertised or presented for supply in a particular way;
- prohibit the importation, manufacture, supply and commercial possession of vaping goods, with specified exceptions that are designed to reflect lawful dealings with therapeutic vaping goods and which include an exception for personal use in relation to the offences and civil penalties relating to the possession of less than a commercial quantity of vaping goods;
- enable the Secretary to consent to the manufacture, supply or commercial possession of vaping goods, with the effect that a person to whom such a consent is granted would be covered by an exception in relation to the relevant offences and civil penalties for such conduct – this measure is designed to ensure that persons who lawfully deal in therapeutic vaping goods will not be subjected to sanction for such dealings;
- introduce a new, tailored advertising framework for vaping goods, with requirements, and offences and civil penalties, designed to protect consumers from the advertising of vaping goods, including vulnerable audiences such as young Australians. Consistent with the existing advertising framework for therapeutic goods, the new framework will not apply to advertisements directed exclusively at health practitioners and other specified kinds of persons such as practice managers for health practitioners;
- introduce a number of new measures to enhance the compliance and enforcement framework for both vaping goods and therapeutic goods,

principally through powers for the Secretary to give enforceable directions to persons requiring them to do specified things in relation to particular products, such as to relabel the goods to bring them into compliance with the TG Act, or to deliver the goods for destruction or disposal, and through the introduction of new arrangements relating to the forfeiture and retention of products;

- allow for the delegation of certain powers of the Secretary to an officer of a Department of State of a state, a Department or administrative unit of the Public Service of a territory or an authority of a state or territory, in order to empower state and territory officials to carry out enforcement powers under the new vaping reforms, as part of measures to ensure a comprehensive and consistent approach to addressing unlawful vaping goods;
- ensure that the Secretary may release information about vaping goods to the public and to specified persons, bodies or authorities or kinds of persons, bodies or authorities, such as state and territory health departments and law enforcement bodies to support compliance and enforcement efforts and inform the public in relation to risks posed by particular vaping goods; and
- make a small number of more minor amendments, including updating the offences and civil penalties in the Act for breaching a condition of an exemption or approval for therapeutic goods. This will help ensure that therapeutic vapes supplied in Australia meet minimum benchmarks including the requirement for sponsors to notify the Secretary in relation to the compliance of their products with applicable quality standards.

The amendments complement the recent amendments to:

- the CPI Regulations to ban the importation of non-therapeutic and disposable single use vapes (subject to certain exceptions) and to require a licence and permit to import non-disposable therapeutic vapes; and
- the TG Regulations and MD Regulations to strengthen the regulatory controls for therapeutic vapes that are exempt from the requirement to be included in the Australian Register of Therapeutic Goods (the Register).

Part 1—Definitions and objects of Act

Therapeutic Goods Act 1989

Item 1 – Subsection 3(1) (after paragraph (b) of the definition of therapeutic goods)

This item amends the definition of ‘therapeutic goods’ in subsection 3(1) of the TG Act to insert new subparagraph 3(1)(ba), consequential to the introduction of new section 7AAA.

New subparagraph 3(1)(ba) has the effect that the definition of ‘therapeutic goods’ in subsection 3(1) of the TG Act includes goods determined to be therapeutic goods under new section 7AAA.

Item 2 - Subsection 3(1) (paragraphs (e) and (f) of the definition of therapeutic goods)

This item makes a minor amendment to paragraphs (e) and (f) of the definition of ‘therapeutic goods’ in subsection 3(1) of the TG Act consequential to the introduction of new section 7AAA.

Item 3 – At the end of subsection 4(1)

This item amends subsection 4(1) of the TG Act to include the regulation of vaping goods. The amendment makes it clear that the objects of the TG Act include the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are imported, manufactured, supplied in Australia or exported from Australia.

Item 4 - After section 7

This item inserts new subsections 7AAA(1) and (2) into the TG Act.

New subsection 7AAA(1) provides that the Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods (other than goods declared not to be therapeutic goods under an order in force under section 7 and goods covered by a determination under subsection 7AA(1) or (2) (excluded goods)):

- (a) are therapeutic goods; or
- (b) when used, advertised, or presented for supply in a particular way, are therapeutic goods.

New paragraph 7AAA(2)(a) sets out the matters that the Minister must have regard to before making a determination under new subsection 7AAA(1). These matters include whether:

- (a) it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;

- (b) it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;
- (c) the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

New paragraph 7AAA(2)(b) provides that the Minister may have regard to any other relevant matter before making a determination under new subsection 7AAA(1).

Allowing the definition of therapeutic goods to be broadened in delegated legislation will enable rapid amendments to cater for novel and unanticipated products that it is desired should be regulated as therapeutic goods. Despite the broad definition of therapeutic goods, the importation, manufacture, supply, export and advertising of goods in novel and unanticipated forms that should be regulated as 'therapeutic goods' may not readily fit within the current definition is still a possibility and may pose a risk to public health. This is intended to be a broad power for the Minister to specify any good to be a therapeutic good.

Allowing the Minister to determine specified goods to be therapeutic goods through delegated legislation is important, as that definition could be readily amended to capture a new range of goods that for public health reasons should be regulated as therapeutic goods under the TG Act.

Subsection 57(1) of the TG Act allows the Minister to delegate this power to a broad class of delegates. This ensures that those with the most relevant expertise in regulating new and emerging therapeutic goods can participate in the decision-making process. It is also important to note that any amendments to the defined term in delegated legislation would be subject to Parliamentary scrutiny and disallowance.

Item 5 - After paragraph 8(1)(b)

This item amends subsection 8(1) of the TG Act to insert new paragraph 8(1)(ba). In effect, this amendment broadens the classes of person from whom the Secretary may, by giving written notice, request information under subsection 8(1).

The amendment broadens the classes of person to include a person who has imported into Australia, or supplied in Australia, goods in relation to which the Minister is considering making a determination under the new section 7AAA(1) (goods that are therapeutic goods).

This will allow the Secretary to collect relevant information of the kind referred to above which can then be provided to the Minister for the purposes of making such a determination.

Part 2—Regulation of vaping goods

Division 1—Main amendments

Therapeutic Goods Act 1989

Item 6 – Subsection 3(1)

This item inserts two definitions in subsection 3(1) of the TG Act. The definitions provide that ‘commercial quantity’ of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations, and ‘evidential burden’, in relation to a matter means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist. The definition of ‘evidential burden’ reflects the definition in section 13.3 of the Commonwealth *Criminal Code*.

Definition of commercial quantity of a kind of vaping goods to be prescribed in the Regulations

Formatted: Font: Not Bold, Italic

It is necessary and appropriate for a quantity of a kind of vaping goods that would amount to a commercial quantity (item 6 of Schedule 1) to be ~~left to~~ prescribed in delegated legislation, noting the importance of this definition to the offence provisions proposed to be inserted by the Bill.

Formatted: Font: Italic

This definition ~~also~~ applies to ~~both the offence and~~ civil penalty provisions proposed to be inserted by the Bill ~~relating to possession~~. However, the definition has greater significance ~~for~~ the offence provisions due to the cascading ~~maximum~~ penalties that apply under clause 41QC (possession of a commercial quantity of vaping goods). This is because the applicable offence provision and ~~maximum~~ penalty depends on the quantity of vaping goods found in a person’s possession.

Necessary and appropriate

Formatted: Indent: Left: 0 cm

It is necessary and appropriate for a quantity of a kind of vaping goods that would amount to a commercial quantity to be prescribed in regulations to:

- ensure flexibility to change the quantity in line with prescribing practices of health professionals with respect to therapeutic vapes for personal use;
- ensure the commercial quantity is adaptive to new and emerging design specification, which could affect the types of vaping substance used, the delivery of vaping substance, the volume and concentration capacity of the vaping device and the number and types of vaping accessories available for use with vaping devices and substances;
- allow quantities to be amended efficiently, if necessary, in response to illicit trade of vapes to ensure that the criminal offences continue to act as a sufficient deterrent; and
- maintain a workable connection between a commercial quantity of vaping goods and acceptable or legitimate volumes or quantities of therapeutic vaping goods.

Quantity prescribed for personal use

Formatted: Indent: Left: 0 cm

The vaping reforms are not intended to prohibit the possession of vaping goods for personal use, provided the vapes in a person's possession are appropriately less than a commercial quantity. Accordingly, the phrase 'commercial quantity' serves as a marked distinction between commercial possession and possession for personal use.

The medical advice as to the appropriate quantity of vaping goods for personal use is evolving and differs significantly depending on the patient's individual circumstances. This makes it difficult to specify with certainty where the relevant line is between a quantity that could reasonably be for personal use, and where that line is clearly crossed, and the possession is for commercial purposes.

By allowing for the quantities to be prescribed in the regulations, the government can more easily and quickly respond as the medical and public health advice evolves. Flexibility will be important in ensuring that by the prohibitions on commercial possession by unlawful actors in Australia are fit for purpose and achieve the regulatory objective of these measures.

The reasoning behind the proposed approach with respect to the meaning of a commercial quantity would, of course, be included in the explanatory statement to the regulations and would be based on expert public health and medical advice and the broader compliance and enforcement experience.

Analogous approach – commercial quantity of serious drugs and precursors

Formatted: Indent: Left: 0 cm

An example of an analogous approach where a commercial quantity of a substance has been prescribed in regulations made under primary legislation is the commercial quantity of a serious drug, controlled precursor or border-controlled precursors in the *Criminal Code Act 1995*.

Formatted: Font: Italic

Section 301.10 of the *Criminal Code Act 1995* provides that the quantity of a serious drug, controlled precursor or border-controlled precursor is prescribed. These quantities are set out in the *Criminal Code Regulations 2019* (the *Criminal Code Regulations 2002* at the time the provision was introduced).

Formatted: Font: Italic

Formatted: Font: Italic

Formatted: Font: Italic

The reason provided for this approach similarly related to the need for flexibility in the face of evolving markets and emerging products. It was felt that any delay in updating quantities would be exploited by 'entrepreneurial criminals and organised crime groups'. The same arguments apply in relation to vaping goods. Further,

Summary

Formatted: Font: Not Italic

Formatted: Heading 2

Formatted: Font: Not Italic

Formatted: Heading 2, Indent: Left: 0 cm

For the reasons set out above, it is necessary and proportionate for the definition of a 'unit' of vaping goods or the quantity of a kind of vaping goods that would amount to a commercial quantity to be prescribed in regulations made by the Governor-General in Federal Executive Council.

~~This would ensure the TG Act can address the ongoing public health risks posed by vaping in a flexible and agile manner. At the same time, the regulations would remain subject to parliamentary scrutiny and disallowance.~~

Item 7 – Section 3(1) (definition of *manufacture*)

This item amends the definition of ‘*manufacture*’ in the TG Act to provide that the term relates to the manufacture of vaping goods, as well as therapeutic goods.

Item 8 – Subsection 3(1)

This item inserts three definitions in section 3(1) of the TG Act, for ‘*medical practitioner*’, ‘*nurse practitioner*’, and ‘*pharmacist*’. These terms are defined as meaning a person who is registered, licensed or authorised (as relevant) under a law of a state or internal territory that provides for such registration, licensing or authorisation.

Item 9 – Subsection 3(1) (paragraph (c) of the definition of *supply*)

This item amends the definition of ‘*supply*’ in subsection 3(1) of the TG Act to provide that the term also relates to vaping goods.

Item 10 – Subsection 3(1)

This item inserts new definitions in subsection 3(1) of the TG Act. It inserts the new definition of ‘*unit*’ of vaping goods, which has the meaning prescribed by the regulations.

This item also inserts new definitions for ‘*vaping accessory*’, ‘*vaping device*’, ‘*vaping goods*’ and ‘*vaping substance*’, all of which are defined in new section 41P of the TG Act. The scope of each of these definitions are discussed in relation to the operation of section 41P.

~~Definition of a “unit” of vaping goods to be prescribed in the Regulations~~

~~It is necessary and appropriate for the definition of a “unit” of vaping goods (in item 10 of Schedule 1) to be left to delegated legislation.~~

The concept of a ‘*unit*’ of vaping goods has no application to the criminal offence provisions proposed to be inserted by the Bill. Rather, it is a matter central only to the enforceability, and application, of the civil penalty provisions in the proposed new Chapter 4A relating to the importation, manufacture, supply and commercial possession of vaping goods in subclauses 41Q(3), 41QA(3), 41QB(3), 41QC(10) and 41QD(4).

The concept is intended to provide an appropriate mechanism for calculating the number of contraventions of a civil penalty provision, as an alternative to the prosecution of corresponding criminal conduct.

Formatted: Font: Not Bold

Formatted: Indent: Left: 0 cm

As a public health measure directed to discourage unlawful conduct relating to vaping, goods to ultimately discourage the uptake of vaping, the definition of a 'unit' needs to be flexible and adaptable as appropriate in the circumstances. It is proposed that a unit of vaping goods is prescribed in regulations made under the TG Act.

The regulations would be subject to appropriate parliamentary scrutiny and disallowance. This supports an approach that is adaptive to evolving public health issues, contemporary clinical and scientific evidence and changes in technology and the market more generally.

Necessary and appropriate

The intention of the new offences and civil penalty provisions is to deter unlawful conduct, arrest the alarming increase in the use of vapes in Australia, particularly among youth and young adults, and to prevent a new generation of persons being exposed to dangerous chemicals and developing nicotine dependence.

It is necessary and appropriate for the definition of a 'unit' of vaping goods (in item 10 of Schedule 1) to be prescribed by regulations having regard to:

- the design, development and marketing of unlawful vaping goods, which will continue to evolve following the vaping reforms; this is because the market has consistently sought to evade compliance efforts in recent years through product design and concealment; successful regulation must remain responsive to industry changes;
- the scientific, medical and public health understanding in relation to vaping goods, which will continue to mature, as the health impact of unlawful vapes is determined particularly with reference to nicotine concentrations and toxicities;
- matters specified in other delegated legislation made under the *Therapeutic Goods Act 1989* (TG Act), such as standards, which may change from time to time and materially impact the determination of a 'unit' of vaping goods.

Given the need for adaptability, it is appropriate for a 'unit' of vaping goods to be prescribed in the regulations having regard to changing scientific, medical, and public health understanding. Any incongruence with acceptable or legitimate volumes or quantities of therapeutic vaping goods would create serious difficulties for compliance and enforcement efforts.

Prescribing a 'unit' of vaping goods in delegated legislation would provide for necessary flexibility and agility to ensure that the public health risks from vaping are expeditiously managed and enforced in response to an aggressive and changing illicit market. The public health risks are significant and are explained at pages 3 to 5 of the explanatory memorandum to the Bill.

The reasoning behind the proposed approach with respect to a 'unit' of vaping goods would be included in explanatory material to the regulations, and based on further consultation, medical advice and the broader compliance and enforcement experience.

Formatted: Indent: Left: 0 cm

Responsive to the evolution of the illicit market

Formatted: Indent: Left: 0 cm

The government's experience in enforcing the existing regulatory framework has demonstrated that the illicit market is quick to adapt to the changing regulatory settings, including making alterations to the manufacturing of vaping goods.

Examples include the removal of all references to nicotine on the label of vaping goods being imported and subsequently supplied in Australia, and the deliberate mischaracterisation of vaping goods as perfume atomisers or the like.

Such steps significantly frustrate the ability for the Australian Border Force and the Therapeutic Goods Administration (TGA) to take appropriate regulatory action to prevent these goods entering Australia and making their way to retailer stores for the purpose of direct supply to the public.

Flexibility in determining a unit of vaping goods will ensure that any changes to the way that vaping goods are designed, manufactured, promoted or characterised can be appropriately responded to by ensuring that a unit of vaping goods reflects the reality of the evolving illicit market.

Responsive for public health reasons

Formatted: Indent: Left: 0 cm

~~As the Committee is aware,~~ Clause 41P provides that vaping goods are to be defined as including all their various permutations: vaping accessories, devices, and vaping substances. Vaping goods can be one, or a combination of these different permutations, and there can be different characteristics, which distinguish the goods from each other, and the objective harm of each permutation of the goods themselves.

Flexibility in determining a unit of vaping goods is critical in ensuring that the harms of the different permutations of vaping goods are internally consistent and correspond to the objective harms of each kind of vaping good.

For example, the objective harm of 20 vaping accessories could be said to correspond to the objective harm of 200ml of vaping substance. However, this assessment may change as over time, and require amendment to ensure consistency, depending on the relevant concentration or toxicity.

There may be circumstances where the objective harm may be linked to the nicotine concentration in the vaping substance, rather than the volume itself. Determining a 'unit' of each of the permutations may be complex and is anticipated to evolve as the scientific and medical knowledge about vaping goods develops and matures.

Relevance of other delegated legislation

Formatted: Indent: Left: 0 cm

Standards, which are disallowable legislative instruments, made under the TG Act set maximum volumes for vaping substances. These volumes are subject to change from time to time and will be relevant to determining a 'unit' of vaping goods. Prescribing 'units' in the regulations allows flexibility to amend this concept if maximum volumes in the standards are changed.

Example – traveller’s exemption

Formatted: Indent: Left: 0 cm

An example of an analogous approach, which has been specified in delegated legislation, is the prescription of the quantity allowable under the traveller’s exemption in regulation 5A of the *Customs (Prohibited Imports) Regulations 1956*.

This exemption allows a person travelling to Australia to bring a small quantity of vaping goods with them for use in their treatment, or someone they are caring for, who is entering Australia on the same ship or aircraft. The current maximum allowable quantity is no more than 2 vapes, 20 vaping cartridges and 200 ml of vaping liquid.

While no explanation was provided in the explanatory statement for the *Customs Legislation Amendment (Vaping Goods) Regulations 2023*, the volumes and quantities specified in the traveller’s exemption are relatively modest and considered to be reasonable in the circumstances for the personal use of a traveller to Australia.

Formatted: Font: *Italic*

Item 11 – After Chapter 4

Formatted: Keep with next

This item inserts new Chapter 4A in the TG Act. This Chapter is titled ‘Vaping goods’ and principally deals with the regulation of vaping goods under the TG Act.

Division 1 in Part 4A-1 deals with introductory matters. Division 1 contains new section 41N which provides the simplified outline of this Chapter.

New section 41NA provides that an offence provision or civil penalty provision in Chapter 4A does not limit the generality of an offence provision or civil penalty provision in any other Chapter, and those provisions in other Chapters do not limit the generality of offence provisions or civil penalty provisions in Chapter 4A.

Division 2—Interpretation

Therapeutic Goods Act 1989

Division 2 in Part 4A-1 provides definitions for relevant terms.

Division 2 contains new subsection 41P(1) which provides a definition for *vaping accessory*, *vaping device*, *vaping goods* and *vaping substance*. These definitions would broadly mirror the definitions inserted into the CPI Regulations by the *Customs Legislation Amendment (Vaping Goods) Regulations 2023*. Where the proposed definitions materially differ from those already present in the CPI Regulations, explanation of this difference is provided below.

The term *vaping goods* is defined to mean a vaping substance, vaping accessory or vaping device, as well as goods the presentation of which includes an express or implied representation that the goods are such goods, or that they are included in a class of goods that are determined to be vaping goods under subsection (3). This definition captures goods in relation to which the name, labelling, packaging, or any advertising or informational material associated with the goods, includes an express or implied representation that the goods are either a *vaping substance*, *vaping*

accessory or *vaping device*. In relation to a *vaping device*, one example where this may arise would include a good that is included in the same package as a *vaping substance* and/or *vaping accessory*, making it apparent that it is intended to be used as a *vaping device*. Similarly, a substance may be characterised as a *vaping substance* where it is labelled as an ‘e-juice’ or an ‘e-liquid’, as it will be apparent that it is for use in, or with, a *vaping device*.

Paragraph (e) of the definition of *vaping goods* would also have the effect that the definition of *vaping goods* would include goods that are, or are included in a class of goods that are, determined to be *vaping goods* by the Minister under subsection 41P(3). This is a broad power that allows the Minister to determine any good to be a *vaping good* where regulation under Chapter 4A is desirable.

The term *vaping device* is defined to mean:

- (a) a device (whether or not filled with a vaping substance) that generates or releases, or is designed or intended to generate or release, using a heating element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user; or
- (b) a device to which paragraph (a) would apply if the device were not temporarily or permanently inoperable, incomplete, damaged, or unfinished.

The note to the definition of *vaping device* provides that humidifiers, diffusers, nebulisers and inhalers are not *vaping devices*.

Devices that release vapour or mist into the air, including devices such as humidifiers, diffusers and some steam inhalers, do not meet the definition of a *vaping device* because the vapour or mist is not for direct inhalation by the user. Devices that release vapour, aerosol or mist into the air, and direct that air towards the user through a mask, such as some inhalers and nebulisers do not meet the definition of a *vape*. Devices that do not produce vapour or mist using a heating element, such as nebulisers and most inhalers, do not meet the definition of a *vape* because they do not generate the vapour or mist using a heating element.

A heat not burn device, which heats, using a heating element and by electronic means, processed tobacco without combustion and produces a vapour for direct inhalation, meets the definition of a *vaping device*. An e-hookah device that vaporises vaping substances for direct inhalation will meet the definition of a *vaping device*, but a traditional non-electronic shisha device will not be a *vaping device* because it does not use electronic means.

A *vaping device* includes both a finished a device (such as a fully assembled device that is either pre-filled with a vaping substance or simply requires the addition of a vaping substance or vaping accessory in order to be operable) and a device that is incomplete, damaged, temporarily or permanently inoperable or unfinished. It should be noted that the words ‘incomplete, damaged, temporarily or permanently inoperable, or unfinished’ refer to goods that are not yet in full working order, but which could be converted to full working order with some additional parts or by assembly of the parts. This would include goods such as mouthpieces, coils and

casements that are intended to be attached to other parts, whether as part of further manufacture or for self-assembly by a consumer. It would also include parts that are intended to be attached to vape accessories, such as batteries intended for use with vape cartridges. Other than the CPI Regulations referring to a *vape*, rather than a *vaping device*, the definition of vaping device to be inserted in the TG Act is not materially different to that definition in the CPI Regulations.

The term *vaping accessory* is defined to mean a cartridge, capsule, pod or other vessel that is for use in, or with, a *vaping device*, and whether or not the cartridge, capsule, pod or other vessel contains a *vaping substance* or is designed or intended to be refilled. This definition would not include a good that would meet the definition of a *vaping device*. In practice this definition intends to capture goods that are vape cartridges, whether or not they are filled with a *vaping substance* or are refillable. A *vaping accessory* would also include a vape cartridge that is integrated with components that would otherwise be considered parts of a *vaping device*, such as a mouthpiece and heating coil. It is not uncommon that vape cartridges are supplied already integrated with both mouthpieces and coils. It is intended that these goods would be captured by the definition for a *vaping accessory*.

The primary difference between this definition of *vaping accessory* and the definition of vape accessory in the CPI Regulations is that this definition is limited in scope to vape cartridges and other vessels that are intended to be used with, or in, vaping devices. By contrast, the definition of vape accessory in the CPI Regulations is broader and is designed to capture any container of vaping substances, including dripper bottles of e-liquid. This proposed definitional difference is attributable to the differing purposes of the TG Act and the CPI Regulations. The CPI Regulations seek to provide definitions which are most readily identifiable and enforceable by border officials.

In the context of vaping goods, having a definition that captures any small or handheld containers of vaping substances (rather than large vats of liquid for further manufacture) enables border officials to readily identify a class of vaping goods. The definition of *vaping accessory*, as inserted by the new 41P definition into the TG Act, needs to be able to effectively interact with the therapeutic goods framework maintained under the TG Act. As such, the proposed definitions would need to account for the qualitative difference between a filled vape cartridge and filled dripper bottle despite being similar in size and containing vaping substances. Due to the potential inclusion of medical device-like elements, such as a heating coil, in a vape cartridge, it would be regulated differently to a therapeutic good that is (for example) a dripper bottle containing a vaping substance.

The term *vaping substance* is defined to mean nicotine in solution in any concentration (including in a salt or base form) or any liquid or other substance for use in, or with, a vaping device, and includes a container, or part of a container (other than a vaping accessory or vaping device), in which such a liquid or other substance is present.

Vaping substance means a liquid or other substance for use in, or with, a *vaping device* or nicotine in solution in any concentration, including in salt or base form. This definition would extend to the container holding the vaping substance unless the

container is a *vaping accessory* or *vaping device*. In practice this means a dripper bottle containing e-liquid would be considered a *vaping substance*. The substances referred to in this definition would include, but are not limited to, a liquid, gel, solid or salt that is intended for use in a *vaping device*. This also applies to bulk *vaping substances*, irrespective of the quantity.

It should be noted that there is no unique chemical or substance that is used only in vaping liquids, gels, solids. Vaping substances can vary greatly in their component ingredients, and may include ingredients that are dangerous chemicals in their own right, as well as ingredients that have a significant range of ‘ordinary’ uses such as in the manufacture of cosmetics, pharmaceuticals, foods and industrial goods (for example, glycerine, propylene glycol, essential oils and vitamins). Where these ingredients that are in widespread use in the community for ordinary purposes are not intended or presented for use for vaping, they will not be affected by this definition.

Finished goods that contain nicotine as an ingredient, but are not nicotine in solution, and are not for use in or with a *vaping device*, such as nicotine patches and nicotine gum, do not meet the definition of a *vaping substance*. However, nicotine in solution, including as a raw material or finished good, will meet the definition of a *vaping substance* even if the solution is not for use with a *vaping device*. All substances for use with a *vaping device* that contain nicotine (as well as substances for use with a *vaping device* that do not contain nicotine in solution), will meet the definition of a *vaping substance*.

Substances made from dried plants, including but not limited to heat-sticks made of tobacco intended for use in a heat not burn *vaping device*, meet the definition of *vaping substance*. Substances for use with e-hookah devices will meet the definition of *vaping substance*, but shisha tobacco is not generally considered to be for use with an electronic shisha device and therefore will not ordinarily meet the definition of a *vaping substance*.

New subsection 41P(2) provides that for paragraph (d) of the definition of ‘vaping goods’ in subsection (1), the presentation of goods includes matters relating to the name of the goods, labelling and packaging of the goods, and any advertising or informational material associated with the use or supply of the goods. New subsection 41P(2) also provides that the goods are taken to be presented as being a particular kind of goods even if the presentation is capable of being misleading or confusing as to the content or proper use or identification of the goods, or suggests that the goods have ingredients, components or characteristics that they do not have.

In practice, subsection 41P(2) will enable the offences in the new Chapter 4A to operate even if goods have inaccurate claims or are the subject of misleading marketing. Subsection 41P(2) is intended to prevent persons from evading the regulatory controls in Chapter 4A by:

- modifying the components or ingredients of vaping goods; or
- designing the vaping goods to make them difficult to identify or detect; or

- describing the goods in a way that conceals their purpose to an uninformed observer but signals the intended use to the user.

Marketing can make individuals believe these goods are safe for human consumption when they are not. Vaping goods are frequently designed to look like other ubiquitous objects such as pens, USB devices, toys, lip glosses and sippy cups, reinforcing the idea that vaping goods are safe for children when this is not the case. For adults using vaping goods, the variability in concentration of the ingredients and potential toxicity of the goods, increases the risk of harm, particularly when the label is misleading.

The effect of subsection 41P(2) would be that there is no requirement for testing or identification by an expert to determine whether a good is a *vaping good*. Goods can be *vaping goods* solely on the basis of express or implied representations made through the presentation of the goods, including the name, labelling, packaging and any advertising or informational material associated with the goods.

Examples of terms that, when used in the presentation of goods, would ordinarily have the effect that those goods are taken to be *vaping goods* include: vapes, e-cigarettes, e-cigs, e-smoke, e-pens, e-sticks, vape pens, vape sticks, pv (personal vaporiser), ENDS (electronic nicotine delivery system), doubler, shortfills, e-liquid and e-juice.

Examples of terms that may, in particular contexts, imply that a good is for vaping include tanks, pods, capsules, cartridges, doubler, shortfills, flavour or cloud, as well as references to nicotine and derivatives of the word nicotine, such as nic, and reference to the type of nicotine such as salt or freebase.

Some vaping goods are designed with colours and cartoons to be attractive to children and their presentation does not include terms commonly associated with vaping. Similarly, vaping goods aimed at adults may have no terms on the label or packaging that explicitly relate to vaping and may have associated informational material and advertising that is explicitly designed to avoid references to vaping. These may nonetheless be *vaping goods* if they are designed or intended for vaping, or the overall presentation indicates that they are a *vaping substance*, a *vaping accessory*, a *vaping device*, or a good determined to be a vaping good under subsection 41P(3).

New subsection 41P(3) provides that the Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods or a specified class of goods are or are not vaping goods or, when used, advertised, or presented for use or supply in a particular way, are or are not vaping goods. This power will enable the Minister to respond to a rapidly evolving market that has repeatedly sought to evade regulation since the Commonwealth Government first regulated nicotine vaping products in 2021.

The ability to determine that things are not vaping goods is broadly analogous to section 7AA of the TG Act. Section 7AA enables the Minister to exclude goods that would otherwise be therapeutic goods from the therapeutic goods regulatory framework. This power also enables exclusion based on how goods are used, advertised or presented for supply. Determining that goods are not vaping goods would have a similar effect to section 7AA in that it would exclude those goods from

the regulatory framework for vaping in the new Chapter 4A. Goods excluded from the new Chapter 4A under subsection 41P(3), would, however, still be subject to the other Chapters of the TG Act (as applicable) if they are therapeutic goods.

The power to exclude vaping goods from the operation of the new Chapter 4A is also similar to the power found in subregulation 5A(5) of the CPI Regulations. This subregulation enables the Minister to approve, by legislative instrument, the importation of vaping goods without an import licence or permit. Like the 7AA power, this in effect excludes certain goods from the operation of regulation 5A of the CPI Regulations.

The subsection 41P(3) is intended to allow the Minister to determine that goods are vaping goods despite those goods not otherwise meeting the definition of vaping goods provided in 41P(1). Such a power is crucial if the Government is to maintain parity with an ever-evolving market.

A principal purpose of subsection 41P(3) will be to capture vape-like products. In 2021, when the Commonwealth Government first addressed the growing vaping problem by changing the scheduling status of nicotine found in vapes in the *Poisons Standard*, the market immediately pivoted to supplying vaping goods that were silent on their nicotine content. This hampered enforcement efforts domestically, as well as at the border, as officers were unable to ascertain the lawfulness of goods in the absence of lab testing for nicotine content.

-With respect to the present reforms, a sufficiently precise definition for vaping goods is needed so as to avoid inadvertent capture of unrelated goods such as nebulisers or humidifiers. The Government is already aware of products that are being branded as non-vape, but vape-like, alternatives to vaping. These goods may have systems of direct inhalation but do not heat substances by electronic means and may technically evade the definition of vaping goods. Subsection 41P(3) will enable the Minister to determine such goods to be vaping goods. However, the power is not limited to including vape-like goods. It is a broad power to include or exclude any goods from the definition of a vaping good.

Part 4A-2—Offences and civil penalty provisions relating to vaping goods

Division 1 – General

Division 1 in Part 4A-2 creates a number of offences and civil penalties for importing, manufacturing, supplying and commercially possessing vaping goods. Division 1 contains new sections 41Q to 41QD.

These provisions ban certain activities unless permitted by the TG Act, the Customs Act and by state and territory medicine and poisons laws, as the case may be.

In relation to possession, the intent is not to criminalise or otherwise prohibit the personal possession of vaping goods. It is only commercial possession that is intended to be prohibited or possession other than for personal use.

The sponsor defence will not be available for these offences and civil penalty provisions. This is because the bans are intended to apply to all persons in the supply chain and ensure that supply is through the legitimate pathways.

The intent of the bans is to ensure that vaping goods are only supplied through the same supply chains that apply to goods containing substances included in Schedule 4 to the Poisons Standard (prescription medicines). This will give effect to the policy intention of ensuring that nicotine vapes are only supplied to consumers under medical supervision with a prescription at a pharmacy, subject to very limited exceptions.

Overview of penalties for the prohibitions

The TG Act includes a tiered penalty regime for most offences, with two fault-based offences (one with an aggravated factor) and a strict liability offence. There is also usually a corresponding section which makes the relevant physical conduct a contravention of a civil penalty provision.

This is an example of dual track regulation where the legislation gives regulators a choice of responses in respect of the same physical conduct and a range of enforcement options. Examples include sections 19B and 19D of the TG Act. Providing these options will enable the utilisation of a range of regulatory tools, including the issuing of an infringement notice, commencing civil penalty proceedings or criminal prosecution with a view to specifically and generally deterring the proscribed conduct.

Criminal offences

A criminal offence conviction is considered to be the ultimate sanction for breaching the law. According to the Australian Law Reform Committee Report No 95 – *Principled Regulation* at paragraph 2.9:

The main purpose of criminal law is traditionally considered to be **deterrence and punishment**. Central to the concept of criminality is the notation of individual culpability and the criminal intention for one's actions.

Where the proscribed conduct involves considerable harm to the public health of Australians and requisite mental elements relating to the conduct can be established, the TGA will generally pursue criminal prosecutions through the Director of Public Prosecutions. This is particular the case where the level of culpability of the person warrants criminal sanction.

Conviction of a crime however carries with it a range of serious consequences beyond the immediate penalty, whether the conviction results in imprisonment or a pecuniary penalty, including ineligibility to hold public office or be a director, principal officer or auditor of a company, or to travel to certain countries, and disqualification from being accredited under various legislation. Therefore, the TGA would generally elect to deal with breaches by way of a criminal prosecution where there is an element of culpability. This is particularly so where there is an organised crime element to the offending. Where culpability and criminality of the conduct are not apparent but there

is a need to address breaches of the Act and deter future non-compliance, it would be appropriate for the TGA to opt for a civil penalty fine, or other enforcement mechanism such as the giving of an infringement notice, accepting an enforceable undertaking or issuing a forfeiture direction.

A criminal prosecution is considered to be a more appropriate sanction where a contravention is deliberate, where fraud may be involved, where the conduct demonstrates recklessness, where there is a serious pattern of continuous intentional contraventions, or where conduct has endangered lives or has caused death or serious injury.

For the vaping offences, it is proposed that there would be a single fault and strict liability offences, with the fault-based offence considered similar to the existing counterfeit provisions in s 42E of the TG Act. This is because:

- the health risks of vaping are substantial. The widespread supply of vaping goods in the community represents a serious risk of harm to the health of the population, especially among youth and young adults; and
- vape use is increasing, with research undertaken by Cancer Council Victoria showing that 77,200 Victorians who had previously never smoked had used e-cigarettes in the past year.¹⁴

The Guide to Framing Commonwealth Offences at page 39 provides that '[a] penalty should be consistent with penalties for existing offences of a similar kind or of a similar seriousness. This should include a consideration of existing offences within the legislative scheme and other comparable offences in Commonwealth legislation such as the *Criminal Code*'.

Set out below is a table of maximum penalties for comparable offences relating to therapeutic goods and illicit tobacco which serve as a helpful comparator which determined the appropriate maximum penalties for vaping goods.

Offence	Description	Maximum penalty – imprisonment	Maximum penalty – financial
s 19B(1) of the TG Act (aggravated offence)	unlawful importation, exportation, manufacture, supply of therapeutic goods by the sponsor of the goods	5 years	4,000 penalty units (or both)
s 19B(2) of the TG Act (fault-based offence)	unlawful importation, exportation, manufacture, supply of therapeutic goods by the sponsor of the goods	12 months	1,000 penalty units (or both)
s 19B(3) of the TG Act (strict liability)	unlawful importation, exportation, manufacture	Nil	100 penalty units

¹⁴ [Alarming rise in e-cigarette usage and purchasing ... | Quit Victoria](#)

Offence	Description	Maximum penalty – imprisonment	Maximum penalty – financial
	or supply of therapeutic goods by the sponsor of the goods		
s 42DL(1) of the TG Act (aggravated offence)	unlawful advertisement of therapeutic goods	5 years	4,000 penalty units (or both)
s 42DL(1) of the TG Act (fault-based offence)	unlawful advertisement of therapeutic goods	12 months	1,000 penalty units (or both)
s 42DL(1) of the TG Act (strict liability)	unlawful advertisement of therapeutic goods	Nil	100 penalty units
s 42E of the TG Act (fault-based offence)	importation, exportation, manufacture or supply of counterfeit therapeutic goods	7 years	2,000 penalty units (or both)
s 308-10 of Schedule 1 to the <i>Taxation Administration Act 1953</i>	possession of tobacco (500 kilograms or above)—reasonable suspicion offence	5 years	1,000 penalty units or both 5 years and the greater of 1,000 penalty units or 5 times the excised duty
s 308-15 of Schedule 1 to the <i>Taxation Administration Act 1953</i>	possession of tobacco (100 kilograms or above)—reasonable suspicion offence	2 years	500 penalty units or both 2 years and the greater of 5 times the excise duty
s 308-20 of Schedule 1 to the <i>Taxation Administration Act 1953</i>	possession of tobacco (5 kg or above)—reasonable suspicion offence	Nil	200 penalty units or the greater of 5 times the excise duty
s 320.2 of the <i>Criminal Code</i>	importation of psychoactive substances	5 years	300 penalty units (or both)

In this context, the maximum penalties for offences relating to the importation, manufacture and supply of vaping goods are considered appropriate, being 7 years imprisonment for fault-based offences and 200 penalty units for strict liability offences. Equally, the sliding scale maximum penalties for offences relating to the possession of vaping goods are also appropriate. Depending on the quantity of vaping

goods possessed, a maximum penalty of 7 years, 5 years, 2 years or 12 months will apply for fault-based offences and 420 penalty units, 240 penalty units, 120 penalty units or 60 penalty units will apply for strict liability offences.

Civil penalty provisions

A civil penalty is a punitive sanction of a financial nature, with no aggravating element and no-fault element, imposed through civil court proceedings rather than through the criminal prosecution process. It takes the form of a monetary penalty only and does not result in any criminal conviction.

The focus of a civil penalty is generally the regulation of commercial activity and is directed against corporate or white collar wrongdoing. Therefore, civil penalties are appropriate in regulating commercial activities involving the importation, manufacture, supply and possession of a commercial quantity of vaping goods. This is particularly so where the relevant activities are undertaken by incorporated bodies, including subsidiaries of multinational companies engaged in commercial operations in Australia. The financial disincentive that a civil penalty regime provides to address and deter breaches of the TG Act is likely to be more effect than criminal sanctions in appropriate circumstances.

A civil penalty regime is intended to strengthen the TGA's enforcement options to deter non-compliance with the bans with respect to vaping goods designed to protect public health and safety. A civil penalty is an appropriate measure where other sanctions may not be as effective or appropriate in the circumstances.

For the civil penalty provisions relating to the import, manufacture, supply and possession of vaping goods, consistent with existing approaches to framing commonwealth civil penalty provisions, each unit of vaping good will constitute a separate contravention. A unit of vaping goods will be prescribed in the regulations. This will ensure that there is clarity in the proscribed conduct in these provisions and avoid ambiguity and unintended consequences such as the treating of a 500000ML gallon of vaping liquid as a single contravention in the same way as 100ML would be. The conduct in each case is not equal and the penalty that is warranted to deter such conduct differs significantly.

As an example, the importation of 1000 unlawful vaping goods may attract a theoretical maximum penalty in the hundreds of millions, or even over a billion dollars. However, the penalty imposed by the court will very likely be much lower than this amount. There are well established principles applied by the courts to ensure that penalties imposed are proportionate to the conduct in such circumstances, without being overly oppressive. While the per unit approach could result in significant theoretical penalty maximum amounts, on a mathematical basis, it is important to note that the court takes several factors into account to ensure that the total penalty does not exceed what is proper for deterrence for the entire contravening conduct.

It is not unusual for civil penalty provisions to attract very significant numbers of contraventions. For example, section 81 of the *Anti-Money Laundering and Counter-Terrorism Financing Act 2006* attracts contraventions for each designated service provided by a reporting entity during the period a risk management program is not

compliant. The number of contraventions is often unquantifiable. Similarly, civil penalty provisions involving false or misleading conduct under the Australian Consumer Law can also attract large or unquantifiable contraventions. In the Act itself, the advertising prohibitions, such as section 42DLB can attract thousands of contraventions as can the prohibitions relating to supply of therapeutic goods in section 19D.

Framing the civil penalty contraventions in this way, on a per unit approach will also allow the Secretary to give a person an infringement notice(s) as an alternative to having the penalty determined by the court and provides greater flexibility for the Secretary to decide an appropriate penalty amount.

Higher civil penalties than the existing penalties in the TG Act are also warranted for the same reasons as provided for above in relation to criminal penalties. It is anticipated that the level of civil penalties will act as an effective financial disincentive against non-compliance with regulatory requirements, especially for corporations for whom imprisonment is not available.

The current civil penalty provisions in the TG Act for importation, manufacture and supply of unlawful therapeutic goods provide for a corporate multiplier of 10 times the penalty for the individual. That is the 5,000 penalty units for an individual and 50,000 for a body corporate. The new civil penalty provisions relating to vaping goods adopt the same approach due to the seriousness of the conduct and the public health harms associated with vaping goods. However, given the need to curb a large black-market in vapes and to effectively deter non-compliance given high profit margins associated with illicit vape supply, a higher maximum penalty of 7,000 penalty units for an individual and 70,000 for a body corporate is considered appropriate and proportionate to the proscribed conduct.

A summary table of the new offences and civil penalty provisions is provided below with the relevant maximum penalties.

Provision	Offence	Maximum penalty (fault-based offence)	Maximum penalty (strict liability offence)	Maximum penalty (civil penalty)
41Q	Importation of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QA	Manufacture of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QB	Supply of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QC	Possession of commercial quantity of vaping goods	For an individual— At least the commercial quantity – 2 years imprisonment/1,000 penalty units. At least 100 times the commercial quantity – 4 years imprisonment/3,000 penalty units. At least 1000 times the commercial quantity – 7 years imprisonment/5,000 penalty units. For a body corporate—	For an individual— At least the commercial quantity – 120 penalty units. At least 100 times the commercial quantity – 240 penalty units. At least 1000 times the commercial quantity – 420 penalty units. For a body corporate —	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.

Provision	Offence	Maximum penalty (fault-based offence)	Maximum penalty (strict liability offence)	Maximum penalty (civil penalty)
		At least the commercial quantity – 5,000 penalty units. At least 100 times the commercial quantity – 15,000 penalty units. At least 1000 times the commercial quantity – 25,000 penalty units.	At least the commercial quantity – 600 penalty units. At least 100 times the commercial quantity – 1,200 penalty units. At least 1000 times the commercial quantity – 2,100 penalty units.	
41QD	Possession of less than commercial quantity of vaping goods	For an individual—Imprisonment for 12 months and/or 500 penalty units. For a body corporate—2,500 penalty units.	For an individual—60 penalty units. For a body corporate—300 penalty units.	For an individual—1,000 penalty units. For a body corporate—10,000 penalty units.

Banning the importation of unlawful vaping goods

Section 41Q establishes offences and a civil penalty provision for importing vaping goods into Australia, with exceptions in certain circumstances. Importation is not defined and will be given its ordinary meaning.

Subsection 41Q(1) provides that a person commits an offence if the person imports vaping goods into Australia, with an associated maximum penalty of imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the importation of vaping goods into Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41Q(2) provides an offence of strict liability for importing vaping goods into Australia, with an associated maximum penalty of 200 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

A strict liability offence has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41Q(3) provides a civil penalty for importing vaping goods into Australia, with a maximum civil penalty of 7,000 penalty units for an individual and 70,000 penalty units for a body corporate.

Subsection 41Q(4) provides that a person who contravenes the civil penalty provision in subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods imported by the person into Australia. The note to this subsection references subsection 3(1) for the definition of unit of vaping goods.

Subsection 41Q(5) provides an exception to the application of these offence and civil penalty provisions if the importation would not be prohibited under the Customs Act. The note to subsection 41Q(54) provides that the person bears an evidential burden in relation to the matter in subsection (54), in accordance with section 13.3(3) of the *Criminal Code* and section 41QE# of the TG Act. Section 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

The import offences and civil penalty provisions in this part are intended to complement the Customs Act.

Explanation of exception

A licence and permit would likely be the evidence a person would need to produce to avail themselves of the exception. Whether a person has an import licence and permit is a matter peculiarly within their knowledge.

There is also a traveller's exemption for persons bringing vaping goods into country in connection with their visit to Australia. Whether the person has in their possession vaping goods under the maximum allowable traveller's limit is a matter peculiarly within their knowledge and control and would be easily produced.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this element than for the defendant to establish the matter. Whether a person is relying on a traveller's exemption will be a matter peculiarly within their knowledge.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the effective regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Licence and permit

The importation of vaping goods is subject to regulation 5A of the CPI Regulations which requires the importer to hold a licence and permit. The importer will need to meet certain criteria to be granted a licence or a permit to import vaping goods into Australia. A permit to import each specific type of vaping good is required.

Before an import permit can be granted under a vaping good import licence, the vaping good must either be entered on the Register, or a notice must be given to the Secretary which complies with applicable requirements under the TG Act (sponsor notice). Exceptions to this requirement apply to vaping goods imported for medical or scientific research, and vaping goods of a kind or for a purpose specified in a legislative instrument made by the Secretary. No such legislative instrument has been made at this time.

A sponsor notice (other than a sponsor notice for a vaping device used to administer medicinal cannabis) requires a sponsor to state that a vaping good complies with applicable standards and that the only indications of the vaping good are for smoking cessation or the management of nicotine dependence. If a sponsor notice is required but cannot be given because the goods do not comply with applicable standards or the indications are broader than smoking cessation or the management of nicotine dependence, importation and supply of the goods will be unlawful.

A sponsor notice for a vaping device used to administer medicinal cannabis requires a sponsor to state that the vaping device complies with the essential principles or is imported with the consent of the Secretary under section 41MA or 41MAA of the Act. This notice is required for a vaping device or vaping device accessory that is intended to be used *only* to contain or administer medicinal cannabis. If a sponsor notice is required but cannot be given because the goods do not comply with the essential principles and consent has not been granted, or the goods are not intended to be used *only* to contain or administer medicinal cannabis, importation and supply of the goods will be unlawful.

A sponsor notice is not required for a vaping good in relation to which a licence and permit under regulation 5 of the CPI Regulations has been granted, for example, a disposable single use vape or a pod or cartridge containing medicinal cannabis that has been imported in accordance with a permit given under regulation 5 of those regulations.

The TGA will publish a list of vaping goods in relation to which sponsor notices have been given (other than sponsor notices for cannabis vaping devices) and that can be made available for lawful supply.

Traveller's exemption

Under regulation 5A of the CPI Regulations, there is also traveller's exemption which allows persons entering Australia to carry no more than 2 vapes, 20 vape accessories and 200mL of vaping substance in liquid form. This exemption gives effect to the intention not to criminalise possession of vaping goods for personal use.

Banning the manufacture of unlawful vaping goods

Section 41QA establishes offences and a civil penalty provision for manufacturing vaping goods in Australia, where the manufacturer does not have a relevant licence, certificate, exemption or consent in certain circumstances.

Subsection 41QA(1) provides that a person commits an offence if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia, with an associated maximum penalty of imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of

their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the manufacture of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Manufacture, in relation to vaping goods, will have the same meaning as subsection 3(1) or section 41BG depending on the nature of the vaping goods.

Subsection 41QA(2) provides an offence of strict liability for manufacturing, or carrying out a step in the manufacture of, vaping goods in Australia, with an associated maximum penalty of 200 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice(s) as an alternative to criminal prosecution.

Subsection 41QA(3) provides a civil penalty for manufacturing vaping goods in Australia with a maximum civil penalty of 7,000 penalty units for an individual and 70,000 penalty units for a body corporate.

Subsection 41QA(4) provides that a person who contravenes the civil penalty provision in subsection (3) commits a separate contravention of that subsection in respect of the manufacture, or the carrying out of the step in the manufacture, by the person of each unit of vaping goods manufactured in Australia. The note to this subsection references subsection 3(1) for the definition of unit of vaping goods.

Subsection 41QA(5) provides an exception to the application of these offence and civil penalty provisions if the vaping goods are therapeutic goods and one of the following applies:

- (i) the person is the holder of a licence in force under Part 3-3 that authorises the manufacture of the vaping goods, or the carrying out of the step in the manufacture of the vaping goods, at the manufacturing site where the manufacture, or the step, was carried out;
- (ii) the person is the holder of a conformity assessment document that applies to the vaping goods;
- (iii) the Secretary has given the person a consent under subsection 41RC(1) to manufacture the vaping goods, or carry out a step in the manufacture of the vaping goods and the manufacture, or the step, is carried out in accordance with the consent.

The note to subsection 41QA(5) provides that the person bears an evidential burden in relation to the matter in subsection (54), in accordance with subsection 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Subsection 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Formatted: Highlight

Explanation of exception

Australian manufacturers of vaping goods must obtain a Part 3-3 licence from the TGA, unless a relevant exemption applies. In relation to vaping devices they may also hold a conformity assessment document under Chapter 4 of the TG Act, that relates to the manufacture of vaping goods.

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

Whether a manufacturer has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the efficient regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia.

Banning the supply of unlawful vaping goods

Section 41QB establishes offences and a civil penalty provision for supplying vaping goods in Australia, with exceptions in certain circumstances.

Subsection 41QB(1) provides that a person commits an offence if the person supplies vaping goods in Australia, with an associated maximum penalty of imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to

prevent the breaches. There is significant public harm from the supply of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QB(2) provides an offence of strict liability for supplying vaping goods in Australia, with an associated maximum penalty of 200 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QB(3) provides a civil penalty for supplying vaping goods, with a maximum civil penalty of 7,000 penalty units for an individual and 70,000 penalty units for a body corporate.

Subsection 41QB(4) provides that a person who contravenes the civil penalty provision in subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods supplied by the person in Australia. The note to this subsection references subsection 3(1) for the definition of unit of vaping goods.

Subsection 41QB(5) provides exceptions to the application of these offence and civil penalty provisions if subsections (6) to (8) or subsections (9) to (11) apply to the supply of the vaping goods by the person. The note to subsection 41QB(5) provides that the person bears an evidential burden in relation to the matters in subsections (6) to (8) or (9) to (11), in accordance with section 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Section 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Wholesale supply exception

Subsections (6), (7) and (8) have the effect of providing an exception to these offences and civil penalty provisions for supply if the supply was part of the wholesale supply chain for prescription medicines. The wholesale supply chain for prescription medicines is intended to be the primary lawful pathway for the supply of vaping goods in Australia. This supply chain is made up of controls at both the Commonwealth and state and territory levels.

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

The exception in subsections (6), (7) and (8) is directed to persons who are supplying vaping goods to persons who are not the ultimate consumer of the goods. For a person to avail themselves of the exception they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the effective regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Subsection (6) is directed to the status of the vaping goods. Subsection (7) is directed to the identity of the person supplying the vaping goods. Subsection (8) is directed to the identity of the person receiving the vaping goods.

Subsection 41QB(6) provides that this subsection applies in relation to the supply of the vaping goods by the person if the vaping goods are:

- (a) therapeutic goods that are entered on the Register; or
- (b) both:
 - (i) exempt under subsection 18(1) or 41HA(1) of the TG Act and the sponsor has given a notice in compliance with the exemption; and
 - (ii) the vaping goods are not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or
- (c) covered by a determination made by the Minister under section 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QB(6)(b). It

is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

The type of evidence that a person is likely to produce to make out this subsection includes a current certificate of registration of the vaping goods on the Register, a sponsor notification provided to the Secretary, evidence from the Department's website that the vaping good is not the subject of a determination or a current determination applicable to the vaping goods made by the Minister.

These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(7) provides that this subsection applies in relation to the supply of vaping goods by the person if:

- (a) the person holds a licence or a permission granted under regulations made for the purpose of section 50 of the Customs Act, to import the vaping goods, or is otherwise approved to import the vaping goods under those regulations; or
- (b) the person is the holder of a licence in force under Part 3-3 of the TG Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is a holder of a conformity assessment document that applies to the vaping goods; or
- (d) the person is a wholesaler who is the holder of a licence or is otherwise authorised to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occurs, and the supply occurs in accordance with the licence or authority;
- (e) the Secretary has given the person a consent under subsection 41RC(1) to supply the vaping goods, and the supply is in accordance with the consent; or
- (f) where the goods are covered by a determination made under section 41R—the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods, and the supply occurs in accordance with the determination.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters within the persons' knowledge.

Subsection 41QB(8) provides that this subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the person to whom the vaping goods are supplied, i.e. the recipient, is the holder of a Part 3-3 licence in force under the TG Act that authorises a step in the manufacture of the vaping goods; or
- (b) the recipient is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence or is otherwise authorised to supply one or more substances in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the recipient carries on a business, practises or is employed; or
- (c) the Secretary has given the recipient a consent under subsection 41RC(1) to supply the vaping goods; or
- (d) in the case of vaping goods covered by a determination made under section 41R—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters within the persons' knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Retail supply exception

Subsections (9), (10) and (11) have the effect of providing an exception to these offences and civil penalty provisions for supply as part of a retail supply chain.

The exception in subsections (9), (10) and (11) is directed to persons who are supplying vaping goods to persons who are the ultimate consumer of the goods. For a person to avail themselves of the exception, they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Subsection (9) is directed to the status of the vaping goods. Subsection (10) is directed to the identity of the person supplying the vaping goods. Subsection (11) is directed to the identity of the person receiving the vaping goods.

Subsection 41QB(9) provides that this subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered on the Register; or
- (b) both the following apply:

- (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption; and
 - (ii) the vaping goods are not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or
- (c) the vaping goods are covered by a determination under section 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QB(9)(b). It is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

The type of evidence that a person is likely to produce to make out this subsection includes a current certificate of registration of the vaping goods on the Register, a sponsor notification provided to the Secretary, evidence from the Department's website that the vaping good is not the subject of a determination or a current determination applicable to the vaping goods made by the Minister.

These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(10) provides that this subsection applies in relation to the supply of the vaping goods by the person if the person is a:

- (a) pharmacist; or
- (b) medical practitioner or nurse practitioner who is the holder of a licence or is otherwise authorised to supply one or more substances in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occurs.

The type of evidence that a person is likely to produce to make out this subsection includes evidence of current registration as a pharmacist, medical practitioner or nurse practitioner and, if applicable, their authorisation or licence. These are all matters that can be easily produced by a person if required and are matters within the persons' knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(11) provides that this subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the supply is:
 - (i) to another person for use by that person for smoking cessation or management of nicotine dependence, or for another indication determined by the Minister under section 41RA; or
 - (ii) to another person, who is the carer of a third person, for use by the third person for smoking cessation or management of nicotine dependence, or for another indication determined by the Minister under section 41RA; and
- (b) if the vaping goods are, or contain, a vaping substance—the vaping substance is in final dosage form; and
- (c) the supply is:
 - (i) in accordance with this Act (apart from this section); and
 - (ii) consistent with the person’s authority to supply the vaping goods under a law of the state or territory in which the supply occurs.

It is anticipated that a determination would be made by the Minister under section 41RA that would determine indications appropriate for medicinal cannabis vapes.

The type of evidence that a person is likely to produce to make out this subsection includes a prescription for the supplied vaping good, a tax invoice and product specification or some other material which indicates that the good is in final dosage form. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters peculiarly within the persons’ knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(12) provides that for the purposes of paragraph (11)(b), a vaping substance is in final dosage form if the vaping substance is in a form that can be administered to a person without any change or modification (other than vaporisation).

Banning the possession of at least a commercial quantity of unlawful vaping goods

Section 41QC establishes offences and civil penalties for possessing commercial quantities of a kind of vaping goods, with exceptions in certain circumstances.

Subsection 3(1) provides that ‘commercial quantity’ of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

Subsections (1), (2) and (3) relate to commercial quantities that are less than 100 times the commercial quantity, subsections (4), (5) and (6) relate to quantities of 100 times the commercial quantity but less than 1,000 times the commercial quantity, and subsections (7), (8) and (9) relate to 1,000 times the commercial quantity or more.

Subsection 41QC(1) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods. The maximum penalty for this offence is imprisonment for 2 years or 1,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the possession of a commercial quantity of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QC(2) provides that absolute liability applies to paragraph (1)(b), that is that the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods. This applies to a physical element of the offence. Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person’s state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QC(3) provides an offence of strict liability for the same conduct, with an associated maximum penalty of 120 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not

established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QC(4) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least 100 times the commercial quantity, but less than 1000 times the commercial quantity, of that kind of vaping goods. The maximum penalty for this offence is imprisonment for 4 years or 3,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the possession of a commercial quantity of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QC(5) provides that absolute liability applies to paragraph (4)(b), that is that the quantity is at least 100 times the commercial quantity, but less than 1000 times the commercial quantity, of that kind of vaping goods. This applies to a physical element of the offence. Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person's state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QC(6) provides an offence of strict liability for the same conduct, with an associated penalty of 240 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QC(7) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least 1,000 times the commercial quantity or more of that kind of vaping goods. The maximum penalty for this offence is imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the possession of a commercial quantity of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QC(8) provides that absolute liability applies to paragraph (7)(b), that is that the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods, of that kind of vaping goods. This applies to a physical element of the offence. Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person's state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QBC(9) provides an offence of strict liability for the same conduct, with an associated penalty of 420 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

Formatted: Highlight

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QC(10) provides a civil penalty where a person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least the commercial quantity of that kind of vaping goods. The maximum civil penalty is 7,000 for an individual and 70,000 for a body corporate.

A person is only liable for a civil penalty contravention of subsection (10) if they are in possession of a kind of vaping goods of at least a commercial quantity and the exceptions do not apply to them. Each contravention also takes into consideration each kind of vaping good in the possession of a person which is at least of a commercial quantity.

Subsection 41QC(11) provides that a person who contravenes subsection (10) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia.

It is intended that the per unit is to apply to each individual unit of vaping goods in the person's possession. For example, each vaping device, accessory or substance or

combination thereof, would comprise of one unit for the purposes of calculating the number of contraventions.

By way of example, if commercial quantity is 10 vaping devices, and a person is in possession of 11 vaping devices then this will be 11 contraventions of the civil penalty provision in subsection (10). If the person is in possession of 9 vaping devices, they will not contravene the civil penalty provision in subsection (10). These are only examples and for illustrative purposes. Commercial quantity for each **kind** of vaping goods will be prescribed in the regulations.

Formatted: Highlight

Another example is if a person is found in possession of a large shipment of vaping goods and the shipment contains 5,000 vaping devices, 5,000 vaping substances and 5,000 vaping accessories (each of which exceed the prescribed commercial quantity), there will be 15,000 contraventions of subsection (10) in relation to the shipment; 5,000 contraventions in respect of each kind of vaping good.

This approach to the civil penalty provision is justified to achieve consistency across the other civil penalty prohibitions for import, manufacture and supply of vaping goods.

Tiered maximum penalties for criminal offences

Tiered penalties depending on the quantity of the vaping goods involved is appropriate in circumstances where there will be a wide spectrum of conduct captured under these offences. Tiered penalty structures also appear in other legislation such as Schedule 1 to the *Taxation Administration Act 1953* for possession of illicit tobacco and various offences under the *Criminal Code*.

Exception

Subsection 41QC(12) provides an exception to the application of the offence and civil penalty provisions in subsections (1) to (10) if subsections (13) and (14) apply to the possession of the vaping goods by the person. The note to subsection 41QC(12) provides that the person bears an evidential burden in relation to the matters in subsections (13) and (14), in accordance with subsection 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Section 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Subsections (13) and (14) have the effect of providing an exception to these offences and civil penalty provision for the possession of vaping goods if the possession occurs as part of the wholesale supply chain or retail supply chain for prescription medicines. These supply chains are made up of controls at both the Commonwealth and state and territory levels. The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

For a person to avail themselves of the exception they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Subsection (13) is directed to the status of the vaping goods. Subsection (14) is directed to the identity of the person in possession of the vaping goods.

Subsection 41QC(13) provides that this subsection applies in relation to the possession of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered on the Register; or
- (b) the vaping goods are:
 - (i) therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption; and
 - (ii) not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or
- (c) the vaping goods are covered by a determination under section 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QB(9)(b). It

is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

The type of evidence that a person is likely to produce to make out this subsection includes a current certificate of registration of the vaping goods on the Register, a sponsor notification provided to the Secretary, evidence from the Department's website that the vaping good is not the subject of a determination or a current determination applicable to the vaping goods made by the Minister.

These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods. The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

For a person to avail themselves of the exception they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying. The Bill provides a list of the necessary evidence that a defendant needs to produce, such as an authority to prescribe a prescription only medicine in a state or territory or otherwise deal with vaping goods.

Subsection 41QC(14) provides that this subsection applies in relation to the possession of the vaping goods by the person if:

- (a) the person is the holder of a licence and a permission granted under regulations made for the purposes of section 50 of the Customs Act to import the vaping goods or is otherwise approved under those regulations to import the vaping goods;

- (b) the person is the holder of a licence in force under Part 3-3 of this Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
- (d) both of the following apply:
 - (i) the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the person possesses the goods; and
 - (ii) the possession of the goods is in accordance with the licence or authority; or
- (e) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods and the possession is in accordance with the consent; or
- (f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R—the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods, the possession is in accordance with the determination.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination, or a prescription for the supplied vaping good. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters peculiarly within the persons' knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying. Given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Banning the possession of less than a commercial quantity of unlawful vaping goods

Section 41QD establishes offences and civil penalties for possessing a quantity of vaping goods less than the commercial quantity of that kind of vaping goods, with exceptions in certain circumstances including when the vaping goods are for personal use. The intention of these provisions is to deter persons possessing vaping goods less than a commercial quantity other than for personal use, including retailers or vendors who may be in possession of less than a commercial quantity of vaping goods in a retail setting not for personal use.

Subsection 3(1) provides that 'commercial quantity' of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

Subsection 41QD(1) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is less than the commercial quantity of that kind of vaping goods.

The penalty for this offence is imprisonment for 12 months or 500 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Subsection 41QD(2) provides that absolute liability applies to paragraph (1)(b), that is that the quantity is less than the commercial quantity of that kind of vaping goods of that kind of vaping goods. This applies to a physical element of the offence.

Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person's state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QD(3) provides an offence of strict liability for possessing a quantity of vaping goods less than the commercial quantity of that kind of vaping goods, with an associated penalty of 60 penalty units.

Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QD(4) provides a civil penalty where a person possesses a quantity of a kind of vaping goods in Australia and the quantity is less than the commercial quantity of that kind of vaping goods. The maximum civil penalty is 1,000 for an individual and 10,000 for a body corporate.

A person is only liable for a civil penalty contravention of subsection (4) if they are in possession of a kind of vaping goods of less than a commercial quantity and the exceptions do not apply to them. The commercial quantity for each kind of vaping goods will be different depending on the kind of vaping goods in question, for example whether it is a device, accessory or substance, or combination.

Exceptions apply in relation to vaping goods possessed for personal use for smoking cessation or management of nicotine dependence, or another indication determined by the Minister under section 41RA. It is anticipated that a determination would be made by the Minister under section 41RA that would determine indications appropriate for medicinal cannabis vapes.

Subsection 41QD(5) provides that a person who contravenes subsection (4) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia. The note to this subsection references section 3(1) for the definition of unit of vaping goods.

It is intended that the per unit is to apply to each individual unit of vaping goods in the person's possession. For example, each vaping device, accessory or substance or combination thereof, would comprise of one unit for the purposes of calculating the number of contraventions.

By way of example, if commercial quantity is 10 vaping devices, and a person is in possession of 9 vaping devices then this will be 9 contraventions of the civil penalty provision in subsection (4). This is only an example and for illustrative purposes. Commercial quantity for each kind of vaping goods will be prescribed in the regulations.

Formatted: Highlight

This approach to the civil penalty provision is justified to achieve consistency across the other civil penalty provisions relating to the importation, manufacture and supply of vaping goods.

Exception – authorised persons

Subsection 41QD(6) provides an exception to the application of the offence and civil penalty provisions in section 41QD for authorised persons, if subsections (7) and (8) or (9) apply to the possession of the vaping goods by the person. The note to subsection 41QD(6) provides that the person bears an evidential burden in relation to the matters in subsections (7) and (8), or subsection (9), in accordance with subsection 13.3(3) of the *Criminal Code* and section 41QE of the TG Act.

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Subsection (7) is directed to the status of the vaping goods. Subsection (8) is directed to the identity of the person in possession of the vaping goods.

Subsection 41QD(7) provides that this subsection applies in relation to the possession, or custody, of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered in the Register; or
- (b) the vaping goods are:
 - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption; and
 - (ii) the vaping goods are not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply

of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or

- (c) the vaping goods are covered by a determination under subsection 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QB(9)(b). It is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

Subsection 41QD(8) provides that this subsection applies in relation to the possession, or custody, of the vaping goods by the person if:

- (a) the person is the holder of a licence or a permission granted under regulations made for the purpose of section 50 of the Customs Act, or is otherwise approved to import the vaping goods under those regulations; or
- (b) the person is the holder of a licence in force under Part 3-3 of the TG Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
- (d) the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the person possesses the goods, and the possession of the goods is in accordance with the licence or authority; or
- (e) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods, and the possession is in accordance with the consent; or
- (f) where the goods are covered by a determination made under subsection 41R—the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods, the possession is in accordance with the determination.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination, or a prescription for the supplied vaping good. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters peculiarly within the persons' knowledge.

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

For a person to avail themselves of the exception, they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Exception—personal use or possession on behalf of another person

Subsection 41QD(9) provides that this subsection applies in relation to the possession, or custody, of the vaping goods by the person if:

- (a) the vaping goods are for use by the person personally; or
- (b) the person possesses the vaping goods on behalf of another person for whom the vaping goods have been lawfully supplied.

This exemption gives effect to the intention not to criminalise possession of vaping goods less than a commercial quantity for personal use. The context and surrounding circumstances in which the vaping goods are possessed will likely be the primary factor which will determine whether this exception is available, such as whether the possession is in a retail setting. The type of evidence that a person is likely to produce to make out this subsection includes, but is not limited to, a prescription or written authority to possess the vaping goods. However, such evidence is not necessary.

Subparagraph (b) has been included to protect persons who may be possessing vaping goods on behalf of someone who requires the vaping goods in connection with treatment for smoking cessation or the management of nicotine dependence, including carers and nurses in a hospital or nursing home setting.

Exception to civil penalty provisions – burden of proof

Formatted: Right: -0.04 cm, Keep with next

Division 2 in Part 4A-2 contains section 41QE which provides that if, in proceedings for a pecuniary penalty order against a person for contravention of a civil penalty provision in this Chapter, the person wishes to rely on any exception, exemption, excuse, qualification or justification that applies in relation to the civil penalty provision, then the person bears an evidential burden in relation to that matter.

Part 4A3—Other provisions

Division 1—Determinations by Minister

Section 41R provides that the Minister may, by legislative instrument determine that specified goods, or a specified class of vaping goods can be supplied or possessed in Australia by a specified person, or a specified class of persons, and in certain circumstances and subject to any conditions. The note to this section provides an example of the conditions that may be imposed, for example conditions relating to the value or amount of specified vaping devices, or the manner in which specified vaping goods may be supplied.

The purpose of this provision is to provide a mechanism by which the Minister can authorise the possession or supply of specified vaping goods by certain people in circumstances where they may not be authorised under other relevant statutory provisions. The Minister does not need to receive an application to decide whether to make a determination, however, there is nothing preventing a person from requesting that the Minister consider exercising the power in a particular circumstance.

A determination made under this section is not subject to merits review. This is because determinations are not intended to be directed towards the circumstances of particular persons. Rather they are proposed to apply generally.

Section 41RA provides that the Minister may, by legislative instrument, determine for the purposes of paragraph 41QB(1)(a) or subparagraph 41QD(1)(c)(i), (3)(c)(i) or (4)(c)(i), other indications for which vaping goods may be used. It is anticipated that a determination would be made by the Minister under section 41RA that would determine indications appropriate for medicinal cannabis vapes.

Division 2—Consent of Secretary

Section 41RB creates an application provision to allow the Secretary to provide consent to the manufacture, supply or possession of vaping goods.

Subsection 41RB(1) provides that a person may apply to the Secretary for consent to manufacture, supply or possess vaping goods.

Subsection 41RB(2) provides that an application under subsection (1) must be in accordance with a form approved by the Secretary.

Subsection 41RB(3) provides that the Secretary may, by notice in writing given to the applicant, require the applicant to give to the Secretary, within such reasonable time

as is specified in the notice, such further information concerning the application as is specified in the notice.

Subsection 41RB(4) provides that an approval of a form referred to in subsection (2), or a notice referred to in subsection (3), may require or permit an application or information to be given in accordance with specified software requirements including on a specified kind of data processing device or by way of a specified kind of electronic transmission.

Section 41RC provides that the Secretary may give consent in certain circumstances.

Subsection 41RC(1) provides that the Secretary must decide whether to give, or refuse to give the consent if the person has applied to the Secretary under section 41RB, and the applicant has complied with any requirements made by the Secretary under subsection 41RB(3) in relation to the application.

Subsection 41RC(2) provides that the Secretary may give consent under subsection (1) unconditionally or subject to conditions or in respect of particular vaping goods or classes of vaping goods. The note to this subsection provides that a person may commit an offence or be liable to a civil penalty if the person does an act or omits to do an act and the act or omission breaches a condition of consent given under subsection (1). The note further directs to section 41RD in this regard.

Subsection 41RC(3) requires the Secretary to cause particulars of the decision to be published on the Department's website as soon as practicable after making a decision to give consent under subsection (1).

Subsection 41RC(4) provides that if the Secretary decides to refuse to give consent under subsection (1), the Secretary must, within 28 days after making the decision, notify the applicant in writing of the decision and the reasons for the decision.

Section 41RD creates offences and civil penalty provisions for breaching a condition of a consent given under subsection 41RC(1).

Subsection 41RD(1) creates a fault-based offence with an aggravating element. The subsection provides that a person commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1) and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

The maximum penalty is 2,000 penalty units. Note 1 to this subsection provides that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead, with reference to section 53A.

The ~~n~~Note 2 to this subsection refers to section 54AB and 54BA with respect to the liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of

Formatted: Highlight

their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from breaching a condition of consent to undertake activity in relation to vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41RD(2) creates a fault based offence and provides that a person commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1). The maximum penalty is 500 penalty units.

Subsection 41RD(3) creates an offence of strict liability and provides that a person commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1). The maximum penalty is 100 penalty units.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41RD(4) creates a civil penalty provision and provides that a person contravenes this subsection if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1). The maximum penalty for an individual is 3,000 penalty units and 30,000 penalty units for a body corporate.

Division 2—Other amendments

Therapeutic Goods Act 1989

Item 12 – Paragraph 14B(a)

This item amends paragraph 14B(a) to add a reference to subsections 41Q(1) or (2).

Item 13 – Paragraph 14B(a)

This item amends paragraph 14B(a) to add a reference to subsection 41Q(3).

Item 14 – Subsection 19(9)

This item repeals subsection 19(9) of the TG Act.

Item 15 – Subsection 30EK(6)

This item repeals subsection 30EK(6) of the TG Act.

Item 16 – Subsection 30EL(1)

Formatted: Keep with next

This item omits the subsection number for subsection (1) in section 30EL(1).

Item 17 – Subsection 30EL(2)

This item repeals subsection 30EL(2) of the TG Act.

Item 18 – Subsection 32CM(8)

This item repeals subsection 32CM(8) of the TG Act.

Item 19 – At the end of section 41BG

This item adds a note to section 41BG to provide that this section applies in relation to vaping goods that are a medical device.

Item 20 – Subsection 41HC(7)

This item repeals subsection 41HC(7) of the TG Act.

Item 21 – Section 53A (after table item 33)

This item introduces item 33AA in the table in section 53A to include reference to subsection 41RD(1) and subsection 41RD(2).

Item 22 – Section 54BA (after table item 43)

This item adds new items 43AA to 43AF to the table in section 54BA.

Item 23 – After subsection 56A(4A)

This item introduces subsection 56A(4B) to provide that, in proceedings for an offence against section 41QDA, 41QDB, 41QDC or 41QDD, or the contravention of subsection 41QDA(3), 41QDB(3), 41QDC(107) or 41QDD(43), which are civil penalty provisions, a certificate by the Secretary to the effect that the Secretary did not consent to the manufacture, supply or possession that is the subject of the proceedings, or consented to that manufacture, supply or possession subject to conditions specified in the certificate, is prima facie evidence of the matters specified in the certificate.

Although this power, in effect, reverses the onus of proof, this reversal is considered reasonable in the circumstances. The existence of a consent is a matter of fact, that, outside of the Secretary's belief as expressed in a certificate, is peculiarly within the knowledge of the defendant. If the Secretary is of belief that the consent did, or did not exist, it is reasonable that only the defendant would be aware of the counter position. Adducing evidence to that effect would be most easily adduced by the defendant and would likely exist in the form of documentary evidence. The defendant need only meet an evidential burden of proof to rebut the certificate issued under 56A.

Item 24 – Subsection 57(10)

This item amends subsection 57(10) to include a reference to subsection 41P(3). Subsection 57(10) limits the power of the Minister to be delegated to:

- the Secretary;
- an SES employee, who holds or performs the duties of, an SES Band 3 position in the Department; or
- a person who is registered, in a state or internal territory, as a medical practitioner and who holds or performs the duties of, a position that is equivalent to or higher than, an SES Band 2 position in the Department.

The making of these instruments under 41P(3) may be time-critical, to respond to a rapidly evolving market that has repeatedly sought to evade regulation since the Commonwealth Government first regulated nicotine vaping products in 2021. As such, it is important to have a sufficient number of delegates, at a senior level available to make such an instrument.

Item 25 – Subsection 60(1) (after paragraph (k) of the definition of *initial decision*)

This item amends subsection 60(1) to introduce paragraph 60(1)(ka), which provides that refusing to give a consent under subsection 41RC(1), or giving such a consent subject to conditions under subsection 41RC(2), is an initial decision.

Division 3—Application and transitional provisions**Item 26 – Application of amendments**

This item provides that the amendments of the TG Act made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 3—Advertising relating to vaping goods

Division 1—Main amendments

Therapeutic Goods Act 1989

Item 27 – After Part 5-1

This item introduces new Part 5-1A to Chapter 5 of the TG Act. Part 5-1A sets out the requirements relating to advertising of vaping goods.

Part 5-1A—Vaping Goods

Division 1—Preliminary

This Part not to apply to advertisements directed at health professions etc. (new section 42DZ)

New subsection 42DZ(1) provides that Part 5-1A does not apply to advertisements directed exclusively to:

- (a) health practitioners included in a class of health practitioners specified for the purposes of this paragraph under subsection (2); or
- (b) persons who are practice managers for a health practitioner covered by paragraph (a); or
- (c) persons who are engaged in the business of wholesaling vaping goods and are included in a class of persons specified for the purposes of this paragraph under subsection (2); or
- (d) a class of persons specified for the purposes of this paragraph under subsection (2).

New subsection 42DZ(2) provides that the Minister may, by legislative instrument, specify any or all of the following:

- (a) a class of health practitioners for the purposes of paragraph (1)(a);
- (b) a class of persons who are engaged in the business of wholesaling vaping goods for the purposes of paragraph (1)(c);
- (c) a class of persons for the paragraph (1)(d).

New subsection 42DZ(3) provides that Part 5-1A does not apply to advice or information given directly to a patient by a health practitioner covered by paragraph (1)(a) in the course of treatment of that patient.

This Part not to apply to certain advertisements for exported goods (new section 42DZA)

New section 42DZA provides that Part 5-1A does not apply to advertisements that are solely for vaping goods that have been exported, or are intended exclusively for export, if the advertisements are not available to consumers in Australia.

Definitions (new section 42DZB)

New section 42DZB introduces a definition of ‘generic information’ for the purposes of new Part 5-1A.

The term *generic information* in relation to vaping goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of the vaping goods, but does not include:

- (a) an advertisement about the goods;
- (b) generic information included in an advertisement about the goods; or
- (c) bona fide news.

Division 2—General provisions about advertising vaping goods

Authorised advertisement etc (new section 42DZC)

This section provides for authorisation of advertising of vaping goods.

Secretary may authorise advertising—general

Advertising of vaping goods are absolutely prohibited in view of the health risks associated with vaping and the significant increase in the uptake of vaping in the last few years, in particular, by young people. However, there may legitimate reasons where advertising may in limited circumstances could be justified. For example, advertising for participants in a possible clinical trial, or advertising to discourage the use of vaping goods due to particular presence of an additive. The authorisation is not intended to be granted to a particular individual and there is no application process.

New subsection 42DZC(1) provides that the Secretary may, by writing, authorise the advertising, or a class of advertising, of specified vaping goods.

New subsection 42DZC(2) provides that an authorisation under subsection (1) may authorise specified representations or information to be included in an advertisement of specified vaping goods.

Secretary may authorise specified representation on label or package etc.

New subsection 42DZC(3) provides that the Secretary may, by writing, authorise the use of specified representations:

- (a) on the label of specified vaping goods; or
- (b) on the package in which specified vaping goods are contained; or
- (c) on any material included with the package in which specified vaping goods are contained;

if the Secretary is satisfied that the representations are necessary for the appropriate use of the vaping goods.

Conditions

New subsection 42DZC(4) provides that an authorisation under this section may be subject to conditions specified in the authorisation.

Authorisation not a legislative instrument

New subsection 42DZC(5) provides that an authorisation under this section is not a legislative instrument. The authorisation deals with the administrative matter of specifying representations that may be authorised as part of the advertisement and does not determine or alter the law.

Publication

New subsection 42DZC(6) provides that as soon as practicable after giving the authorisation under this section, the Secretary must cause the authorisation to be published on the Department's website.

Division 3—Offences and civil penalty provisions

Offences—no authorisation or conditions of authorisation not complied with (new section 42DZD)

New section 42DZD provides offences for unauthorised advertising of vaping goods. A person will commit an offence if the person advertises by any means, or causes the advertising, by any means, of vaping goods and there is no authorisation under section 42DZC in relation to the advertising, or where an authorisation is in force, the advertisement is not in accordance with that authorisation.

New subsection 42DZD(1) provides that a person commits an offence if:

- (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods; and
- (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or

- (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representation or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

The maximum penalty for an offence under subsection 42DZD(1) is imprisonment for 7 years or 5,000 penalty units, or both. As supply and access of vaping goods are significantly influenced by advertising (including online advertising) and prohibition of advertising is an effective way of curbing and stopping supply, the high penalties are justified and are consistent with the maximum civil penalties in relation to the supply, importation, manufacture and possession of vaping goods. In assessing the level of penalties to be imposed it is considered that advertisements directed to minors (under 18's), advertisements of vaping goods close to schools and facilities, and advertisements indicating safety of vaping goods would attract the maximum penalty.

The note to subsection (1) references sections 54B and 54BA for the liability of an executive officer of a body corporate. Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from breaching a condition of consent to undertake activity in relation to vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

New subsection 42DZD(2) provides that a person commits an offence of strict liability if:

(a) the person:

- (i) advertises, by any means, vaping goods; or
- (ii) causes the advertising, by any means, of vaping goods; and

(b) either:

- (i) no authorisation under section 42DZC is in force in relation to the advertising; or
- (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representation or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

The maximum penalty for an offence under subsection 42DZD(2) is 200 penalty units.

Continuing offences

New subsection 42DZD(3) provides that a person who contravenes subsection (1) or (2) commits a separate offence in respect of each day (including a day of conviction for the offence or any later day) during which the contravention continues.

New subsection 42DZD(4) provides that the maximum penalty for each day that an offence against subsection (1) or (2) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

Civil penalty—no authorisation of conditions of authorisation not complied with (new section 42DZE)

New section 42DZE sets out corresponding civil penalty provision for unauthorised advertising of vaping goods.

New subsection 42DZE(1) provides that a person contravenes this subsection if:

- (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods; and
- (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or
 - (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representation or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Contravention of this provision attracts a maximum penalty of 7,000 penalty units for an individual, and 70,000 penalty units for a body corporate. These levels of penalties are consistent with the levels of penalties for the contravention of civil penalties applying to vaping goods in new Chapter 4A.

Continuing contraventions

New subsection 42DZE(2) provides that a person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the relevant order under subsection 42Y(2) is made or any later day)

New subsection 42DZE(3) provides that the maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Division 4—Secretary may require information or documents

Secretary may require information or documents (new section 42DZF)

Advertisements

New section 42DZF introduces a new information gathering power in relation to the advertisements of vaping goods. This notice is referred to as a ‘substantiation’ notice. The approach in section 42DZF is consistent with existing provisions in the TG Act, including section 42DR which relates to the advertising of therapeutic goods.

New subsection 42DZF(1) provides that the Secretary may, by written notice given to a person apparently responsible for advertising vaping goods, or for causing the advertising of vaping goods, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the advertisement.

Generic information

New subsection 42DZF(2) provides that the Secretary may, by written notice given to a person apparently responsible for disseminating, or for causing the disseminating of, generic information in relation to vaping goods to the public or a section of the public, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the dissemination.

Manner of compliance

New subsection 42DZF(3) provides the manner of compliance including that the person must give the information, or produce the documents to the Secretary within a period of not less than 14 days after the day the notice is given and in the form specified in the notice.

The note to subsection 42DZF(3) makes it clear that a person may commit an offence under section 42DZG for failing to comply with the notice or giving false or misleading information or documents and may be liable to a civil penalty under section 42DZH for giving false or misleading information or documents.

New subsection 42DZF(4) provides that the form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

- (a) on a specified kind of data processing device; or
- (b) by way of a specified kind of electronic transmission.

Notice not a legislative instrument

New subsection 42DZF(5) makes it clear that a notice under subsection (1) or (2) is not a legislative instrument. Notices given under subsections 42DZF(1) and (2) are administrative in character as they are directed to a specific person (that is the person apparently responsible), and have no general application.

Offences—failing to comply with a notice etc. (new section 42DZG)

New section introduces offences for failing to comply a notice under section 42DZF. The approach in section 42DZG is consistent with existing provisions in the TG Act, including section 42DS.

New subsection 42DZG(1) provides a fault-based offence if the person is given a notice under subsection 42DZF(1) or (2) and the person fails to comply with the notice.

The maximum penalty is 500 penalty units.

New subsection 42DZG(2) is the equivalent strict liability offence of subsection 42DZG(1) and attracts a maximum penalty of 100 penalty units.

New subsection 42DZG(3) provides a fault-based offence if the person is given a notice under subsection 42DZF(1) or (2) and the person gives information or produces a document in compliance or purported compliance with the notice and the information or document provided by the person is false or misleading in a material particular.

The maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

New subsection 42DZG(4) is the equivalent strict liability offence of subsection 42DZG(3) and attracts a maximum penalty of 100 penalty units.

Civil penalty—giving false or misleading information or document in compliance with a notice (new section 42DZH)

New section 42DZH introduces a civil penalty provision for providing information or documents, in purported compliance with a notice given under subsection 42DZF(1) or (2), that are false or misleading in a material particular. The approach in section 42DZH is consistent with existing provisions in the TG Act, including section 42DT.

Contravention of this provision attracts a maximum penalty of 5,000 penalty units for an individual, and 50,000 penalty units for a body corporate.

Self-incrimination (new section 42DZJ)

New section 42DZJ abrogates the privilege against self-incrimination in relation to the giving of information or producing a document under section 42DZF. The approach in section 42DZJ is consistent with existing provisions in the TG Act, including section 42DU.

Without abrogating the privilege against self-incrimination, a person would withhold pertinent information that could seriously undermine the Secretary's power to investigate possible contraventions of the TG Act or regulations and the ability to take timely regulatory action, criminal prosecutions or civil penalty proceedings in relation to such contraventions. While in some cases it may be feasible to obtain information by other means or from other persons, there will be occasions where the relevant information is only known by that person or it is not feasible or timely to do so, which could significantly increase the risk of harm or injury to consumers particularly where the information or documents relate to unlawful vaping goods.

This information could potentially be critical to preventing a serious threat to public health or could lead to a finding of serious safety concerns that pose a significant risk to the health and wellbeing of Australian consumers. The ability to enforce and undertake effective and timely post-market monitoring of the safety of vaping goods under the therapeutic goods regulatory scheme would be compromised and this could have serious public health risks. As such, the public benefit of the abrogation of this privilege outweighs the loss of personal liability.

Any information given in response to such a notice cannot be used as evidence against the person in criminal proceedings or civil proceedings, except for the following:

- (a) proceedings for an offence against subsections 42DZG (3) or (4) due to giving false or misleading information or document in compliance with a notice; or
- (b) proceedings for a civil penalty contravention under section 42Y for a contravention of section 42DZH due to giving false or misleading information or document in compliance with a notice.

New subsection 42DZJ(1) provides that a person is not excused from giving information or producing a document under section 42DZF on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

New subsection 42DZJ(2) provides that in the case of an individual:

- (a) the information given or the document produced; and
- (b) giving the information or producing the document; and
- (c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

- (d) in criminal proceedings, except proceedings for an offence against subsection 42DZG(3) or (4); or
- (e) in civil proceedings, except proceedings under section 42Y for a contravention of section 42DZH.

Division 5—Directions about advertisements or generic information

Directions about advertisements of generic information (new section 42DZK)

New section 42DZK empowers the Secretary to direct a person apparently responsible for advertising vaping goods or disseminating generic information about vaping goods to take certain actions. The approach in section 42DZK is consistent with existing provisions in the TG Act, including section 42DV.

Advertisements

New subsection 42DZK(1) empowers the Secretary to direct, in writing, a person who is apparently responsible for advertising vaping goods, or for causing the advertising of the vaping goods to do one or more of the following:

- (a) cease the advertisement;
- (b) make a retraction;
- (c) make a correction;
- (d) recover any advertisement that is still in circulation;
- (e) destroy the advertisement;
- (f) cease making a particular claim or representation made by the advertisement.

In making a decision to issue a direction, the Secretary must be satisfied that there has been a contravention of the TG Act or regulations.

Generic information

New subsection 42DZK(2) empowers the Secretary to direct, in writing, a person who is apparently responsible for the dissemination, or for causing the dissemination of generic information in relation to the vaping goods to do one or more of the following:

- (a) withdraw the generic information;
- (b) make a retraction;
- (c) make a correction;
- (d) recover any generic information that is still in circulation;
- (e) destroy the generic information;
- (f) cease making a particular claim or representation made by the generic information.

In making a decision to issue direction the Secretary must be satisfied that there has been a contravention of the TG Act or regulations.

Conditions

New subsection 42DZK(3) provides that a direction under subsection (1) or (2) may be subject to conditions specified in the direction.

New subsection 42DZK(4) provides that without limiting subsection (3), the conditions may relate to one or more of the following:

- (a) the period for doing a thing the subject of the direction;
- (b) in relation to the making of a retraction or correction, either or both of the following:
 - (i) the form and manner of the retraction or correction;
 - (ii) the period for which the retraction or correction must be made publicly available;
- (c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

New subsection 42DZK(5) makes it clear that a direction under subsection (1) or (2) is not a legislative instrument within the meaning of subsection 8(1) of the *Legislation Act 2003*. Directions given under subsections 42DZK(1) and (2) are administrative in character as they deal with the administrative matter of issuing directions to a specific person, where the Secretary is satisfied there has been a contravention of the TG Act or regulations. The direction is given to a particular person to comply with the action specified in the direction, and is not directed to the public in general. In addition, the decision to issue a direction under subsection 42DZK(1) or (2) is a reviewable decision under section 60 of the TG Act.

Publication

New subsection 42DZK(6) imposes the requirement for the Secretary to cause the direction to be published on the Department's website as soon as practicable after giving a direction.

Offences—contravening direction under section 42DZK (new section 42DZL)

New section 42DZL introduces fault-based offence (new subsections 42DZL(1) and (2) refer) and a strict liability offence (new subsection 42DZL(3)) for contravening a direction given to a person under subsection 42DZK(1) or (2) of the TG Act in relation to vaping goods. The approach in section 42DZL is consistent with existing provisions in the TG Act, including section 42DW.

New subsection 42DZL(1) provides that a person commits an offence if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2) in relation to vaping goods; and
- (b) the person does an act or omits to do an act;
- (c) and the act or omission contravenes the direction or a condition of the direction;
- (d) either:
 - (i) the use of the vaping goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
 - (ii) the use of the vaping goods, if the vaping goods were used, would result in, or would be likely to result in, harm or injury to any person; and
- (e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

The maximum penalty is imprisonment for 5 years or 4,000 penalty units, or both.

Note 1 to subsection (1) provides that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead, with reference to section 53A.

Note 2 to subsection (1) references sections 54B and 54BA for the liability of an executive officer of a body corporate. Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches.

There is significant public harm from breaching a condition of consent to undertake activity in relation to vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

New subsection 42DZL(2) provides that a person commits an offence if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

The maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

New subsection 42DZL(3) provides that a person commits an offence of strict liability if:

- (a) a direction is given to a person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

The maximum penalty is 100 penalty units.

Civil penalty—contravening direction under section 42DZK (new section 42DZM)

New section 42DZM introduces a civil penalty provision for contravening a direction given to a person under subsection 42DZK(1) or (2) of the TG Act in relation to vaping goods. The approach in section 42DZM is consistent with existing provisions in the TG Act, including section 42DX.

New section 42DZM provides that a person contravenes this section if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

Contravention of this provision attracts a maximum penalty of 5,000 penalty units for an individual, and 50,000 penalty units for a body corporate.

Division 6—Public warning notices

Secretary may issue a public warning notice (new section 42DZN)

New section 42DZN empowers the Secretary to issue a public warning notice. The approach in section 42DZN is consistent with existing provisions in the TG Act, including section 42DY.

New subsection 42DZN(1) provides that the Secretary may issue to the public a written notice containing a warning about vaping goods if:

- (a) the Secretary reasonably suspects that there has been a contravention of this Act or the regulations in relation to:
 - (i) the advertising of the vaping goods; or

- (ii) the dissemination of generic information in relation to the vaping goods to the public or a section of the public; and

(b) the Secretary is satisfied that it is in the public interest to issue the notice.

New subsection 42DZN(2) provides that if:

- (a) the Secretary has given a person a notice (the *substantiation notice*) under subsection 42DZF(1) or (2); and
- (b) the person fails to comply with the substantiation notice; and
- (c) the Secretary is satisfied that it is in the public interest to issue a notice under this subsection;

the Secretary may issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related.

New subsection 42DZN(3) provides that subsection (2) does not limit subsection (1).

New subsection 42DZN(4) makes it clear that a notice under subsection (1) or (2) is not a legislative instrument within the meaning of subsection 8(1) of the *Legislation Act 2003*. Notices given under subsections 42DZN(1) and (2) are administrative in character.

Division 2—Other amendments

Therapeutic Goods Act 1989

Item 28 – Subsection 3(1) (definition of *advertise*)

This item amends the definition of ‘advertise’ in subsection 3(1) of the TG Act to provide that term also relates to vaping goods.

Item 29 – Section 5A

This item amends section 5A of the TG Act to provide that section 15.2 of the *Criminal Code* applies to offences against new subsection 42DZD(1) and (2) and new sections 42DZG and 42DZL.

Item 30 – Subparagraph 25(1)(fa)(ii)

This item amends subparagraph 25(1)(fa)(ii) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 31 – Paragraphs 30(1)(f) and (fa)

This item amends paragraphs 30(1)(f) and (fa) of the TG Act to include a reference to subsection 42DK(1).

Item 32 – Paragraph 30(1)(fb)

This item amends paragraph 30(1)(fb) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 33 – Paragraphs 30(2)(eaa) and (eab)

This item amends paragraphs 30(2)(eaa) and (eab) of the TG Act to include a reference to subsection 42DK(1).

Items 34 to 37 (amendments to subparagraph 30(2)(ea)(ii), subparagraph 31(1)(h)(ii), subparagraph 31(2)(gaa)(ii), and subparagraph 41FD(h)(ii))

These items amend subparagraphs 30(2)(ea)(ii), 31(1)(h)(ii), 31(2)(gaa)(ii) and 41FD(h)(ii) of the TG Act to include a reference to new Part 5-1A consequential to the introduction of that part above.

Item 38 – Paragraphs 41GL(g) and (ga)

This item amends paragraphs 41GL(g) and (ga) of the TG Act to include a reference to subsection 42DK(1).

Item 39 – Paragraph 41GL(h)

This item amends paragraph 41GL(h) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 40 – Paragraphs 41GN(1)(i) and (j)

This item amends paragraphs 41GN(1)(i) and (j) of the TG Act to include a reference to subsection 42DK(1).

Items 41 and 42 (Amendments to subparagraph 41GN(1)(k)(ii) and subparagraph 41JA(1)(h)(ii))

These items amend subparagraphs 41GN(1)(k)(ii) and 41GN(1)(k)(ii) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 43 – After section 42AC

This item amends the TG Act to insert new section 42AD.

New subsection 42AD(1) provides that Part 5-1 of the TG Act does not apply in relation to advertisements about vaping goods.

New subsection 42AD(2) provides that new Part 5-1A applies in relation to advertisements about vaping goods.

Item 44 – After subsection 42DLB(10)

This item amends the TG Act to insert new subsections 42DLB(10A) and (10B) to provide for continuing contraventions for civil penalties relating to advertisements.

New subsection 42DLB(10A) provides that a person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each of day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

New subsection 42DLB(10B) provides that the maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Item 45 – After subsection 42DMA(2)

This item amends the TG Act to insert new subsections 42DMA(2A) and (2B) to provide for continuing contraventions for civil penalties relating to non-compliance with the Therapeutic Goods Advertising Code.

New subsection 42DMA(2A) provides that a person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each of day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

New subsection 42DMA(2B) provides that the maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Item 46 – Section 53A (after table item 33D)

This item inserts new table item 33E into the table in section 53A of the TG Act. Section 53A provides for alternative verdicts for various offences.

Item 47– Section 45BA (after table item 43D)

This item inserts new table items 43E and 43F into the table in section 45BA of the TG Act. Section 45BA sets out offences to which the chief executive officer of a body corporate has personal liability.

Item 48 – Subsection 60(1) (at the end of the definition of *initial decision*)

This item amends subsection 60(1) of the TG Act to make it clear that a decision made by the Secretary under subsection 42DZK(1) or (2) is an initial decision and therefore subject to merits review (comprising internal reconsideration and external review by the AAT) under section 60 of the TG Act.

Division 3—Application and transitional provisions

Item 49 – Application of amendments

This item provides that the amendments made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 4—Enforceable directions and forfeiture

Forfeiture and destruction

These amendments create new forfeiture provisions which overcome the limitations of the existing forfeiture provisions in the TG Act and expand the circumstances in which forfeiture may occur. The existing forfeiture (and related) provisions are set out below:

- under section 54 of the TG Act, forfeiture orders can only be obtained following a criminal conviction, an order under section 19B of the *Crimes Act 1914*, or a finding by a court that the person has contravened a civil penalty provision;
- under section 48H of the TG Act, seized goods may be required to be returned to the owner if they are no longer needed for evidentiary purposes, regardless of whether it is lawful for the owner to possess or deal with the goods.

These enhanced forfeiture powers will enable the TGA to disrupt the trafficking of unlawful goods more efficiently, as well as address potential storage and destruction issues where large quantities of unlawful vapes are seized.

These new powers only apply where goods have been seized pursuant to a search warrant. The intention is that the Secretary would be empowered to initiate a process for the goods to be forfeited to the Commonwealth where there is a *reasonable belief* the goods have been unlawfully imported, manufactured, supplied or are otherwise non-compliant with the TG Act including in relation to possession.

Once the goods have been forfeited, the Secretary should have a broad power to dispose of the goods.

Enforceable directions

An emerging issue with vaping goods is that they are costly to destroy because component parts such as plastics, batteries, and hazardous nicotine need to be separated and appropriately disposed of.

To manage waste issues associated with enforcement of vaping laws, but also to give the Secretary a broad range of compliance and enforcement tools to manage unlawful vapes and therapeutic goods generally, these amendments include a new power which permits the Secretary to make directions to a person to take one or more steps, within the time specified in the notice, to comply with the TG Act if the Secretary believes, on reasonable grounds, that:

- a person is not complying with the TG Act; and
- it is necessary to exercise this power to protect the health and safety of humans.

This power allows directions to be made requiring one or more of the following:

- to relabel or label goods in compliance with the requirements under the TG Act;
- to repackage goods in compliance with the requirements under the TG Act; or
- to destroy or dispose of goods at their own cost, including by delivering the goods to specific service providers who will dispose of the goods responsibly.

Warrants

Sections 49 and 50 of the TG Act require warrants to be issued by a magistrate. The TGA often experiences operational when seeking timely access to magistrates to issue warrants. This is problematic when there is urgency in the obtaining and execution of a warrant.

Consequently, these amendments extend the authority to issue monitoring, offence and civil penalty related warrants in relation to premises to court registrars and other legislative officers of a court of a state or territory.

Such an approach is not unprecedented, with the *Crimes Act 1914* providing for the issuing of warrants by an ‘issuing officer’ which means:

- a magistrate; or
- a justice of the peace or other person employed in a court of a state or territory who is authorised to issue search warrants or warrants for arrest, as the case may be.

Amendments to sections 49 and 50 of the TG Act allow for a registrar of the court or other officers employed in a court of a state or territory to issue monitoring, offence or civil penalty related search warrants in relation to premises.

Therapeutic Goods Act 1989

Item 50 - Subsection 3(1) (paragraph (b) of the definition of *authorised person*)

This item amends the definition of ‘authorised person’ in subsection 3(1) of the TG Act to include a reference to new Part 6-2A.

Item 51 - At the end of Chapter 5A

This item introduces Part 5A-5 in Chapter 5A of the TG Act. Part 5A-5 includes provisions relating to enforceable directions.

New section 42YS provides a simplified outline for Part 5A-5 of the TG Act.

New section 42YT provides that the Secretary may give directions if the TG Act or an instrument is not being complied with. Subsection 42YT(1) provides that this section applies if the Secretary believes, on reasonable grounds, that a person is not

complying with this Act or an instrument made under the TG Act in relation to particular goods and it is necessary to exercise powers under this section to protect the health and safety of humans.

The note to subsection 42YT(1) provides that paragraph 42YT(1)(b), which requires the Secretary to believe on reasonable grounds that it is necessary to exercise powers under this section to protect the health and safety of humans, covers protecting the health and safety of humans in relation to the environment.

Subsection 42YT(2) provides that the Secretary may, by written notice, give directions to the person requiring the person to do any of the following, within the period specified in the notice and at the person's own cost:

- (a) relabel, or label, the goods in compliance with this Act or the instrument;
- (b) repackage the goods in compliance with this Act or the instrument;
- (c) destroy or otherwise dispose of the goods;
- (d) deliver the goods to a specified person to be destroyed or otherwise disposed of in an appropriate manner;
- (e) any other thing prescribed by the regulations in relation to the goods.

The note to this subsection references, in relation to variation and revocation of the directions, subsection 33(3) of the *Acts Interpretation Act 1901*.

Subsection 42YT(3) provides that a period specified in a notice given under subsection (2) must be reasonable having regard to the circumstances.

Subsection 42YT(4) provides that a person commits an offence if the person is given a notice under subsection (2) and the person fails to comply with the notice within the period specified in the notice, with an associated penalty of imprisonment for 12 months or 1,000 penalty units, or both.

Subsection 42YT(5) provides for civil penalties for the same conduct, with the maximum civil penalty for an individual of 5,000 penalty units and for a body corporate of 50, 000 penalty units.

Item 52 - At the end of section 48H

This item introduces a note at the end of section 48H, which provides that section 48H does not apply in relation to the thing if section 52AAB applies in relation to the thing (in accordance with subsection 52AAB(2)).

Item 53 - At the end of section 48J

This item introduces a note at the end of section 48J, which provides that section 48J does not apply in relation to the thing if section 52AAB applies in relation to the thing (in accordance with subsection 52AAB(2)).

Item 54 – After Part 6-2

This item introduces Part 6-2A to the TG Act, which includes provisions relating to forfeiture of things seized.

New section 52AAA provides for the forfeiture of things seized under search warrants in certain circumstances.

Subsection 52AAA(1) provides that if an authorised person seizes a thing under a warrant issued under section 50, and the Secretary believes on reasonable grounds that the thing has been imported, manufactured or supplied, or been in the possession, custody or control of a person, in contravention of this Act or an instrument made under this Act or a requirement under this Act or such an instrument has not been complied with in relation to the thing, the thing is forfeited to the Commonwealth.

Subsection 52AAA(2) provides that the Secretary must give a written notice, i.e. a forfeiture notice, in accordance with subsection (3) to the owner of the thing or, if the owner cannot be identified after reasonable inquiry, the person who had possession, custody or control of the thing immediately before it was seized.

Subsection 52AAA(3) provides that the forfeiture notice must identify the thing, and state a number of matters, including the day it was seized, that it was seized under warrant, the grounds on which it was seized, and that the owner or person who had possession, custody or control of the thing may, within 2 months of the forfeiture notice being given, commence proceedings against the Commonwealth for a declaration that the thing is not forfeited to the Commonwealth. Subsection 52AAA(4A) provides that the owner of the thing, or person who had possession, custody or control of the thing, may commence proceedings for a declaration that the thing is not forfeited to the Commonwealth. Subsection 52AAA(5B) provides that proceedings may be commenced under subsection (4A) even if the forfeiture notice has not been given and may only be commenced before the end of the period of 2 months beginning on the day the forfeiture notice is given.

Subsection 52AAA(6A) provides that, if the owner or person who has possession, custody or control of the thing does not commence such proceedings within 2 months specified in the forfeiture notice, or commences such proceedings but a court has not made a declaration, then the thing is condemned as forfeited to the Commonwealth, and the Secretary may cause notice of the forfeiture of the thing to be published on the Department's website and the Secretary may either retain the thing for the purpose of proceedings in respect of which the thing may afford evidence or cause the thing to be disposed of in such manner as the Secretary directs. The note to subsection (6A) references section 54 dealing with offences and forfeiture.

Section 52AAB provides for the return or retention of a thing that is declared not to be forfeited to the Commonwealth.

Subsection 52AAB(1) provides that this section applies in relation to a thing if the thing was forfeited to the Commonwealth under subsection 52AAA(1) and a court has

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

Formatted: Highlight

made a declaration that the thing is not forfeited to the Commonwealth under that subsection.

Subsection (2) provides that sections 48H and 48J do not apply in relation to the thing.

Subsection (3) provides that at the end of 120 days after a court has made a declaration that the thing is not forfeited, an authorised person must take reasonable steps to return the thing to the person from whom it was seized unless:

- (a) proceedings in which the thing may afford evidence were commenced before the end of the 120 day period and have not been completed;
- (b) an authorised person may retain the thing because of an order under subsection (6); or
- (c) an authorised person is otherwise authorised by a law or order of a court of the Commonwealth, a state or a territory, to retain, destroy or dispose of the thing.

Subsection 52AAB(4) provides that the thing may be returned either unconditionally or on such terms and conditions as the Secretary sees fit.

Subsection 52AAB(5) provides that the secretary may apply to an issuing officer for an order that an authorised person may retain the thing for a further period. The application must be made before the end of the 120 day period or, if an order is made under subsection (6), before the end of the period specified in the most recent order.

Subsection 52AAB(6) provides that if the issuing officer is satisfied that it is necessary for an authorised person to continue to retain the thing for one of the following purposes, the issuing officer may order that an authorised person may retain the thing for a period specified in the order not exceeding 3 years:

- (a) for the purposes of an investigation as to whether an offence against this Act has been committed;
- (b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution;
- (c) for the purposes of an investigation as to whether a civil penalty provision has been contravened;
- (d) to enable evidence of a contravention of a civil penalty provision to be secured for the purposes of civil proceedings.

Subsection (7) provides that before making an application to an issuing officer for an order that an authorised person may retain the thing for a further period, the Secretary must take reasonable steps to discover who has an interest in the retention of the thing and, if it is practicable to do so, notify each person who the Secretary believes to have such an interest of the proposed application.

Formatted: Font: Times New Roman

Formatted: Indent: Left: 1.27 cm, No bullets or numbering

Formatted: Highlight

Item 55 – Application of Amendment

Formatted: Keep with next

This item provides that Part 6-2A of the TG Act, as inserted by this Part, applies in relation to a thing that is seized under a warrant issued under section 50 of the TG Act on or after the commencement of this Part.

Item 56 – Subsection 54(3)

This item amends subsection 54(3) to include a reference to vaping goods.

Item 57 – At the end of section 54

This item introduces a note at the end of section 54, which provides a reference to Part 6-2A which deals with forfeiture of things seized under a warrant in certain circumstances.

Part 5—Entry, searches and warrants

Therapeutic Goods Act 1989

Background

These amendments extend the power to issue warrants and extension of time to retain seized goods to a registrar and other officers of the state or territory court who are authorised under a state or territory law to issue search warrants. These officers are not carrying out judicial powers. These amendments allow additional flexibility for authorised officers to apply for a warrant from other officers of the state or territory court or a Registrar. Thus, an authorised person can apply for a warrant even when the court is not sitting and the Magistrate is not available.

Details of the amendments

Item 58 - Subsection 3(1)

This item inserts a new definition in the TG Act for *issuing officer*, who is defined as a magistrate or a registrar or other officer of a state or territory court who is authorised under a state or territory law to issue search warrants.

Item 59 - Paragraphs 46A(1)(b) and (2)(b)

This item amends paragraphs 46A(1)(b) and 2(b) of the TG Act to insert “or vaping goods” after “therapeutic goods” (wherever occurring).

Item 60 - Before subparagraph 46A(4)(a)(ia)

This item inserts a new subparagraph 46A(4)(a)(iaa) in the TG Act and provides that subsection 46A(4) applies to premises of a person who is required to comply with a condition of an exemption of vaping goods under sections 18 or 41HA of the TG Act.

Item 61 - Paragraph 48(1)(b)

This item amends paragraph 48(1)(b) of the TG Act to insert “or vaping goods” after “therapeutic goods” (wherever occurring).

Item 62 – Subsection 48A(3)

This item amends subsection 48A(3) of the TG Act to omit the term “magistrate” and substitute it with “issuing officer”.

Item 63 - Subparagraph 48AA(2)(b)(ii)

This item amends subparagraph 48AA(2)(b)(ii) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 64 - Subparagraph 48AA(3)

This item amends subsection 48AA(3) of the TG Act to omit the term “a magistrate” and substitutes it with “an issuing officer”.

Item 65 – Subsection 48AA(5)

This item amends subsection 48AA(5) of the TG Act to omit the term “A magistrate” and substitute it with “An issuing officer”.

Item 66 - Paragraph 48AA(5)(b)

This item amends paragraph 48AA(5)(b) of the TG Act to omit the term “magistrate” and substitute it with “issuing officer”.

Item 67 - Subsections 48BA(7) and 48C(7)

This item amends subsections 48BA(7) and 48C(7) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 68 - Section 48J (heading)

This item amends the heading in section 48J of the TG Act to omit the term “Magistrate” and substitute it with “Issuing Officer”.

Item 69 - Subsection 48J(1)

This item amends subsection 48J(1) of the TG Act to omit the term “a magistrate” (wherever occurring) and substitute it with “an issuing officer”.

Item 70 - Subsection 48J(2)

This item amends subsection 48J(2) of the TG Act to omit the term “a magistrate” (wherever occurring) and substitute it with “an issuing officer”.

Item 71 - Subsection 49(1)

This item amends subsection 49(1) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 72 - Subsections 49(2) and (3)

This item amends subsections 49(2) and (3) of the TG Act to omit the term “magistrate” (wherever occurring) and substitute it with “issuing officer”.

Item 73 - Subsection 50(1)

This item amends subsection 50(1) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 74 – Subsections 50(2) and (3)

This item amends subsection 50(2) and (3) of the TG Act to omit the term “a magistrate” (wherever occurring) and substitute it with “an issuing officer”.

Item 75 – Subsection 51(1)

This item amends subsection 51(1) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 76 - Subsections 51(4) to (9)

This item amends subsections 51(4) to (9) of the TG Act to omit the term “magistrate” (wherever occurring) and substitute it with “issuing officer”.

Item 77 - Subsection 51(10)

This item amends subsection 51(10) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 78 - Paragraph 51B(2)(a)

This item amends paragraph 51B(2)(a) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 79 - Paragraph 51B(2)(a)

This item amends paragraph 51B(2)(a) of the TG Act to omit the term “that magistrate” and substitute it with “that issuing officer”.

Item 80 - Paragraph 51B(2)(b)

This item amends paragraph 51B(2)(b) of the TG Act to omit the term “magistrate” and substitute it with “issuing officer”.

Item 81 - Subparagraphs 51B(2)(c)(i) and (ii)

This item amends subparagraphs 51B(2)(c)(i) and (ii) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 82 - Paragraph 51B(2)(d)

This item amends paragraph 51B(2)(d) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 83 - After section 51B

This item inserts new section 51C in the TG Act, which provides that a power conferred on an issuing officer by Part 6-2 of the TG Act is conferred on the officer in a personal capacity and not as a court or as a member or an officer of a court. An issuing officer is not required to accept the powers conferred on them by Part 6-2 of the TG Act.

Further, an issuing officer exercising a power under Part 6-2 of the TG Act has the same protection and immunity as if the officer were exercising the power as the court of which it is a member or officer, or as a member or an officer of the court of which the issuing officer is a member or an officer.

Part 6—Delegation and authorised persons

Therapeutic Goods Act 1989

Background

The vaping reforms are intended to achieve a timely and nationally consistent approach for the regulation of vaping goods by relying on the federal cooperative scheme for therapeutic goods. All states and territories have enacted corresponding laws to adopt the Commonwealth TG Act as amended from time, with Western Australia having recently introduced legislation to the Parliament of Western Australia to enact their own corresponding law. The corresponding laws fill the gap in the Commonwealth's constitutional power to ensure appropriate coverage for the regulation of therapeutic goods.

To empower state and territory officials to carry out enforcement powers under the new reforms, the Bill allows for the delegation of the powers of the Secretary under Chapter 5A, new section 52AA and new section 52AAB to an officer of a Department of State of a state, a Department or administrative unit of the Public Service of a territory or an authority of a state or territory. The Department, unit or authority must have functions relating to therapeutic goods, health or law enforcement. Section 7 of the TG Act already provides for the Secretary to authorise these officers to exercise powers under a specified provision of the TG Act. State and territory officers authorised by the Secretary under section 7A exercise powers and functions under Part 6-2 (Entry, searches and warrants) of Chapter 6 of the TG Act.

In practice, the Secretary only provides authorisation and delegation of powers to officers who have the relevant skills and experience in relation to enforcement powers such as entry to premises, execution of search, monitoring and investigation warrants, testing of things and samples, and the seizing of evidential materials. Current delegates and authorised officers range from APS 5 to SES officers. Although delegation and authorisation are given to APS officers, they are generally accompanied by high level APS officers, and depending on the risks associated with the search and seizure, will be accompanied by law enforcement officers. In addition, these officers are given appropriate training and must adhere to standard operating procedures developed by the Department of Health. It is intended that the same criteria will be applied by the Secretary in the making of delegation and authorisation for state and territory officers.

To ensure consistency in the application of enforcement powers under the Commonwealth therapeutic goods legislation and applied laws, authorised officers and delegates must comply with any directions of the Secretary or of the person who delegated the function or power. The binding directions could relate to compliance with standard operating procedures developed by the Department of Health.

Details of specific amendments

Item 84 - Section 7A

This item makes an editorial amendment to section 7A to provide for subsection (1)

Item 85 – At the end of section 7A

This item amends section 7A of the TG Act to introduce subsection 7A(2), which provides that in exercising a power under a provision of this Act under an authorisation under subsection (1), the authorised person must comply with any directions of the Secretary.

Item 86– After subsection 57(1)

This item inserts a new subsection 57(1A) in the TG Act, which provides that the Secretary may, in writing, delegate all or any of the Secretary's powers and functions under Chapter 5A (enforcement), section 52AAA (forfeiture of things seized under search warrant) or section 52AAB (return of retention of a thing declared not to be forfeited) to an officer of:

- a Department of State of a state; or
- a Department or administrative unit of the Public Service of a territory; or
- a state or territory authority;

being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement.

The new subsection 57(1A) does not limit the delegations set out under subsection 57(1) of the TG Act.

~~Operation and formulation of the d)Delegation of these powers to sState and tTerritory officers specified in new subsection 57(1A).~~

Formatted: Font: Not Bold, Italic

Formatted: Font: Not Bold, Italic

Formatted: Indent: Left: 0 cm

The intended formulation of the delegation in subclause 57(1A) is to officers of a department, unit or authority that have functions relating to therapeutic goods, health or law enforcement. It is not intended that the delegation be limited to the head of the relevant departments and administrative units. ~~The explanatory materials will be updated to reflect this intention.~~

~~This is because it is not practical nor appropriate for enforcement related functions, such as entry, search and seizure powers to be only delegated to heads of relevant departments and administrative units. It is expected that significant enforcement activities will be required by the Commonwealth, states and territories. By way of indication of the expected extent of enforcement activities, the TGA since 1 October 2021, has seized under warrant more than 340,000 nicotine vaping products, and over 19,500 voluntarily surrendered. Enforcement related functions. This will require a number of persons with varying technical skills due to the significant amount of seizures of illicit goods that will be executed. Such powers are appropriately delegated to experienced and skilled persons who undertake investigations and related regulatory functions. It is anticipated that there may be a number of persons with different technical skills, including forensic data analysts, health officials and police officers, who will have jurisdiction to exercise powers under the applied laws.~~

The approach to delegation of these powers is an extension of the current regulatory framework, which enables state and territory officers to exercise the powers of authorised officers under the TG Act. The enforcement of controls on therapeutic goods (and proposed under this Bill, vaping goods) is carried out under a national system of controls; essentially, a federal cooperative scheme between the Commonwealth, states and territories. Consistent with the scheme, the Commonwealth will take responsibility for enforcing importation, manufacture, sponsor supply and advertisement. The states and territories will take responsibility for enforcing wholesale supply, retail supply and commercial possession.

Formatted: Indent: Left: 0 cm

The national approach to the regulation of vaping goods is a centrepiece of the vaping reforms and will be critical to the success of the measures to achieve the public health objectives. By extending the power to delegate the powers and functions of the Secretary to state and territory officers, the Bill would complement existing arrangements in relation to authorised officers and therefore further enhance the compliance and enforcement effort in Australia.

Formatted: Indent: Left: 0 cm

Finally, it is intended that the delegation of these powers and functions would be subject to a binding direction that officers must adhere to standard operating procedures created by the Secretary to ensure consistency for the carrying out of enforcement powers (refer to Item 87 below), regarding the addition of new subsection 57(12)]

Item 87 - At the end of section 57

This item introduces new subsection 57(12), which provides that in exercising any powers or performing any functions under a delegation under section 57, the delegate must comply with any directions of the person who delegated the power or function.

Item 88 - Subsection 61A(4) (at the end of paragraph (c) of the definition of protected person)

This item amends the definition of *protected person* in subsection 61A(4) of the TG Act and adds “(1A)” after “subsection 57(1)”.

Part 7—Release of information

Therapeutic Goods Act 1989

Section 61 of the TG Act principally provides for powers to release certain kinds of information to specified persons or the public, in certain circumstances. While these powers are not exhaustive of the ways in which the Department may use or release the kinds of information specified in section 61, they are an important mechanism by which the Department may inform the public, health departments, law enforcement bodies and others of certain information, including critical safety and regulatory information, in a timely manner and in accordance with specified requirements.

Most of the information release powers in section 61 permit the release of ‘therapeutic goods information’, which is defined in subsection 61(1) as being information relating to therapeutic goods that is held by the Department and that relates to the performance of the Department’s functions.

The amendments contained in this Part would create new powers to release information relating to vaping goods which mirror existing information release powers relating to therapeutic goods, and make consequential amendments to expand the application of section 61 to vaping goods.

Items 89 – Subsection 61(1)

This item inserts a new definition in subsection 61(1) of the TG Act for *vaping goods information*, which refers to information in relation to vaping goods that is held by the Department and relates to the performance of the Department’s functions.

This definition is intended to include a wide range of information concerning vaping goods and aligns with the definition of ‘therapeutic goods information’ contained in subsection 61(1).

Consistent with the definition of ‘therapeutic goods information’, the Department’s functions to which information may relate in order to be within the definition of ‘vaping goods information’ is not limited to functions under the TG Act. It may include, for example, functions under other legislation administered by the Department, such as the *National Health Act 1954*.

It is anticipated that some kinds of information may be simultaneously ‘vaping goods information’ and ‘therapeutic goods information’, such as information about a vaping device included in the Register. Such information is intended to be able to be released under one or more existing information release powers relating to therapeutic goods, one or both of the information release powers relating to vaping goods proposed in Item 137, or both.

Item 90 - After subsection 61(7)

This item inserts new subsections 61(7A), (7B), (7C) and (7D) in the TG Act.

Subsection 61(7A) will permit the Secretary to release vaping goods information of a kind specified under subsection 61(7B) to one or more persons, bodies or authorities (or one or more kinds of persons, bodies or authorities) specified under that subsection, for one or more purposes specified under that subsection.

The new subsection 61(7B) of the TG Act empowers the Minister to specify, by legislative instrument, one or more of the following:

- a person, body or authority, such as the World Health Organisation or the Department of Home Affairs;
- kinds of persons, bodies or authorities, such as state or territory health departments, or Australian law enforcement agencies;
- kinds of vaping goods information, such as information about enforcement action taken in relation to vaping goods, or all information within the meaning of ‘vaping goods information’;
- purposes, such as to support cooperation in relation to the enforcement of border controls relating to vaping goods, to promote industry awareness, or for any purpose related to the Department’s functions.

Subsections 61(7A) and (7B) reflect the existing information release powers concerning therapeutic goods contained in subsections 61(5AA) and (5AB) of the TG Act.

Subsection 61(7C) will permit the Secretary to release vaping goods information of a kind specified under subsection 61(7D) to the public. The new subsection 61(7D) of the TG Act empowers the Minister to specify, by legislative instrument, the kinds of information that the Secretary may release to the public. Subsections 61(7C) and (7D) are modelled on the existing information release powers concerning therapeutic goods contained in subsections 61(5C) and (5D) of the TG Act.

The amendments will provide flexibility for the release of a wide range of information relating to vaping goods. This may include, for example:

- providing safety alerts to the public about the dangers associated with the use of particular vaping goods (e.g. instances of vaping goods being contaminated with high levels of toxic substances), to ensure that users are informed about such risks and are able to take steps to avoid a threat to their health by not using products for which such alerts are made;
- informing Commonwealth, state and territory health authorities or law enforcement bodies about vaping goods which have been, or are suspected of having been, imported, manufactured or supplied in contravention of the TG Act; or
- informing the public about decisions or actions taken under the TG Act or its regulations in relation to vaping goods, such as information about enforcement action taken against the suppliers of prohibited vaping goods.

Items 91 to 94 (Amendments to subsection 61(8), paragraphs 61(3)(a) and (b), subsection 61(8) (note) and subsection 61(9))

Subsection 61(8) of the TG Act provides that, subject to the data protection regimes for medicines in sections 25A and 26AF of the TG Act, therapeutic goods information (as defined in subsection 61(1) of the TG Act) provided to the Department in relation to a matter may be:

- used by the Department in the consideration of another matter that relates to therapeutic goods; or
- given to a committee appointed to advise the Minister or Secretary on matters relating to therapeutic goods.

Items 91~~138~~ and 92~~139~~ are principally intended to expand the operation of subsection 61(8) so that it also applies to vaping goods information (as intended to be defined in subsection 61(1) of the TG Act). Together, these items would amend subsection 61(8) so that vaping goods information or therapeutic goods information may be:

- used by the Department in consideration of another matter that relates to therapeutic goods or vaping goods; or
- given to a committee appointed to advise the Minister or Secretary on matters relating to therapeutic goods or vaping goods.

These amendments are primarily intended to ensure that information held by the Department in relation to a particular vaping-related matter (for example, intelligence about the kinds of prohibited vaping goods attempted to be illegally imported into Australia), may be used in relation to other functions, such as broader public health policy.

Item 91~~138~~ also replaces the phrase ‘... information provided to the Department...’ with ‘... information held by the Department...’. This amendment will align subsection 61(8) with the description of information being ‘held by’ the Department in the definition of ‘therapeutic goods information’ (and the proposed definition of ‘vaping goods information’) in subsection 61(1).

This amendment is intended to clarify, for the avoidance of doubt, that the information to which subsection 61(8) applies includes information which is created or generated by the Department, and is not limited to information ‘provided to’ the Department.

It is the Department’s position that subsection 61(8) already applies to information created or generated by the Department. However, this amendment is intended to provide certainty about the application of the provision. For example, information provided to the TGA by a person when applying for the inclusion of a vaping device in the Register would be information ‘provided to’ the Department, and therefore would be within the scope of subsection 61(8). However, it may be less clear whether

Formatted: Highlight

Formatted: Highlight

the TGA's report which evaluated that application is also information 'provided to' the Department.

This amendment is intended to put beyond doubt that information like an evaluation report (or the results of testing conducted by the TGA's laboratories of a vaping substance) is information to which subsection 61(8) applies.

Item 93 139AA makes a minor amendment to the note in subsection 61(8) of the TG Act to clarify that, pursuant to section 132C of the *National Health Act 1953* (the NH Act), the Secretary of the Department may disclose therapeutic goods information 'held by' the Department to the Chief Executive Medicare for the purpose of certain data matching.

Formatted: Highlight

~~Item 139AA makes a minor amendment to the note in subsection 61(8) of the TG Act to clarify that, pursuant to section 132C of the NH Act, the Secretary of the Department may disclose therapeutic goods information 'held by' the Department to the Chief Executive Medicare for the purpose of certain data matching.~~

Formatted: Highlight

Commented [WB1]: Repeat of paragraph above

Currently, the note says than information 'provided to' the Department may be disclosed for the purpose of data-matching. However, subsection 132C(1) of the NH Act does not include the words 'provided to'. That provision instead states that the Secretary may disclose 'therapeutic goods information (within the meaning of subsection 61(1)' of the TG Act, which is relevantly defined as information 'held by' the Department. Consequently, item 139AA is intended to ensure that the note to subsection 61(8) aligns more closely with subsection 132C(1) of the NH Act.

Item 94 139A makes a minor, technical amendment to subsection 61(9) of the TG Act, to provide that an instrument made under the proposed subsections 61(7B) or (7D) may apply, adopt or incorporate, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time. In relation to vaping goods, an instrument made under those subsections might incorporate, for example, a matter contained in that might be incorporated by is a standard concerning the quality or safety of vaping devices.

Formatted: Highlight

Formatted: Highlight

The current subsection 61(9) already makes this allowance in relation to the other instrument-making powers contained in section 61, namely subsections 61(5AB) and (5D).

Item 95 - Application of amendments

This item provides that the amendments made by Part 6 of the Bill apply in relation to the release, disclosure or use of information on or after the commencement of Part 6, whether the information started to be held, or was obtained or created, before or after that commencement.

Part 8—Laboratory testing

Therapeutic Goods Act 1989

This Part contains amendments to the regulation-making powers in section 63 of the TG Act. These amendments are intended to expand existing regulation-making powers concerning the testing of therapeutic goods to include the testing of vaping goods (or any kind of goods, to ascertain whether the goods are vaping goods or therapeutic goods).

Item 96 - Paragraph 63(2)(d)

Paragraph 63(2)(d) of the TG Act provides that regulations may provide for the procedures to be followed by the Department in the sampling and testing of therapeutic goods.

This item repeals and substitutes paragraph 63(2)(d) to provide that the regulations may provide for the procedures to be followed in the sampling and testing of:

- therapeutic goods;
- vaping goods;
- any kind of goods, for the purpose of ascertaining whether the goods are therapeutic goods or vaping goods.

This amendment is intended to ensure that the regulations may make appropriate provision for the procedures to be followed by the Department or others (such as commercial testing laboratories engaged by the Department) in relation to the sampling and testing of vaping goods.

The new paragraph 63(2)(d) also enables the making of regulations to prescribe procedures for the sampling and testing of any kind of goods for the purpose of ascertaining whether or not they are therapeutic goods or vaping goods (or both). The phrase ‘any kind of goods’ is intended to capture a broad array of things, including physical possessions and digital possessions (like software).

This amendment is intended to expressly permit the making of procedures related to obtaining and testing samples of kinds of goods where, for example, it is not apparent that the goods are therapeutic goods or vaping goods until after they have been sampled and tested, or where sampling and testing would be preferable to confirm a suspicion that the goods are therapeutic goods or vaping goods.

Consistent with the current paragraph 63(2)(d), it is not intended for paragraph 63(2)(d), or regulations made under this paragraph, to exhaustively provide for:

- the ways that the Department may sample or test therapeutic goods, vaping goods, or any kind of goods for the purpose of determining whether the goods are vaping goods or therapeutic goods; or

- the procedures that the Department may or must follow when sampling or testing those kinds of goods.

Item 97 – Saving of regulations

This item provides that regulations made for the purposes of paragraph 63(2)(d) of the TG Act, which are in force immediately before the commencement of this item, continue in force for the purposes of that paragraph as in force after that commencement. This will notably include regulations contained in Part 5 of the *Therapeutic Goods Regulations 1990*.

Item 98 – Paragraph 63(2)(g)

Paragraph 63(2)(g) of the TG Act provides that the regulations may make provision for:

- the testing of therapeutic goods;
- the inspection of manufacturing operations; or
- the evaluation of data concerning therapeutic goods,

by the Department at the request of persons.

This item expands paragraph 63(2)(g) to expressly provide that the regulations may make provision for the testing of vaping goods, or the evaluation of data concerning vaping goods, by the Department at the request of persons.

Part 9—Approvals for certain Part 3-2 exempt goods

Therapeutic Goods Act 1989

Item 99 - Subsection 19(1)

This item amends subsection 19(1) of the TG Act to enable the Secretary to grant approvals under that provision—i.e., Special Access Scheme Category B (“SAS B”) and clinical trial approvals—in relation to the importation, exportation or supply of exempt goods.

Under subsection 18(1) of the TG Act, the regulations may, subject to any conditions, exempt specified therapeutic goods, or a specified class of therapeutic goods, from the operation of Part 3-2 of the TG Act (save for a small number of provisions in that Part). The effect of this provision is to enable the regulations to specify therapeutic goods, or classes of therapeutic goods, that may be imported into, manufactured in, and supplied in Australia, despite the goods not being included in the Register.

Relevantly, therapeutic vaping goods are exempt from the operation of Part 3-2 of the TG Act if, among other things:

- the only indications (i.e., therapeutic uses) of the goods are for smoking cessation or the management of nicotine dependence; and
- the sponsor of the goods, and any other person involved in the wholesale or retail supply of the goods, intend for the goods to be supplied to the ultimate consumer in accordance with an approval or authority under section 19 of the TG Act.

However, subsection 19(1) of the TG Act currently precludes the Secretary from granting SAS B and clinical trial approvals in relation to therapeutic goods that are exempt goods. As such, sponsors wishing to import, manufacture or supply unregistered therapeutic vaping goods in Australia can only do so if they intend for the goods to be supplied to the ultimate consumer in accordance with an authority granted under the TG Act (namely, under the Authorised Prescriber Scheme, which is established by subsection 19(5) of the TG Act).

This impacts the flexibility of the exemption for therapeutic vaping goods, as it establishes a barrier to legitimate patient access to such goods for smoking cessation, and the management of nicotine dependence, under appropriate clinical supervision.

Consequently, this item amends subsection 19(1) of the TG Act by omitting “registered goods, listed goods or exempt goods” and substituting “registered goods or listed goods”. This amendment ensures that the lawful supply of therapeutic vapes under the relevant exemption can operate in conjunction with SAS B and clinical trial approvals granted by the Secretary under subsection 19(1).

Part 10—Offences and civil penalty provisions for breach of condition of certain exemptions or approvals

Therapeutic Goods Act 1989

Item 100 - Section 22(5A)

This item creates a new fault-based offence with an aggravating factor if a person does an act, or omits to do an act and the act or omission results in the breach of a condition of an exemption applicable under regulations made for the purposes of subsection 18(1) or a condition of approval under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A) or a condition of an approval under section 19A and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

The maximum penalty is imprisonment for 5 years or 4,000 penalty units or both. The notes for this subsection provide that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A and refers to section 54B and 54BA in relation to the liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the supply of unapproved therapeutic goods which do not comply with a condition of an unapproved supply pathway under the TG Act in Australia caused by corporate offending. Such unapproved therapeutic goods may include vaping goods. The liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Item 101 - At the end of subsection 22(7)

This item amends this subsection by adding that the maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

Item 102 - Subsection 22(7AA)

This item repeals the existing subsection and substitutes with an offence of strict liability if a person does an act, or omits to do an act and the act or omission results in the breach of a condition of an exemption applicable under regulations made for the purposes of subsection 18(1) or a condition of approval under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A) or a condition of an approval under section 19A. The maximum penalty is 100 penalty units.

Item 103 – Section 22AA (heading)

Formatted: Keep with next

This item omits “a condition of an exception” and substitutes it with “conditions”.

Item 104 – Section 22AA

This item inserts “(1)” before “A person”.

Item 105 – Section 22A

This item omits “this section” and substitutes it with “subsection”.

Item 106 – At the end of section 22AA

This item creates a civil penalty provision if a person does an act, or omits to do an act and the act or omission results in the breach of a condition of an exemption applicable under regulations made for the purposes of subsection 18(1) or a condition of approval under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A) or a condition of an approval under section 19A. The maximum penalty for an individual is 5,000 penalty units and 50,000 penalty units for a body corporate.

Item 107 - Subsection 41HA(2) (note)

This item omits “subsection 41MN(9)” and substitutes it with “subsections 41MN(9), (9A) and (9B)”.

Item 108 - Subsection 41HB(2) (note)

This item omits “subsection 41MN(9)”, substitutes it with “subsections 41MN(9), (9A) and (9B)”.

Item 109 - Subsection 41HB(7) (note)

This item omits “subsection 41MN(9)”, substitutes it with “subsections 41MN(9), (9A) and (9B)”.

Item 110 - Subsection 41HD(7) (note)

This item omits “subsection 41MN(9)”, substitute “subsections 41MN(9), (9A) and (9B)”.

Item 111 - Subsection 41MN(9)

This item repeals the existing subsection, and substitutes it with offences relating to breaching a condition of an exemption or approval, or a condition applicable under regulations.

The new subsection (9) creates a fault-based offence with an aggravating factor if a person does an act or omits to do an act and the act or omission breaches a condition

of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2) and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

The maximum penalty is imprisonment for 5 years or 4,000 penalty units or both. The notes for this subsection provide that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A and refers to section 54B and 54BA in relation to the liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the supply of unapproved therapeutic goods which do not comply with a condition of an unapproved supply pathway under the TG Act in Australia caused by corporate offending. Such unapproved therapeutic goods may include vaping goods. The liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

The new subsection (9A) creates a fault-based offence if a person does an act or omits to do an act and the act or omission breaches a condition of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2). The maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

The new subsection (9B) creates an offence of strict liability if a person does an act or omits to do an act and the act or omission breaches a condition of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2). The maximum penalty is 100 penalty units.

Item 112 – After subsection 41MNA(2)

This item inserts subsection (2A) after subsection (2) and creates a civil penalty provision if a person does an act or omits to do an act and the act or omission breaches a condition of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2).

The maximum civil penalty is 5,000 penalty units for an individual and 50,000 for a body corporate.

Item 113 - Section 53A (after table item 9A)

This item inserts new table item 9B into the table in section 53A of the TG Act. Section 53 provides for alternative verdicts for various offences.

Item 114 - Section 53A (after table item 31)

This item inserts new table item 31 AA into the table in section 53A of the TG Act. Section 53A provides for alternative verdicts for various offences.

Item 115 - Section 54BA (table item 5)

This item inserts “(6)” after “22(2)” in item 5 in the table.

Item 116 - Section 54BA (table item 40)

This item inserts “(9)” after “(5)” in item 40 in the table.

Item 117 - Application of amendments

This item provides that the amendments of the *Therapeutic Goods Act 1989* made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 11—Other amendments

Therapeutic Goods Act 1989

Item 118 - After subsection 58(2)

Section 58 provides for export certifications. Subsection 58(1) provides that the Secretary may issue export certification for goods for therapeutic use in humans. Subsection 58(2) then provides that a state or territory must not issue like export certifications.

This item inserts new subsections 58(2A) and (2B), which are analogous to the existing subsections 58(1) and (2). Subsection 58(2A) will permit the Secretary to issue export certifications for vaping goods for use in humans, except goods for which export certifications may be used under subsection 58(1). Subsection 58(2B) will provide that a state or territory must not issue like export certifications.

Consequently, it is intended for export certifications concerning therapeutic vaping goods to be issued under subsection 58(1), and export certifications concerning non-therapeutic vaping goods to be issued under subsection 58(2A).

Additionally, it is intended that the existing subsection 58(3) will apply to the new subsection 58(2A). Therefore, fees may be prescribed in respect of an application for a certification under subsection 58(2A), or the inspection of a manufacturing site if necessary for the purposes of the issue of a certification under subsection 58(2A).

Items 119 and 120 (Amendments to subsection 61A(4) (after paragraph (g) of the definition of *protected person* and paragraph (h) of the definition of *protected person*)

Item 119 inserts new paragraph (ga) into the definition of ‘protected person’ contained in subsection 61A(4) of the TG Act, to provide that the regulations may prescribe kinds of persons who are ‘*protected persons*’ for the purposes of subsection 61A(1).

Subsection 61A(1) of the TG Act provides the Commonwealth and protected persons with immunity from civil actions or proceedings in certain circumstances. Relevantly, it provides that no civil action lies against a protected person in respect of loss, damage or injury that is suffered by another person, because of an act or omission of the protected person in connection with their performance or exercise, or purported performance or exercise, of a function, duty or power under the TG Act or regulations. An act or omission in connection with the purported performance or exercise of a relevant function, duty or power includes, for example, an act done in accordance with the purported exercise of a power under the TG Act, but where it is later determined that the decision to exercise that power was of no legal effect because it was infected by jurisdictional error.

Importantly, however, the immunity conferred by subsection 61A(1) of the TG Act does not apply in relation to an act or omission of the Commonwealth or a protected person in bad faith (subsection 61A(2)).

Subsection 61A(4) of the TG Act specifies the kinds of persons who are protected persons for the purposes of section 61A. The list includes, for example, the Minister, the Secretary, persons to whom a power of the Minister or Secretary has been delegated under the TG Act, and persons and officers that the Secretary has authorised to perform certain functions and exercise certain powers under the TG Act and its regulations.

However, the list of protected persons does not include all persons who may perform or exercise a function, duty or power under the TG Act or its regulations. For example, it does not expressly include an officer of the Department to whom powers or functions under the MD Regulations are delegated under regulation 10.5 of those regulations.

Consequently, item 119 amends subsection 61A(4) to provide flexibility to, by regulation, broaden the range of persons to whom the immunity in subsection (1) applies.

This will ensure that, for example, any new category of persons empowered to perform functions under the regulations may be subject to the immunity (by disallowable regulation), without the need for a commensurate amendment to the TG Act.

Item 120 makes a minor, consequential amendment to paragraph (h) of the definition of ‘protected person’. Paragraph (h) provides that a ‘protected person’ includes a person assisting any person referred to in another paragraph of the definition of ‘protected person’ (i.e. paragraphs (a) to (g)) in certain circumstances. Item 120 expands paragraph (h) to also include a person assisting a person of a kind prescribed as a protected person under regulation made under paragraph (ga).

Items 121 to 123 (Amendments to subsection 62(1), subsection 62(2) and at the end of section 62)

These items amend section 62 of the TG Act to provide flexibility to, by regulation, broaden the range of persons that are protected from criminal responsibility when carrying out certain investigatory actions under the TG Act or its regulations.

Section 62 enables APS employees in the Department to obtain, possess or convey (or facilitate the conveyance of) goods—in circumstances where such conduct would ordinarily be an offence against a Commonwealth law or a state law (which is defined in section 3 of the TG Act as meaning a law of a state, the Australian Capital Territory, or the Northern Territory)—for the purposes of identifying whether the TG Act or its regulations have been complied with.

Enforcement of the vaping reforms will require the engagement and cooperation of state and territory officials (and Commonwealth officials outside of the Department) in assessing compliance with the TG Act and its regulations.

For example, a state or territory official may seize or purchase vaping goods within their jurisdiction, and then arrange for the same to be conveyed to the TGA for

testing. As section 62 of the TG Act does not currently apply in relation to such cases, the relevant official may be prohibited from doing so (particularly if the goods contain, or are, prescription medicines).

Consequently, it is necessary to extend the protection that is provided by section 62 so that it also applies to persons other than APS employees in the Department. The amendments made by these items give effect to this measure, by providing flexibility to, by disallowable regulation, prescribe kinds of persons as protected persons.

Specifically, item 123 inserts new subsection 62(3) in the TG Act, which provides that for the purposes of section 62, a protected person means:

- an APS employee in the Department; or
- a person of a kind prescribed by the regulations.

Items 121 and 122 make minor, consequential amendments to subsections 62(1) and (2) of the TG Act, by omitting references to “[an] APS employee in the Department” and substituting “[a] protected person”.

SCHEDULE 2 – Amendment of the *Customs Act 1901*

Background

The *Customs Act 1901* (the Customs Act) provides for the forfeiture of a range of goods upon importation into Australia. This includes all smuggled or unlawfully imported goods and all prohibited imports. The *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations) prescribe goods as prohibited imports for the purposes of the Customs Act. Since 1 January 2024, vaping goods imported without permission are prohibited imports for the purposes of the Customs Act. Prohibited imports fall within the definition of ‘special forfeited goods’, and can be seized with or without a warrant in certain circumstances.

Subdivision G of Division 1 of Part XII of the Customs Act sets out a process for dealing with goods which have been seized as forfeited goods. The Customs Act currently requires seized prohibited imports to be stored in an approved place for a minimum of 30 days before they can be disposed of. The Customs Act also requires that a seizure notice be served on the owner of the goods, or if the owner cannot be identified, on the person in whose possession or under whose control the goods were at the time of seizure. The owner or person in possession may make a claim for the return of seized goods. If no claim is made within 30 days after the day the seizure notice is served, the goods are taken to be condemned as forfeited to the Crown.

Existing section 206 provides that certain goods may be dealt with outside of this process. Relevantly, subsection 206(2A) states that where:

- goods are seized under the relevant provisions of the Customs Act; and
- the Comptroller-General of Customs is satisfied the goods are a prohibited psychoactive substance, tobacco products or a prohibited serious drug alternative;

then the Comptroller-General may cause the goods to be dealt with in such a manner as he or she considers appropriate (including the destruction of the goods). This can include the immediate destruction of the goods which provides streamlined administrative processes and reduced storage time.

Applying this approach to seized vaping goods will significantly enhance the ability of Australian Border Force officials to effectively deal with imported vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.

Effect of the amendments

The Bill has one substantive amendment to the Customs Act that would amend section 206 of the Customs Act to extend the provision’s coverage to ‘vaping goods’ as defined in regulation 5A of the CPI Regulations, and three consequential amendments that would give operational effect to the arrangements for vaping goods.

The substantive amendment will allow the Comptroller-General of Customs to immediately destroy (or otherwise deal with) vaping goods which have been seized as prohibited imports under the Customs Act. The term ‘vaping goods’ is defined in regulation 5A of the CPI Regulations to capture a vape, a vape accessory, or a vape substance.

Owners of vaping goods destroyed under subsection 206(2B) may have the right to recover the market value of the goods, if they can establish that the circumstances required to trigger the destruction did not exist. If the Comptroller-General deals with goods under subsection 206(2B), within seven days of doing so they must give or publish a notice which identifies the goods, provides details of the manner in which the goods have been dealt with and the reasons for doing so, and sets out the owner’s right to seek recovery of the market value.

The amendments to the Customs Act in this Bill would have a positive impact on the Australian Government’s ability to effectively regulate vaping goods by empowering the Comptroller-General of Customs to cause vaping goods seized as prohibited imports to be dealt with in a manner he or she considers appropriate, including the immediate destruction of the goods.

Customs Act 1901

The Customs Act provides for the forfeiture of a range of goods upon importation into Australia. This includes all smuggled or unlawfully imported goods and all prohibited imports. The CPI Regulations prescribe goods as prohibited imports for the purposes of the Customs Act.

Prohibited imports fall within the definition of ‘special forfeited goods’, and can be seized with or without a warrant in certain circumstances.

Schedule 2 to the Bill contains amendments to the Customs Act that will result in a positive impact on the Australian Government’s ability to effectively regulate vaping goods by empowering the Comptroller-General of Customs to cause vaping goods seized as prohibited imports to be dealt with in a manner the Comptroller-General considers appropriate, including the immediate destruction of the goods.

Item 1 - Subsection 183UA(1)

This item inserts a new definition of ‘vaping goods’ into subsection 183UA(1) of Subdivision A of Division 1 of Part XII of the Customs Act, which deals with the powers of officers. Since 1 January 2024, ‘vaping goods’ imported without permission are prohibited imports for the purposes of the Customs Act.

This ‘framework’ definition provides that, in Division 1 of Part XII of the Customs Act, ‘vaping goods’ has the same meaning as in regulation 5A of the CPI Regulations, which currently captures a vape, a vape accessory, or a vape substance.

The reason the definition for this term is in delegated legislation rather than on the face of the Customs Act is that it is vital to have flexibility in the definition, to enable

rapid amendments to cater for novel and unanticipated forms of ‘vaping goods’. Despite the broad range of ‘vaping goods’ that are currently prohibited imports under this definition, an attempted importation of goods in novel and unanticipated forms that would be ‘vaping goods’ but would not readily fit within the current definition is still a possibility and may pose a risk to population health and would also threaten to disrupt the significant achievements that Australia has made in tobacco and vaping goods control to date.

Retaining the definition in delegated legislation is therefore important, as that definition could be readily amended to capture a new range of standards, codes and other international regulatory instruments that may have relevant material applying to emerging developments in the ‘vaping goods’ industry. It is also important to note that any future amendments to the defined term in delegated legislation would be subject to Parliamentary scrutiny and disallowance.

Item 2 - After subsection 206(2A)

Subdivision G of Division 1 of Part XII of the Customs Act sets out a process for dealing with goods which have been seized as forfeited goods. The Customs Act currently requires seized prohibited imports to be stored in an approved place for a minimum of 30 days before they can be disposed of. The Customs Act also requires that a seizure notice be served on the owner of the goods, or if the owner cannot be identified, on the person in whose possession or under whose control the goods were at the time of seizure. The owner or person in possession may make a claim for the return of seized goods. If no claim is made within 30 days after the day the seizure notice is served, the goods are taken to be condemned as forfeited to the Crown.

Section 206 of the Customs Act concerns goods that may be dealt with outside of the afore-mentioned process. By way of an example, subsection 206(2A) of the Customs Act provides that, if

- (a) goods are seized under the relevant provisions of the Customs Act; and
- (b) the Comptroller-General of Customs is satisfied the goods are a prohibited psychoactive substance, tobacco products or a prohibited serious drug alternative;

then the Comptroller-General may cause the goods to be dealt with in such a manner as the Comptroller-General considers appropriate (including the destruction of the goods).

This item amends section 206 of the Customs Act to insert a new subsection (2B), which would extend the provision’s coverage to ‘vaping goods’. Specifically, new subsection 206(2B) provides that, if:

- (a) goods are seized under a seizure warrant or under subsection 203B(2) or (2A), 203CA(3) or 203CB(2); and
- (b) the Comptroller-General of Customs is satisfied that the goods are vaping goods that are prohibited imports;

the Comptroller-General of Customs may cause the goods to be dealt with in such manner as the Comptroller-General considers appropriate (including the destruction of the goods).

The manner in which seized vaping goods that are prohibited imports can be dealt with can include the immediate destruction of the goods, providing streamlined administrative processing and reduced storage time.

The purpose of this amendment is to provide authority for regulating ‘vaping goods’ by empowering the Comptroller-General of Customs to cause ‘vaping goods’ seized as prohibited imports to be dealt with in a manner the Comptroller-General considers appropriate, including the immediate destruction of the goods. This amendment will significantly enhance the ability of Australian Border Force officials to effectively deal with imported vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.

Item 3 - Subsection 206(3)

Subsection 206(3) of the Customs Act requires that, as soon as practicable, but not later than 7 days after the goods referred to in subsection (1), (1A), (2) or (2A) have been dealt with, the Comptroller-General of Customs must give or publish a notice in accordance with subsection (5).

This item makes a consequential amendment to subsection 206(3) and has the effect of extending the requirement under subsection 206(3) to goods that have been dealt with under new subsection 206(2B).

Item 4 - Paragraph 206(5)(c)

Subsection 206(5) of the Customs Act provides that the notice must:

- (a) identify the goods; and
- (b) state that the goods have been seized under a seizure warrant or under subsection 203B(2) or (2A), 203CA(3) or 203CB(2) and give the reason for the seizure; and
- (c) state that the goods have been dealt with under subsection (1), (1A), (2) or (2A) and specify the manner in which they have been so dealt with and the reason for doing so; and
- (d) set out the terms of subsection (6).

This item makes a consequential amendment to paragraph 206(5)(c) and has the effect of extending the notice requirements under that provision to goods that have been dealt with under new subsection 206(2B).

Item 5 - Subsections 206(6) and (7)

Formatted: Keep with next

This item contains an amendment to both subsections 206(6) and (7) of the Customs Act.

Subsection 206(6) of the Customs Act provides that, if goods are dealt with in accordance with subsection (1), (1A), (2) or (2A), the owner of the goods may bring an action against the Commonwealth in a court of competent jurisdiction for the recovery of the market value of the goods at the time they were so dealt with.

This item makes a consequential amendment to subsection 206(6) to extend the right to recover the market value of seized goods that have been dealt with under new subsection 206(2B).

Subsection 206(7) of the Customs Act specifies the circumstances in which a person's right to recover the market value of seized goods that have been dealt with under section 206 is enlivened.

This item makes a consequential amendment to subsections 206(7) to apply the circumstances in which the right to recover the market value of seized goods, to goods that have been dealt with under new subsection 206(2B).

The purpose of this clause is to permit the owners of 'vaping goods' destroyed under subsection 206(2B) the right to recover the market value of the goods, if they can establish that the circumstances required to trigger the destruction did not exist. If the Comptroller-General deals with goods under subsection 206(2B), within seven days of doing so they must give or publish a notice which identifies the goods, provides details of the manner in which the goods have been dealt with and the reasons for doing so, and sets out the owner's right to seek recovery of the market value.

SCHEDULE 3 – AMENDMENTS OF OTHER ACTS

Industrial Chemicals Act 2019

Item 1 - Section 8

This item inserts the term “vaping goods” into the Simplified Outline of the *Industrial Chemicals Act 2019*. This ensures that vaping goods are included in the exception of chemicals that are not industrial chemicals, such as chemicals for therapeutic purposes.

Item 2 – Section 9 (after paragraph (d) of the definition of *industrial use*)

This item inserts new paragraph (da) in section 9 of the *Industrial Chemicals Act 2019* to provide that the definition of *industrial use* means a use other than (or in addition to) use as a vaping good (within the meaning of the TG Act) or in the preparation of such a good.

Public Health (Tobacco and Other Products) Act 2023

Item 3 – Section 64

This item amends section 64 of the *Public Health (Tobacco and Other Products) Act 2023* to add a reference to Part 5-1A of the TG Act. New Part 5-1A regulates the advertising of vaping goods, and associated information about vaping goods.

Section 64 provides for the interaction of Part 2.4, Division 1 of the *Public Health (Tobacco and Other Products) Act 2023* with Part 5-1 of the TG Act.

Item 4 - Section 64

This item adds a reference to “vaping goods” to section 64 of the *Public Health (Tobacco and Other Products) Act 2023*. Section 64 currently provides for therapeutic goods and this amendment ensures that vaping goods are also included for the purposes of this section.

Section 64 provides for the interaction of Part 2.4, Division 1 of the *Public Health (Tobacco and Other Products) Act 2023* with the TG Act.

From: s22
To: Minister Butler DLO; GILMOUR-WALSH, Bridget; EDLINGTON, Mandy
Cc: s22; GOODCHILD, Tiali; s22; legislation
Subject: RE: CIRCULATED - CW 2668 - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]
Date: Monday, 24 June 2024 6:52:06 PM
Attachments: image002.png
 image004.jpg
 image005.png

(Govt position oppose)

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Monday, June 24, 2024 6:51 PM
To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>
Cc: s22 @Health.gov.au; s22 @Health.gov.au; s22 @Health.gov.au; GOODCHILD, Tiali <Tiali.Goodchild@health.gov.au>; s22 @health.gov.au; s22 @health.gov.au; s22 @health.gov.au; legislation <legislation@health.gov.au>
Subject: FW: CIRCULATED - CW 2668 - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]
 Hi Bridget and Mandy
 Please see attached substantive amendment to be moved by Senator Roberts.
 Can the MO please have talking points to support debate and any relevant advice via email by **11am tomorrow (Tuesday)**?

Thanks

s22

s22 (he/him)
 Departmental Liaison Officer

Office of the Hon Mark Butler MP
 Minister for Health and Aged Care
 T: s22 | M s22
 E: Minister.Butler.DLO@health.gov.au
 Suite MG.50 | PO Box 6022
 Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Senate Parliamentary Liaison Office <SenatePLO@pmc.gov.au>
Sent: Monday, June 24, 2024 6:16 PM
To: s22 @Health.gov.au; s22 @health.gov.au; Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>; s22 @health.gov.au; s22 @health.gov.au; s22 @health.gov.au; legislation <legislation@health.gov.au>
Cc: s22 @aph.gov.au; s22 @aph.gov.au; chieflaborwhip.senate@aph.gov.au; s22 @pm.gov.au; s22 @finance.gov.au; s22 (Sen A. Urquhart) @aph.gov.au; s22 @finance.gov.au; s22 @pm.gov.au; s22 (Sen P. Wong) @aph.gov.au; Senate Parliamentary Liaison Office <SenatePLO@pmc.gov.au>
Subject: CIRCULATED - CW 2668 - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]

OFFICIAL

Good evening

Please find attached the following amendment to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024, to be moved by Senator Roberts on behalf of the Pauline Hanson's One Nation Party in committee of the whole:

- 2668

Kind regards,

Mark

Mark McCormack

Assistant Secretary | Parliamentary Liaison Officer to the Senate

Department of the Prime Minister & Cabinet

SG89 Parliament House, Canberra

p. (02) 6277 7597 | m. s22

Ngunnawal Country, One National Circuit, Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600

e. mark.mccormack@pmc.gov.au w. pmc.gov.au



The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

From: s22
To: [EDLINGTON, Mandy](#)
Cc: s22
Subject: Amendments TPs [SEC=OFFICIAL]
Date: Sunday, 23 June 2024 9:25:12 PM
Attachments: [Amendment Talking Points - Government Amendments.docx](#)
[image001.png](#)

Hey Mandy,

Would you mind fact checking the attached TPs and just checking if I'm glaringly missing something from the amendments. I am slightly delirious so there is every chance I have. We are briefing Min McCarthy at 9:30am so helpful if it's before then but obviously aware all of your deadlines seem to be landing around then...

Thanks

s22
s22 (He/Him)

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

E: s22 [@health.gov.au](#)

P: s22

M: s22

Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

In moving these Government amendments I'd like to on behalf of the Government extend my thanks to Senators Pocock, Lambie and the Greens – in particular Senator Steele-John - for their collaboration on these amendments and their support for the Bill.

Senators Pocock and Lambie have been strident supporters of the Bill from the beginning and their public support has gone a long way to ensuring this Bill looks to pass the Parliament.

I'm pleased we've been able to work constructively with these Senators and the Greens on the amendments I move which will strengthen the Bill. The amendments ensure legitimate access to therapeutic vaping goods is not unduly obstructed, while fulsome controls remain in place and enforcement agencies are given adequate powers to take action against the illicit vaping trade which has run rampant for too long.

The Bill will operate as initially proposed for a period of 3 months. For this period patients should consult their doctors on smoking and vaping cessation, and for those patients recommended to use therapeutic vaping products as cessation aids, these products will be available at a pharmacy with a script.

During this period the Government will work with pharmacists and public health experts to develop guidance, resources and training to assist pharmacists to play a more active role in supporting smokers and vapers to access therapeutic vaping products.

On 1 October 2024 nicotine vaping products will be down scheduled to schedule 3 of the poisons standard, to enable their supply from pharmacists only – without the need for a script from a doctor.

In order to access vaping products through this pathway, individuals must:

- Be over 18
- Produce identification
- Have a conversation with a pharmacist about the suitability of vaping products to their situation, and alternative smoking cessation methods and resources

This will ensure patients can access the therapeutic vaping products they need and will empower pharmacists to play a larger role in smoking and vaping cessation.

The amendments will also alter the offence provisions in the Bill.

The possession of less than a commercial quantity of vaping goods will now only apply to retailers in a retail setting, ensuring the Government's intention to only capture commercial actors with the offence provisions of the Bill is made clearer. A defence will be

available to individuals such as retail workers who are in possession of a permitted quantity of vaping goods, which will be determined in regulation.

The offence provisions are further clarified by making available a personal use exemption under the possession of greater than a commercial quantity of vaping goods offence, which will apply where an individual possesses up to 5 times a commercial quantity of vaping goods, provided they are for their personal use and have been lawfully supplied.

Amendments to the Bill will also require a statutory review of the reforms after 3 years, further restrict advertising of vaping goods to health professionals, and expand the ability of the owners of seized vaping goods to forfeit the goods if they were seized prior to commencement of the Bill.

In response to the recommendations of the Senate Standing Committee on the Scrutiny of Bills, amendments are made to:

- Make enforceable directions issues under powers in the Bill subject to an internal merits review and independent merits review by the administrative appeals tribunal; and
- Create a new power for the Minister to make a legislative instrument determining matters the Secretary will be required to take into account in deciding whether to grant consent for the manufacture, supply or possession of a vaping good.

I again thank Senators for their collaboration on these amendments which strengthen the Bill and clarify the Government's objectives. I commend the amendments to the Senate.

From: s22
To: EDLINGTON, Mandy; s22
Cc: HENDERSON, Nick; GILMOUR-WALSH, Bridget; s22
Subject: RE: Amendment regulation package (soft copies) [SEC=OFFICIAL]
Date: Sunday, 23 June 2024 8:13:01 PM
Attachments: image001.png
 image001.png
 Boxer_1705833035141024_inline_signature.jpg

Marvellous, thank you Mandy! The Minister is reviewing the sub and previous versions of the attachments this evening. We'll make sure you receive it prior to 9am tomorrow.

Thanks

s22 (He/Him)

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

E: s22 @health.gov.au

P: s22

M: s22

Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

On 23 June 2024 at 7:39:02 PM AEST, EDLINGTON, Mandy

<Mandy.Edlington@health.gov.au> wrote:

Dear s22

s42 & s47C

– please note (if MPS enquires) that provided oral confirmation today by telephone that we did not require a written waiver.

we need to return the signed package to EXCO by 9.00AM tomorrow morning to meet their deadlines so that the amendment regulations can proceed to be considered and made by the GG on Friday.

Kind regards

Mandy Edlington

General Counsel (Acting)

Vaping Legislative Reform Branch
 Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 2910 | E: mandy.edlington@health.gov.au
 PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: EDLINGTON, Mandy

Sent: Sunday, June 23, 2024 12:20 PM

To: s22 [REDACTED]@Health.gov.au; s22 [REDACTED]
 s22 [REDACTED]@Health.gov.au; s22 [REDACTED]
 s22 [REDACTED]@Health.gov.au

Cc: HENDERSON, Nick <Nick.Henderson@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>;
 s22 [REDACTED]@health.gov.au

Subject: Amendment regulation package (soft copies) [SEC=OFFICIAL]

Importance: High

Dear s22 [REDACTED]

Confirming that the regulation amendment package *attached* has been cleared by BGW and Nick Henderson (Acting Deputy Secretary) and submitted through PDMS today.

With thanks

Mandy Edlington
 General Counsel (Acting)

Vaping Legislative Reform Branch
 Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 2910 | E: mandy.edlington@health.gov.au
 PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

[SEC=OFFICIAL]

From: [REDACTED]
To: EDLINGTON, Mandy; s22 [REDACTED]
Cc: GILMOUR-WALSH, Bridget; HENDERSON, Nick; GOODCHILD, Tiali; s22 [REDACTED]; BEDFORD, Chris; MCLAY, Nicole; s22 [REDACTED]
Subject: Re: FW: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]
Date: Thursday, 20 June 2024 5:16:11 PM
Attachments: image001.png
 image020.png
 image023.jpg
 image024.jpg
 image025.jpg
 image026.png
 image002.png
 image003.jpg
 image005.jpg
 image007.jpg
 image004.png
 image001.png
 image016.png
 image020.png
 image023.jpg
 image024.jpg
 image025.jpg
 image026.png
 image002.png
 image003.jpg
 image005.jpg
 image007.jpg
 image004.png
 Boxer_1705833035141024_inline_signature.jpg

Thanks Mandy. I'll chat to you about timelines on this tomorrow after we meet with the Greens

Thanks

s22 [REDACTED] (He/Him)

Office of the Hon Mark Butler MP
 Minister for Health and Aged Care

E: s22 [REDACTED]@health.gov.au

P: s22 [REDACTED]

M: s22 [REDACTED]

Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

On 20 June 2024 at 5:11:34 PM AEST, EDLINGTON, Mandy

<Mandy.Edlington@health.gov.au> wrote:

For information – PM&C has confirmed that separate policy approval would be required from AM Gorman next week once conditions are settled.

Mandy Edlington
 General Counsel (Acting)

Vaping Legislative Reform Branch
 Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 2910 | E: mandy.edlington@health.gov.au

PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the

Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Sent: Thursday, June 20, 2024 4:05 PM
To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Cc: s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

OFFICIAL

Hi Mandy, that is correct. Minister Butler needs to secure separate policy approval for the conditions that would be agreed to, or moved by, the Government. Apologies for the delay – I was triple checking with my lego contact.

Kind regards,

From: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>
Sent: Thursday, 20 June 2024 3:23 PM
To: s22 [REDACTED] <[REDACTED]@pmc.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Cc: [REDACTED] <[REDACTED]@pmc.gov.au>
Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

Hi [REDACTED] – the conditions would be specified in the bill to amend delegated legislation – so presumably, we would need to seek separate policy approval from Gorman in relation to the conditions that would be agreed to, or moved by, the Government next week as part of the down scheduling?

Mandy Edlington
 General Counsel (Acting)

Vaping Legislative Reform Branch

Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care

T: 02 6289 2910 | E: mandy.edlington@health.gov.au

PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Sent: Thursday, June 20, 2024 3:03 PM
To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Cc: s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

OFFICIAL

Hi Mandy,

47C

[REDACTED]

47C [REDACTED] – and can happen quite quickly.

Hope that helps!

From: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>
Sent: Thursday, 20 June 2024 2:17 PM
To: s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>
Cc: s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>
Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

Confirming receipt! Thank you so much. Just one question, 47C [REDACTED]

Mandy Edlington
 General Counsel (Acting)

Vaping Legislative Reform Branch
 Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: 02 6289 2910 | E: mandy.edlington@health.gov.au

PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>
Sent: Thursday, June 20, 2024 2:08 PM
To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>
Cc: s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>
Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

OFFICIAL

Hi Bridget and Mandy – just sent the signed response to your protected emails. Let me know if it doesn't come through ☺

From: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>

Sent: Thursday, 20 June 2024 11:42 AM

To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>

Cc: FREEBAIRN, Will <Will.Freebairn@health.gov.au>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 [REDACTED] <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>;
 s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>;
 s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>

Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

Hi [REDACTED] – a big thank you from me also – we really appreciate all the assistance.

Bridget0

Dr Bridget Gilmour-Walsh
Principal Legal and Policy Adviser

Regulatory Legal Services | Health Products Regulation Group
Australian Government, Department of Health and Aged Care
T: 02 6289 4290 | E: bridget.gilmour-walsh@health.gov.au

Location: Scherger Drive 2.N.119

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Sent: Thursday, June 20, 2024 11:19 AM

To: s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>

Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>;

s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>;

s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>

Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms)
[SEC=OFFICIAL]

Dear [REDACTED] – thanks so much for your response! We really appreciate the support that your team is providing, and note your 47C [REDACTED]

[REDACTED]. We will keep you informed. Kind regards,

Mandy Edlington
General Counsel (Acting)

Vaping Legislative Reform Branch
Regulatory Legal Services Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: 02 6289 2910 | E: mandy.edlington@health.gov.au

PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>

Sent: Thursday, June 20, 2024 10:37 AM

To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>;

s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>;

s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 <[REDACTED]>

s22 <[REDACTED]> <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>

Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms)
[SEC=OFFICIAL]

OFFICIAL

Hi Mandy,

Sorry for the delay in responding, I tried calling you yesterday amongst the mad rush, but must have missed you.

Firstly, thank you for answering all our questions and sharing your briefing materials – this was very helpful! With your help, we were able to progress our brief and draft response letter to the PMO last night.

For your visibility, the draft ^{47C}

[REDACTED] but no

guarantees! Will share the signed copy once we receive it.

I understand you might have chatted to [REDACTED] in our lego team regarding what can be shared with states and territories. Just wanted to add, while the draft amendments/lego cannot be shared (verbatim) at this stage, you may like to consider ^{47C}

[REDACTED] Happy to chat more if needing more clarity on this.

All the best with the National E-Cigarette Working Group meeting today! Keep us updated on any further developments, as we understand how fast this moves ☺

Kind regards,

[REDACTED] (she/her) | Adviser

Population Health, Primary Care and Sport | Health and Aged Care Branch

Intergovernmental Relations and Reform Division | Department of the Prime Minister and Cabinet

p. [REDACTED] | e. ^{s22} [REDACTED] @pmc.gov.au | w. pmc.gov.au

Ngunnawal Country, One National Circuit Barton ACT 2600 | P.O. Box 6500 CANBERRA ACT 2600



<!--[if !vml]--><!--[endif]-->The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

From: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Sent: Wednesday, 19 June 2024 1:32 PM

To: ^{s22} [REDACTED] @pmc.gov.au>

Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-

WALSH@Health.gov.au>; ^{s22} [REDACTED] @health.gov.au>;

^{s22} [REDACTED] @health.gov.au>; ^{s22} [REDACTED]

^{s22} [REDACTED] @health.gov.au>; ^{s22} [REDACTED] @pmc.gov.au>;

^{s22} [REDACTED] @pmc.gov.au>; ^{s22} [REDACTED]

^{s22} [REDACTED] @pmc.gov.au>; ^{s22} [REDACTED]

^{s22} [REDACTED] @health.gov.au>; ^{s22} [REDACTED]

^{s22} [REDACTED] @Health.gov.au>

Subject: RE: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms)

[SEC=OFFICIAL]

Importance: High

Dear [REDACTED]

Apologies for the delay. As, discussed, please find our responses *below* and relevant materials *attached*.

Mandy Edlington

General Counsel (Acting)

Vaping Legislative Reform Branch

Regulatory Legal Services Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: 02 6289 2910 | E: mandy.edlington@health.gov.au

PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>

Sent: Wednesday, June 19, 2024 12:05 PM

To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Cc: s22 [REDACTED] <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>

Subject: : INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

Can you review and send with attachments – I will go to comms meeting

From: s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>

Sent: Tuesday, June 18, 2024 5:56 PM

To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@health.gov.au](mailto:[REDACTED]@health.gov.au)>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>; s22 [REDACTED]

s22 [REDACTED] <[\[REDACTED\]@pmc.gov.au](mailto:[REDACTED]@pmc.gov.au)>

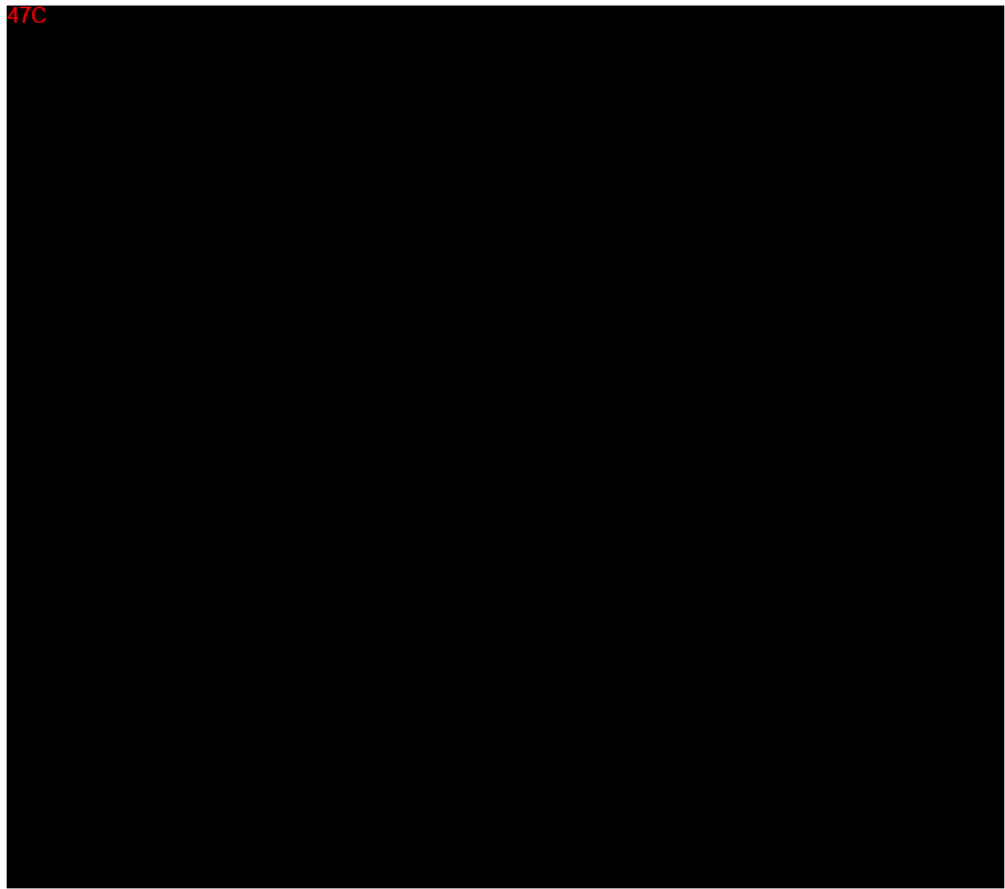
Subject: INPUT by MIDDAY 19/06: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

OFFICIAL

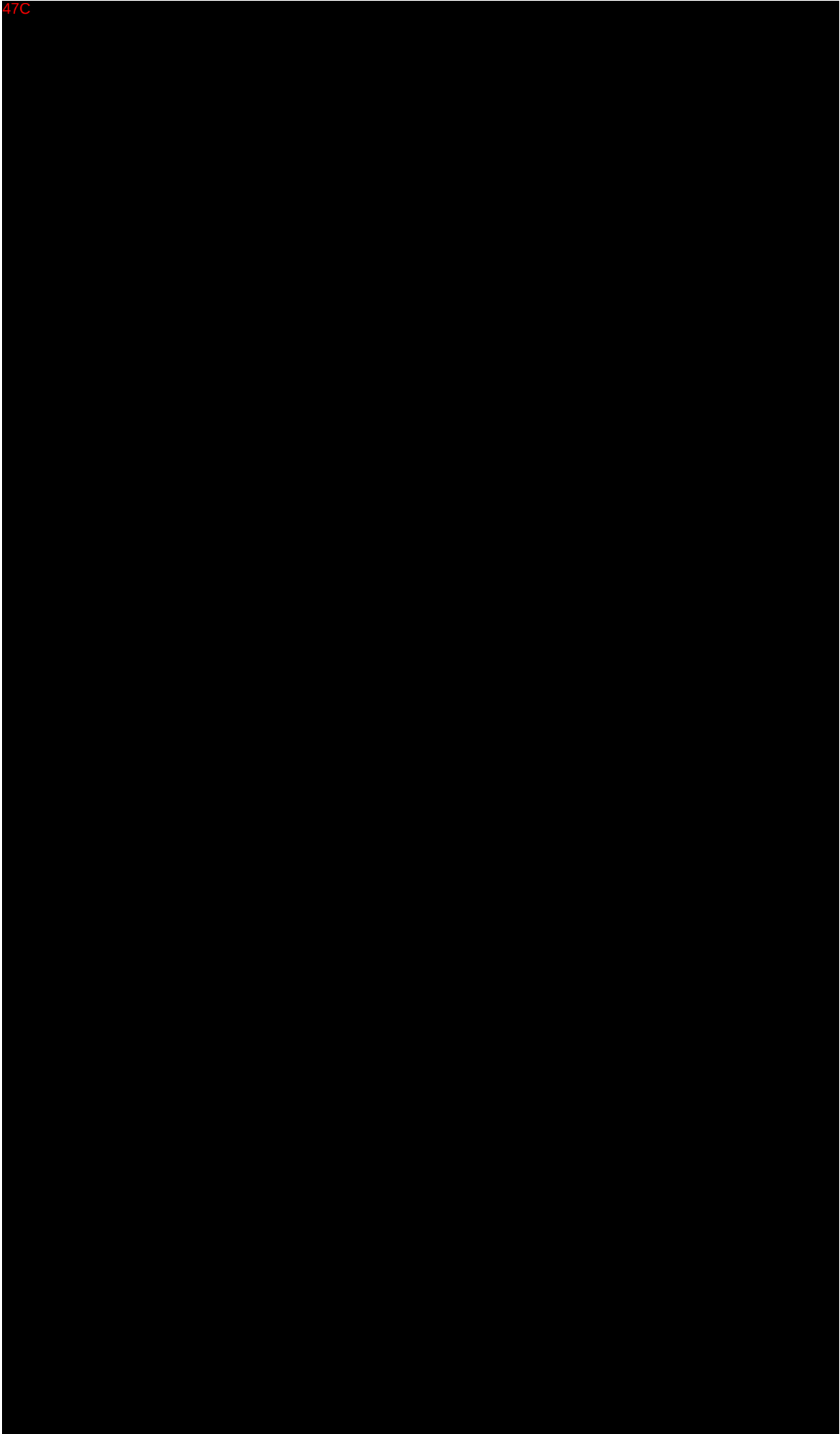
Hi Mandy,

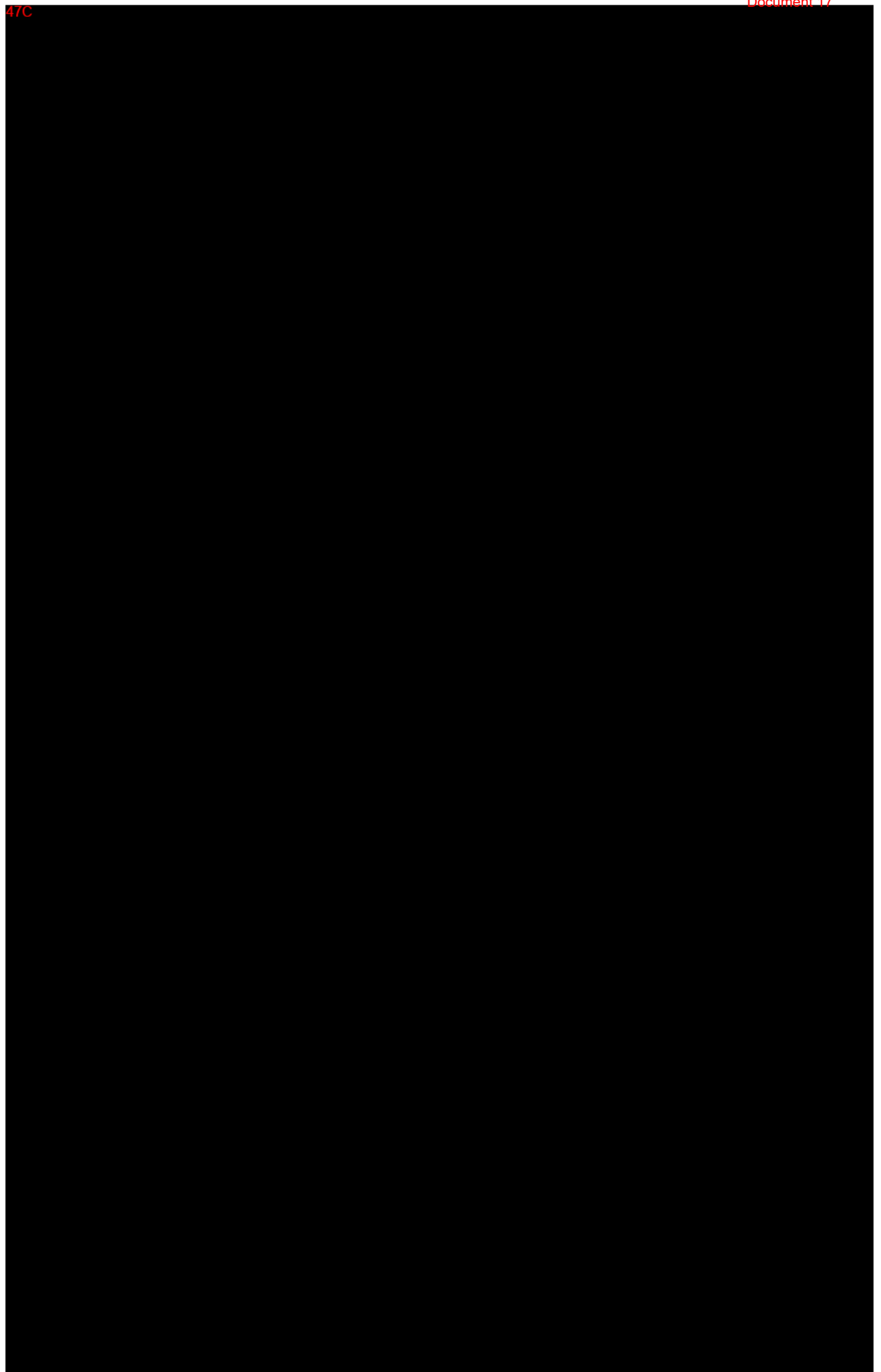
As flagged by [REDACTED] we are seeking your team's timely advice to inform the PM's brief and response to Minister Butler's 17 June 2024 letter (attached). Appreciate if the team can respond to the queries below by midday, Wednesday 19 June 2024.

47C



47C





47C

• s42

•

Happy to discuss. Will let you know if we have any additional questions.
Kind regards,

s22 (she/her) | Adviser
Population Health, Primary Care and Sport | Health and Aged Care Branch
Intergovernmental Relations and Reform Division | Department of the Prime Minister and
Cabinet
p. s22 | e. s22 @pmc.gov.au | w. pmc.gov.au
Ngunnawal Country, One National Circuit Barton ACT 2600 | P O Box 6500 CANBERRA
ACT 2600



The Department acknowledges and pays respect to the past, present and emerging Elders and
Traditional Custodians of Country, and the continuation of cultural, spiritual and educational
practices of Aboriginal and Torres Strait Islander peoples.

From: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Sent: Tuesday, 18 June 2024 5:08 PM

To: s22 @pmc.gov.au; s22
s22 @pmc.gov.au; s22
s22 @pmc.gov.au; s22
s22 @pmc.gov.au

Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22
s22 @health.gov.au; s22
s22 @health.gov.au; s22
s22 @health.gov.au

Subject: RE: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

Thanks s22 for letting me know – much appreciated.

Mandy Edlington
General Counsel (Acting)

Vaping Legislative Reform Branch
Regulatory Legal Services Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: 02 6289 2910 | E: mandy.edlington@health.gov.au
PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

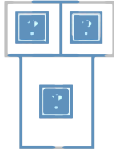
From: s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Sent: Tuesday, June 18, 2024 5:01 PM
To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>;
 s22 [REDACTED] <[REDACTED]@pmc.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@pmc.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@health.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@health.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@health.gov.au>
Subject: RE: Policy approval letter (vaping reforms) [SEC=OFFICIAL]
OFFICIAL

Hi Mandy,
 Just touching base to let know I'll be on leave for the rest of the week but my team (cc'ed) will continue progressing this to the PMO and will reach out with some additional questions to assist with briefing.

Thanks so much,

s22 [REDACTED]
 s22 [REDACTED] (she/her) | Senior Adviser
 Population Health, Primary Care and Sport | Department of the Prime Minister and Cabinet
 p. [REDACTED] | m. [REDACTED] e. [REDACTED] <[REDACTED]@pmc.gov.au>
 Nggunawal Country, One National Circuit Barton ACT 2600 | P O Box 6500 CANBERRA ACT 2600

I don't work on Thursdays.



The Department acknowledges and pays respect to the past, present and emerging Elders and Traditional Custodians of Country, and the continuation of cultural, spiritual and educational practices of Aboriginal and Torres Strait Islander peoples.

From: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>
Sent: Monday, 17 June 2024 5:50 PM
To: s22 [REDACTED] <[REDACTED]@pmc.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@pmc.gov.au>
Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@health.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@health.gov.au>; s22 [REDACTED]
 s22 [REDACTED] <[REDACTED]@health.gov.au>

Subject: Policy approval letter (vaping reforms) [SEC=OFFICIAL]

Dear s22 [REDACTED]

As requested, please find **attached** our policy approval letter, which was submitted to our Minister just now for his urgent consideration. It includes the proposed down scheduling amendments, which are expected to be necessary to secure passage of the Bill. We will keep you informed with developments tomorrow. Drafting continues with OPC on the amendments to the Bill and the regulation package is being finalised for clearance by the EXCO Secretariat.

Kind regards

Mandy Edlington
 General Counsel (Acting)

Vaping Legislative Reform Branch

Regulatory Legal Services Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: 02 6289 2910 | E: mandy.edlington@health.gov.au

PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

IMPORTANT: This message, and any attachments to it, contains information

that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you

must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by

return email informing them of the mistake and delete all copies of the message from your computer system.

IMPORTANT: This message, and any attachments to it, contains information

that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by

return email informing them of the mistake and delete all copies of the message from your computer system.

[SEC=OFFICIAL]

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by

return email informing them of the mistake and delete all copies of the message from your computer system.

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

IMPORTANT: This message, and any attachments to it, contains information that is confidential and may also be the subject of legal professional or other privilege. If you are not the intended recipient of this message, you must not review, copy, disseminate or disclose its contents to any other party or take action in reliance of any material contained within it. If you have received this message in error, please notify the sender immediately by return email informing them of the mistake and delete all copies of the message from your computer system.

[SEC=OFFICIAL]

From: s22
To: s22; EDLINGTON, Mandy; GILMOUR-WALSH, Bridget; s22; GOODCHILD, Tiali
Cc: LAWLER, Tony; FIRTH, Clare; s22
Subject: FW: Draft Amendment: Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL:Sensitive]
Date: Monday, 3 June 2024 5:42:26 PM
Attachments: [image001.png](#)
[v1_2511_CW_Therapeutic_Goods_and_Other_Legislation_Amendment_\(Vaping_Reforms\)_Bill_2024_Lambie.docx](#)
[image002.png](#)

Hi all,

FYI – have just received the proposed amendment from Senator Lambie.

Thanks

s22
s22 (He/Him)

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

E: s22 @health.gov.au

P: s22

M: s22

Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

From: s22 (Sen J. Lambie) s22 @aph.gov.au>

Sent: Monday, June 3, 2024 5:07 PM

To: s22 @Health.gov.au>

Cc: Minister Butler <Minister.Butler@Health.gov.au>; Lambie, Jacqui (Senator) <Senator.Lambie@aph.gov.au>

Subject: Draft Amendment: Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

I hope you have been well.

I am writing to provide you with a copy of the **attached** draft amendment to the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024* ahead of the scheduled meeting between Minister Butler and Senator Lambie on Wednesday 5 June at 9:30AM.

As previously flagged, the purpose of the amendment is to allow pharmacists and nurse practitioners to supply therapeutic vaping goods without a prescription from a medical practitioner for the purpose of smoking cessation or management of nicotine dependence, where clinically appropriate. Very happy to have further conversations about this policy objective whenever suitable.

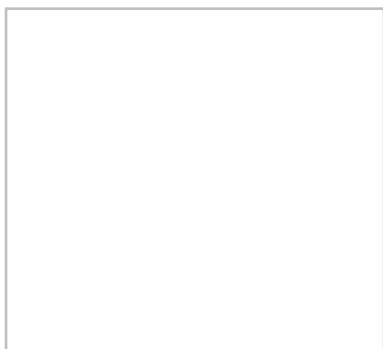
Kind regards,

s22
Advisor

Office of Senator Jacqui Lambie

Phone: s22

4/22 Mount St, Burnie TAS 7320
or Senate Suite 147



senatorlambie.com.au | [Facebook](#) | [Instagram](#)

Privacy Notice: This electronic transmission is strictly confidential and intended solely for the addressee. If you are not the intended addressee, you must not disclose, copy or take any action in reliance of this transmission. If you have received this transmission in error please notify Senator Lambie's Office as soon as possible at Senator.Lambie@aph.gov.au or phone 03 6431 3112.

2511

2022-2024

The Parliament of the
Commonwealth of Australia

THE SENATE

OPC drafter to complete	
3. Should any of these amendments be moved in the Senate as requests? (See OGC advice)	No

Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

(Amendments to be moved by Senator Lambie, on behalf of the Jacqui Lambie Network, in committee of the whole)

(1) Clause 2, page 2 (at the end of the table), add:

5. Schedule 4 At the same time as the provisions covered
by table item 2

[supply of therapeutic vapes by pharmacists without prescription—consequential]

[Senator: The above amendment to the commencement provision of the Bill would ensure that the amendments made by Schedule 4 (see draft below) would commence at the same time as the amendments made by Schedule 1 to the Bill—that is, the later of 1 July 2024 and the day after the Royal Assent. Please let us know if you are comfortable with this commencement or of you would like any changes.]

(2) Clause 3, page 2 (after line 12), at the end of the clause, add:

- Note 1: Subject to item 17 of Schedule 4, the provisions of the *Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022* amended or inserted by this Act, and any other provisions of that instrument, may be amended or repealed by an instrument made under subsection 19(7A) of the *Therapeutic Goods Act 1989* (see subsection 13(5) of the *Legislation Act 2003*).
- Note 2: Subject to item 17 of Schedule 4, the provisions of the *Therapeutic Goods (Poisons Standard—February 2024) Instrument 2024* amended or inserted by this Act, and any other provisions of that instrument, may be amended or repealed by an instrument made under subsection 52D(2) of the *Therapeutic Goods Act 1989* (see subsection 13(5) of the *Legislation Act 2003*).
- Note 3: Subject to item 17 of Schedule 4, the provisions of the *Therapeutic Goods Regulations 1990* amended or inserted by this Act, and any other provisions of those regulations, may be amended or repealed by regulations made under section 63 of the *Therapeutic Goods Act 1989* (see subsection 13(5) of the *Legislation Act 2003*).

[supply of therapeutic vapes by pharmacists without prescription—consequential]

(3) Schedule 1, item 11, page 13 (line 28), omit “Schedule 4”, substitute “Schedule 3”.

1

[supply of therapeutic vapes by pharmacists without prescription]

- (4) Schedule 1, item 11, page 14 (line 14), omit “Schedule 4”, substitute “Schedule 3”.
[supply of therapeutic vapes by pharmacists without prescription]
- (5) Schedule 1, item 11, page 15 (line 13), omit “Schedule 4”, substitute “Schedule 3”.
[supply of therapeutic vapes by pharmacists without prescription]
- (6) Schedule 1, item 11, page 19 (line 25), omit “Schedule 4”, substitute “Schedule 3”.
[supply of therapeutic vapes by pharmacists without prescription]
- (7) Schedule 1, item 11, page 22 (line 18), omit “Schedule 4”, substitute “Schedule 3”.
[supply of therapeutic vapes by pharmacists without prescription]
- (8) Page 69 (after line 15), at the end of the Bill, add:
Schedule 4—Supply of therapeutic vaping goods by pharmacists without prescription

Part 1—Main amendments

Therapeutic Goods (Medicines and OTG—Authorised Supply) Rules 2022

1 Section 4

Insert:

pharmacist means a person who is registered as a pharmacist under a law of a State or Territory providing for the registration of pharmacists.

2 Subsection 5A(1) (heading)

After “medical practitioner”, insert “, pharmacist”.

3 Subsection 5A(1)

After “medical practitioner”, insert “, a pharmacist”.

4 Subsection 5A(2)

After “medical practitioner” (first occurring), insert “, pharmacist”.

5 Paragraph 5A(2)(c)

Repeal the paragraph, substitute:

- (c) for a medical practitioner or nurse practitioner—supply the therapeutic good in accordance with good medical practice; and
- (ca) for a pharmacist—supply the therapeutic good in accordance with good pharmacy practice; and

6 Paragraphs 5A(2)(d) and (e)

After “medical practitioner”, insert “or pharmacist”.

Therapeutic Goods (Poisons Standard—June 2024) Instrument 2024

7 Subsection 49(1) (table item 27, column 1)

Omit “Schedule 4”, substitute “Schedule 3”.

8 In the appropriate position in Schedule 3

Insert:

NICOTINE in preparations for human use **except:**

- (a) in preparations for oromucosal or transdermal administration for human therapeutic use when included in the Register as an aid in withdrawal either from tobacco smoking or nicotine vaping; or
- (b) in tobacco prepared and packed for smoking.

9 Schedule 4 (entry for “NICOTINE”)

Repeal the entry.

10 Schedule 7 (entry for “NICOTINE”, paragraph (a))

Omit “Schedule 4”, substitute “Schedule 3”.

11 Clause 5 of Appendix D (table item 26)

Repeal the item.

12 Index (entry for “NICOTINE”)

Repeal the entry, substitute:

NICOTINE

Schedule 7

Schedule 3

Appendix F, clause 4

Appendix J, clause 1

Therapeutic Goods Regulations 1990

13 Schedule 5A (table item 15, column 3, subparagraph (h)(iv))

Omit “Schedule 4”, substitute “Schedule 3”.

14 Schedule 5A (table item 15, column 3, subparagraph (i)(ii))

Omit “Schedule 4”, substitute “Schedule 3”.

Part 2—Application and other provisions

15 Application of amendments

The amendments made by this Schedule apply in relation to the import, manufacture, possession or supply of therapeutic goods on or after the day this Schedule commences.

16 Amendments of current Poisons Standard

Provisions of the *Therapeutic Goods Act 1989*, or the *Therapeutic Goods Regulations 1990*, in relation to the requirements or procedure for amending the current Poisons Standard (within the meaning of that Act) do not apply to the amendments of the current Poisons Standard made by this Schedule.

17 Affirmative resolution

- (1) This item applies to a legislative instrument made under the *Therapeutic Goods Act 1989* that:
 - (a) is made on or after the commencement of this Schedule; and
 - (b) has the effect of amending or repealing, or otherwise altering the effect or operation of, the amendments made by this Schedule.
- (2) The legislative instrument does not come into effect until the instrument has been approved by a resolution of each House of the Parliament.

[supply of therapeutic vapes by pharmacists without prescription]

[Senator:

1. *We understand your policy is to allow pharmacists to supply therapeutic vaping goods for smoking cessation or management of nicotine dependence without a prescription in order to improve accessibility of these goods and to reduce the pressure on medical practitioners.*

2. *To our understanding, vapes containing nicotine can currently only be supplied on prescription by a person authorised under State or Territory law because nicotine is included as a Schedule 4 poison under the Commonwealth Poisons Standard.*

—*The above amendments to the current Commonwealth [Poisons Standard](#) would move nicotine (other than nicotine in tobacco and other registered preparations) from being a poison included in Schedule 4 (prescription only) to a poison included in Schedule 3 (pharmacist only) of the Poisons Standard. Schedule 3 poisons are “substances, the safe use of which requires professional advice, but which should be available to the public from a pharmacist without a prescription”. Schedule 4 poisons are “substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription”—see the Reader’s Guide to the Poisons Standard.*

—*For your consideration, we have retained nicotine as a Schedule 7 poison (except when available under Schedule 3). We have also made a consequential amendment to remove nicotine from Clause 5 of Appendix D (because that Appendix only relates to Schedule 4 or Schedule 8 poisons).*

Please let us know if the amendments to the Poisons Standard meet your policy intent or if you would like any further changes.

3. *In addition to the Poisons Standards, we also need to amend other Commonwealth legislation to remove barriers to pharmacists being able to supply therapeutic vaping goods without prescription, whether the vaping goods contain nicotine or not. All therapeutic vaping goods are currently regulated as therapeutic goods under the*

Therapeutic Goods Act 1989 and cooperative State and Territory legislation. The import, manufacture and supply of therapeutic goods for human use in Australia is prohibited unless the goods are registered on the Australian Register of Therapeutic Goods or otherwise covered by an exemption.

4. *There are currently no therapeutic vapes registered on the Register, but therapeutic vaping goods are “exempt goods” under items 15 and 16 of Schedule 5A to the Therapeutic Goods Regulations 1990, so that there is a “lawful basis for allowing unregistered therapeutic vaping goods to be imported, manufactured and supplied in Australia despite these goods not being included in the Register, and subject to specified conditions being met” (see the [explanatory statement](#)). The conditions include conditions that therapeutic vaping goods are used for smoking cessation or the management of nicotine dependence, do not contain any medical cannabis product, are intended to be supplied only in accordance with an approval or authority under section 19 of the Therapeutic Goods Act 1989 and are supplied by a pharmacist or other person authorised under a law of a State or Territory to supply a substance included in Schedule 4 to the Commonwealth Poisons Standard.*

—*We have drafted amendments to item 15 of Schedule 5A to the [Therapeutic Goods Regulations 1990](#) to require unregistered therapeutic vaping goods to be supplied by a pharmacist or any other person authorised under a State or Territory law to supply a substance included in Schedule 3 (instead of Schedule 4) to the Poisons Standard.*

—*We have also drafted amendments to the [Therapeutic Goods \(Medicines and OTG—Authorised Supply\) Rules 2022](#) to ensure that pharmacists, in addition to medical practitioners and nurse practitioners, are authorised to supply therapeutic vaping goods under section 19 of the Therapeutic Goods Act 1989. The rules authorise the supply of therapeutic vaping goods by specified health practitioners in specified circumstances. The amendments ensure that pharmacists (consistent with other authorised health practitioners) can supply therapeutic vaping goods for patients who are 16 years of age or over for smoking cessation or the management of nicotine dependence. Pharmacists must inform the patient that the vaping goods are not registered and obtain informed consent in relation to the supply. The amendment requires pharmacists to supply therapeutic vaping goods in accordance with “good pharmacy practice”, like the existing requirement that medical practitioners and nurse practitioners supply therapeutic vaping goods in accordance with “good medical practice”. This amendment will allow pharmacists to supply therapeutic vapes through the [Special Access Scheme Category C](#) (SAS C). We have not made changes to any other special access pathways for unregistered therapeutic vaping goods.*

—*We have also drafted amendments to the offence provisions in [Schedule 1 to the Bill](#), to ensure it is not an offence to supply or possess therapeutic vaping goods in circumstances where the supply or possession is by a pharmacist or another person authorised to supply one or more substances included in Schedule 3 (instead of Schedule 4) of the current Commonwealth Poisons Standard.*

Please let us know if the amendments to the Bill, the Rules and the Regulations meet your policy intent or if you would like any changes.

-
5. For your consideration, we have also included an application of amendments provision (see item 15) to provide that the amendments apply in relation to therapeutic goods imported, manufactured or supplied on or after the commencement of the Schedule (that is, the later of 1 July 2024 and the day after the Royal Assent). Please let us know if you are comfortable with this provision or if you would like any changes.
6. For your consideration, we have included a provision (see item 16) to provide that the requirements and procedure for amending the Poisons Standard do not apply in relation to the amendments made by this Schedule. This provision is intended to avoid doubt that the changes are not legally effective because the legislative requirements and procedure for amending the Poisons Standard have not been followed. Please let us know if you are comfortable with this provision or if you would like any changes.
7. For your consideration, we have also included an “affirmative resolution” provision (see item 17) so that any legislative instrument made under the Therapeutic Goods Act 1989 after the commencement of the amendments does not come into effect until approved by a resolution of each House of the Parliament if the amendments would repeal or otherwise affect the operation of the amendments. This would ensure that the Government could not later amend the legislative instruments to undo these amendments unless agreed by each House of the Parliament. However, this additional requirement would also apply to the making of legislative instruments that you may consider to be beneficial. Please let us know if you would like to include the affirmative resolution provision.
8. As mentioned in our email dated 3 May 2024:
- we note that “responsibility for the regulation of medicines, poisons and therapeutic goods is shared between state, territory and Commonwealth governments” and that the Commonwealth Poisons Standard is “given legal effect through State and Territory legislation” (see the [Bills digest](#)). The amendments to the Commonwealth Poisons Standard and the other Commonwealth legislation on this sheet relies on States and Territories continuing to maintain cooperative legislation to regulate the domestic supply of therapeutic goods and continuing to mirror the Commonwealth Poisons Standard in relation to nicotine. There are instances where States and Territory legislation deviates from the Commonwealth Poisons Standard—see the [TGA website](#).
 - we note that legislation regulating nicotine and vaping goods is complex. In the time available, we have identified the above amendments as necessary to implement your policy objectives under the current law but there is a risk that, without the policy expertise of the TGA and the Department of Health, other amendments or consequential changes may be necessary to comprehensively implement your policy.]

s22

From: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>

Sent: Thursday, June 20, 2024 7:40 PM

To: s22 @Health.gov.au; s22
s22 @Health.gov.au

Cc: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; HENDERSON, Nick
<Nick.Henderson@health.gov.au>; s22 @health.gov.au;
s22 @health.gov.au

Subject: RE: We need sign off from Minister ideally by as to close to 11am tomorrow as possible to meet Monday deadline [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

Thanks s22

From: s22 @Health.gov.au>

Sent: Thursday, June 20, 2024 7:39 PM

To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22
s22 @Health.gov.au>

Cc: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; HENDERSON, Nick
<Nick.Henderson@health.gov.au>; s22 @health.gov.au;
s22 @health.gov.au>

Subject: Re: We need sign off from Minister ideally by as to close to 11am tomorrow as possible to meet Monday deadline [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege] [SEC=OFFICIAL]

Hi Bridget - that's fine. Flick it to us when cleared and I will give you clearance first thing in the morning prior to Min signature.

Thanks

s22

s22 (He/Him)

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

E: s22 @health.gov.au

P: s22

M: s22

Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

On 20 June 2024 at 7:34:06 PM AEST, GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au> wrote:

Hi s22

Time-fames for printing EMs and providing cleared documents to PMC mean that we are going to need to get Min sign off ideally by 11am tomorrow.

We understand the Minister has a slot available at 11am and we will aim to get you the package by 10.30.

But even doing this we have a slight issue, which is that we might need to send the replacement EM to the printers before the Minister can look at it. LAD have advised that the replacement EM needs to be sent for printing no later than 11am tomorrow. I have spoken with the FAS of LAD about this and there is little wiggle room unless tabling office will agree to reduced copies. LAD have followed up with tabling office but have not yet got a response and I will check with LAD if we can have to 11.30 if the printer's deadline cannot be moved.

I will clear the replacement EM tonight and can send it to you as soon as it is cleared if this would help? Not sure if you want a version in track changes – I understand there are a few corrections.

Very happy to discuss this evening.

Bridget

From: s22 @health.gov.au>

Sent: Thursday, June 20, 2024 3:50 PM

To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; s22
s22 @health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>

Cc: s22 @Health.gov.au>; s22
s22 @health.gov.au>

Subject: RE: Timeframes - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

I have just spoken to §22 and she confirmed that CanPrint do not have any more flexibility, even for a higher fee. §22 has added an hour for LAD to submit the EM and ensure that CanPrint receive it and can proceed with printing.

However, **an option is to request printing ahead of the Minister's approval**, if you are confident the Minister will not make any changes to the EMs. We would still need to meet CanPrint's deadlines, but Minister can approve ahead of the deadline for submitting to PMC. The risk is if any change are made after submission to CanPrint, we would need re-printing and would miss deadlines.

§22 confirmed the following deadlines do not have any leeway – for debate on Monday at 10am:

- The Replacement EM needs to go to the Senate Table Office by 10am Monday morning, and CanPrint will need it by midday tomorrow for printing, so LAD need it by 11am tomorrow.
- The Supp EM needs to be provided to CanPrint by 4pm tomorrow, so to LAD by 3pm tomorrow, and PMC by 3pm tomorrow.

If debate is moved to 10am Tuesday, the following deadlines would apply:

- Min approval by Sunday night.
- Supp EM to PMC first thing Monday morning.
- Replacement EM to CanPrint by midday Monday so to LAD by 11am Monday.
- Supp EM to CanPrint by 4pm Monday, so to LAD by 3pm Monday.

Kind regards

§22

§22 (she/her)
Principal Lawyer – Legislation

Regulatory Legal Services Branch
Health Products Regulation Group, including the Therapeutic Goods Administration
Australian Government Department of Health and Aged Care
T: §22 | E: §22@health.gov.au

Please note that this email, and any attachments, may contain confidential or legally privileged information. Please consult with the sender before disclosing any part of this email, or any attachments, to any third party. If you receive this email in error, please notify the sender immediately and delete all copies together with any attachments.

[SEC=OFFICIAL]

From: s22
To: Minister Butler DLO
Cc: EDLINGTON, Mandy; GILMOUR-WALSH, Bridget; s22; HPRG Parliamentary; MPS; s22
Subject: FW: MS24-000790 - Therapeutic goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) – Replacement Explanatory Memorandum [SEC=OFFICIAL]
Date: Friday, 21 June 2024 1:28:50 PM
Attachments: image002.png
 image003.png
 MS24-000790.docx
 ATTACHMENT A - Replacement Explanatory Memorandum for the Therapeutic Goods and Other Legislation Amendment (Vaping .docx

Dear s22

Thanks for your emails this morning.

Just hoping to confirm if you are aware whether this MinSub has been signed? I understand there is currently no update on PDMS.

Thank you.

Kind regards,

s22 (she/her)
 Lawyer – Vaping Legislative Reform Branch
 Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: s22 | E: s22@Health.gov.au
 P.O. Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Please note that this email and attachments may contain confidential or legally privileged information. Please consult with Regulatory Legal Services Branch before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: s22@health.gov.au>
Sent: Friday, June 21, 2024 11:00 AM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22@Health.gov.au>; s22@health.gov.au>; s22@health.gov.au>; s22@Health.gov.au>; s22@health.gov.au>; HPRG Parliamentary <HPRG.Parliamentary@Health.gov.au>; MPS <MPS@health.gov.au>; s22@Health.gov.au>; HENDERSON, Nick <Nick.Henderson@health.gov.au>; s22@Health.gov.au>
Subject: MS24-000790 - Therapeutic goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) – Replacement Explanatory Memorandum [SEC=OFFICIAL]

Dear DLOs,

Please find attached the document package for the Ministerial Submission MS24-000790 - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 Replacement Explanatory Memorandum as cleared by A/g Deputy Secretary Nick Henderson. This has also been assigned to MPS in PDMS.

Kind regards,

s22

s22

A/g Executive Officer to A/g Deputy Secretary Nick Henderson

Health Products Regulation Group

Australian Government, Department of Health and Aged Care

☎: s22 | 📠: s22 @health.gov.au

Location: 27 Scherger Drive Fairbairn, Level 2

*I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.**The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.***From:** s22 @Health.gov.au>**Sent:** Friday, June 21, 2024 10:53 AM**To:** Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>**Cc:** EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 @Health.gov.au>; s22

s22 @health.gov.au>; s22 @health.gov.au>; s22

s22 @health.gov.au> s22 @Health.gov.au>; s22

s22 @health.gov.au>; HPRG Parliamentary s22 @Health.gov.au>; MPS <MPS@health.gov.au>

Subject: MS24-000790 - Therapeutic goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) – Replacement Explanatory Memorandum [SEC=OFFICIAL]

Dear DLOs,

Please find below, critical date waiver request for MS24-000790. Apologies for the tight turnaround.

Thank you

Critical Date – Waiver Request	
MS number	MS24-000790
Subject	Therapeutic goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) – Replacement Explanatory Memorandum
Critical date	By 11:00 am Friday 21 June 2024 to enable the Replacement EM to the Bill to be printed and tabled on Monday 24 June 2024
Brief summary of submission	To recommend Minister approval of prepared replacement EM, which has been initially provided to the Ministers Office this morning.
Why is a waiver to the 5-day critical date rule required? Note – this must include why the critical date cannot be extended to allow the Minister’s Office more than 5 days to consider the submission.	A waiver is required to approval finalisation of the replacement EM, to be printed and tabled on Monday 24 June 2024.
What is the risk to the Minister/Department or Agency if	If the critical date is not met, the Replacement EM may miss the deadline to be printed and tabled on Monday 24

the critical date is not met?	June 2024.
What is preventing/has prevented the Department/Agency providing this Ministerial Submission at an earlier date?	The Replacement EM has been finalised this week. The department has also been preparing proposed Government amendments as approved by the Minister on 4 June 2024 (MS24-000575) in conjunction with this work.
When will the Ministerial Submission be provided to the Minister's Office? Note – if this date is not met, a new waiver must be requested	Friday, 21 June 2024
Waiver approved by	DLOs to complete

Thank you

Kind regards,

s22 (she/her)
 Lawyer – Vaping Legislative Reform Branch
 Health Products Regulation Group
 Australian Government, Department of Health and Aged Care
 T: **s22** | E: **s22**@Health.gov.au
 P.O. Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Please note that this email and attachments may contain confidential or legally privileged information. Please consult with Regulatory Legal Services Branch before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

2022-2023-2024

THE PARLIAMENT OF THE COMMONWEALTH OF AUSTRALIA

HOUSE OF REPRESENTATIVES

**THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT
(VAPING REFORMS) BILL 2024**

REPLACEMENT EXPLANATORY MEMORANDUM

(Circulated by authority of the Minister for Health and Aged Care,
the Hon Mark Butler MP)

THIS MEMORANDUM REPLACES THE EXPLANATORY MEMORANDUM
PRESENTED TO THE HOUSE OF REPRESENTATIVES ON 21 MARCH 2024
AND RESPONDS TO ISSUES RAISED BY THE SENATE STANDING
COMMITTEE FOR THE SCRUTINY OF BILLS IN SCRUTINY DIGESTS NO. 5
AND 6 OF 2024, DATED 27 MARCH 2024 AND 15 MAY 2024 RESPECTIVELY

THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT (VAPING REFORMS) BILL 2024

OUTLINE

The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) amends the *Therapeutic Goods Act 1989* (the TG Act) to prohibit the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable vaping goods. Therapeutic vaping goods will continue to be available and subject to regulation under the TG Act in line with other medicines and therapeutic goods. This is necessary to address the growing risk posed by vaping in Australia, particularly to youth and young adults, while preserving legitimate patient access to therapeutic vaping goods for smoking cessation and the management of nicotine dependence, where clinically appropriate.

The TG Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, and timely availability of therapeutic goods used in, whether produced in Australia or elsewhere, or exported from, Australia. The Bill extends the national system of controls for therapeutic goods under the TG Act to the regulation of vaping goods. The national system is essentially a federal cooperative scheme between the Commonwealth, states and territories. It is achieved through the application of corresponding laws enacted in each state and territory, with Western Australia having recently progressed their own corresponding law.

The Bill provides a single consistent framework that applies nationally to regulate the importation, domestic manufacture, supply, commercial possession and advertisement of all vapes, irrespective of nicotine content or therapeutic claims. The extension of the TG Act to vapes is appropriate and necessary in the circumstances to address the alarming increase of vaping rates in Australia, particularly among youth and young adults, and maintain legitimate patient access to therapeutic vapes where clinically appropriate.

The Government's vaping reforms will be implemented in stages over 2024. The Bill is the centrepiece of these reforms to reduce rates of vaping and prevent long term adverse effects on population health. It represents the second stage of regulatory measures taken this year.

The first stage of the Government's vaping reforms comprised amendments to the *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations), the *Therapeutic Goods Regulations 1990* (the TG Regulations) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations). These amendments commenced on 1 January 2024 and introduced the following changes:

- From 1 January 2024, the importation of disposable single use vapes, irrespective of nicotine content or therapeutic claims, is prohibited, subject to very limited exceptions. The personal importation scheme for disposable single use vapes ceased to apply.

- From 1 March 2024, the importation of all other vaping goods, irrespective of nicotine content or therapeutic claims, is prohibited except in certain circumstances, including where the goods are the subject of a notice from the relevant importer stating compliance with relevant quality standards, and the importation is accompanied by an import licence and permit at the border. The personal importation scheme for all other vaping goods also ceased to apply.
- From 1 March 2024, stronger regulatory controls apply to the domestic manufacture and supply of therapeutic vaping goods in Australia with enhanced requirements relating to pre-market notification imposed under new statutory pathways and the relevant quality and safety standard.

Specifically, the Bill amends the TG Act to implement a new framework for the regulation of vapes, to more readily authorise state and territory officials to undertake enforcement action and other consequential changes. The framework for the regulation of vapes includes certain powers for the Secretary and Minister to determine the scope and coverage of the regulatory scheme for vaping goods.

Importantly, the Bill introduces new offences and civil penalty provisions relating to the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods to support the reforms. Exceptions to the offences and civil penalty provisions specify the circumstances in which importation, domestic manufacture, supply and commercial possession of legitimate therapeutic vaping goods for smoking cessation and the management of nicotine dependence is permitted in Australia.

The intention of the new offences and civil penalty provisions is to deter unlawful conduct, arrest the alarming increase in the use of vapes in Australia, particularly among youth and young adults, and prevent a new generation of persons being exposed to dangerous chemicals, and developing nicotine dependence.

The Bill enhances existing compliance and enforcement powers in the TG Act by:

- enabling state and territory officers to exercise powers and functions, particularly compliance and enforcement powers relating to supply and possession of vaping goods;
- extending the authority of persons able to issue monitoring, offence, and civil penalty related warrants in relation to premises, to court registrars and other officers of a court of a state or territory;
- facilitating information sharing with the states and territories and other compliance and enforcement bodies;
- enabling the publication of information relating to the importation, manufacture, supply and advertisement of vaping goods;

- amending the TG Act to deal more effectively with the seizure of unlawful vaping goods, and create new powers for the forfeiture and destruction of unlawful vaping goods;
- introducing a power to allow enforceable directions to be made to manage unlawful vaping goods and therapeutic goods generally; and
- otherwise facilitating effective enforcement of the new regulatory controls and therapeutic good requirements more generally.

The Bill implements measures that are necessary to give effect to reforms announced by the Minister for Health and Aged Care on 2 May 2023 and 28 November 2023. The reforms support the Government's broader objectives to reduce the prevalence of smoking and vaping in the community and align with the objectives, priorities and targets outlined in the National Tobacco Strategy 2023-2030. All Australian governments are strongly committed to addressing the public health challenge posed by the marketing and use of vaping goods.

Consequential amendments are also included in this Bill to other Commonwealth legislation, namely, the *Customs Act 1901* (the Customs Act), the *Industrial Chemicals Act 2019* and the *Public Health (Tobacco and Other Products) Act 2023*.

The public health problem

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among people aged 14 years and over, current use of vaping nearly tripled between 2019 (2.5%) and 2022–2023 (7.0%). The increase was even more marked among young people, with current use of vaping goods increasing from 5.3% to 21% among people aged 18-24, and from 1.8% to 9.7% among people aged 14-17 during the same period.¹ These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing use and marketing of vaping goods.

Vaping goods are widely marketed, available and accessible to youth and young adults in Australia, and many products have a low purchase price compared to many consumer goods and tobacco products. Advertising occurs across a range of media channels that have broad reach among youth and young adults, including websites, social media, in print and in retail stores. Evidence also suggests that exposure to these advertisements increases the likelihood that youth and young adults will try vaping. Direct exposure to promotional material relating to vaping contributes to decreased risk perceptions for vaping.

Marketing of vaping goods intentionally targets youth and young adults through promotional activities and product features. Vaping goods are aggressively promoted by the vaping industry in online advertising and other youth-focused media channels. Advertising spending is often focused on social media promotion, allowing for lower costs and wider reach, particularly to youth and young adults. Colours and flavours

¹ Australian Institute of Health and Welfare (2024), 'National Drug Strategy Household Survey 2022–2023', AIHW, Australian Government. Available at: <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey/contents/about>

further contribute to the appeal of vaping goods and their uptake among youth and young adults.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration or tobacco smoking. These changes were intended to prevent youth and young adults from taking up vapes, while allowing current smokers to access therapeutic vapes for smoking cessation under appropriate medical supervision.

However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. The latest findings from the 2022/23 Australian secondary school students alcohol and other drug survey show that 1 in 6 (16%) secondary school students (12 to 17 years) reported recent vaping in 2023/24.

Reforms are therefore needed to address the high levels of uptake of vaping among youth and young adults, the health risks that vapes pose to human health, the impacts of vaping on the initiation, continuation and cessation of tobacco product use, and the practice of dual use with conventional tobacco products. Indeed, there is strong and consistent evidence that youth and young adults who vape are more likely to take up smoking, compared to those who do not,² and the long-term health risks of vaping are not yet known. The highly addictive nature of nicotine, and the fact that vapes are inhaled into the lungs, mean the population-wide health risks of these products can be severe.

Vaping involves inhaling a large mix of chemicals, including listed poisons, heavy metals such as nickel and chromium, and chemical by-products produced during heating such as formaldehyde, nitrosamines, acetone, and acrolein. Acrolein, aldehydes, and polycyclic hydrocarbons are ‘probably carcinogenic’ according to the International Agency for Research on Cancer, while nicotine derivatives (nitrosornicotine and nitrosamine ketone) are known potent carcinogens in humans. Further, low concentrations of toxic chemicals in vaping substances convert to high concentrations when aerosolised, after heating, and as chemicals combine.³

A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Studies have shown the many damaging impacts of e-cigarette use include addiction, poisoning, acute nicotine toxicity, seizures, burns, lung injury, and increased uptake of cigarette smoking.⁴

² Baenziger ON et al. (2021) ‘E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis,’ *BMJ Open* 11(3). Available at: <https://pubmed.ncbi.nlm.nih.gov/33785493/>

³ Gordon LG and Preston P. (2024) ‘Healthcare costs attributable to e-cigarette use and subsequent uptake of cigarette smoking by Australians who have never smoked’ *Australian Health Review* 48(1), 52-57. doi: doi.org/10.1071/AH23178

⁴ Gordon LG and Preston P. (2024) ‘Healthcare costs attributable to e-cigarette use and subsequent uptake of cigarette smoking by Australians who have never smoked’ *Australian Health Review* 48(1), 52-57. doi: doi.org/10.1071/AH23178

Based on the available evidence to date, numerous studies have highlighted concerns regarding vaping use and their potential effects on adverse pregnancy outcomes, adolescent brain development, cardiovascular disease risks, cancer risks, respiratory disease and oral health. Second-hand exposure to e-cigarette aerosol is also a further area of concern. Emerging research also suggests that use of nicotine e-cigarettes may worsen mental health, and amplify stress, anxiety and depressive symptoms. However, given that vaping goods remain relatively new, the impact of their use on most clinical outcomes remains highly uncertain.⁵⁶⁷⁸

Broader actions to reduce the prevalence of vaping and smoking in Australia

The regulatory reforms included in this Bill complement a wider set of actions being taken by Governments in Australia in line with the National Tobacco Strategy 2023-2030 to reduce the rates of use of tobacco and nicotine products. The Australian Government is implementing a comprehensive range of regulatory and non-regulatory measures in parallel with this Bill. The *Public Health (Tobacco and Other Products) Act 2023* commencing from 1 April 2024 streamlines and modernises existing Commonwealth tobacco control laws. It also extends advertising regulations to vaping goods. New tobacco excise measures were announced in May 2023 to further reduce the affordability of tobacco products.

New measures will also provide information and support to people seeking to quit vaping and smoking, and to discourage people from starting or taking it back up. The Government will provide \$29.5 million over 4 years to help Australians quit, including through enhanced nicotine cessation, education and training among health practitioners, scaling up state and territory Quitlines and other quit services, and online quit supports including a national consumer online cessation hub and redeveloping and modernising the My Quitbuddy app. A further \$63.4 million investment in public health information campaigns aims to discourage Australians from taking up vaping and smoking and encourage quitting. The Government will provide \$141.2 million to extend the successful Tackling Indigenous Smoking program to reduce uptake of vaping and reduce smoking among First Nations people.

Australia's international obligations

As a party to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC), Australia has legal obligations to develop and implement effective policies not only to prevent and reduce tobacco consumption and exposure, but also to prevent and reduce nicotine addiction.

⁵ Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. (2022) 'Electronic cigarettes and health outcomes: systematic review of global evidence.' Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

⁶ National Health and Medical Research Council (2022) 'CEO Statement: Electronic Cigarettes' National Health and Medical Research Council.

⁷ Obisesan OH, Mirbolouk M, Osei AD, Orimoloye OA, Uddin SMI, Dzaye O, El Shahawy O, Al Rifai M, Bhatnagar A, Stokes A, Benjamin EJ, DeFilippis AP, Blaha MJ. (2019) 'Association Between e-Cigarette Use and Depression in the Behavioral Risk Factor Surveillance System 2016-2017.' JAMA Netw Open. 2;2(12)

⁸ Javed S, Usmani S, Sarfraz Z, Sarfraz A, Hanif A, Firoz A, Baig R, Sharath M, Walia N, Chérrez-Ojeda I, Ahmed S. (2022) 'A Scoping Review of Vaping, E-Cigarettes and Mental Health Impact: Depression and Suicidality'. J Community Hosp Intern Med Perspect. 2;12(3):33-39.

Australia has also committed under Article 5.3 of the WHO FCTC to protect its public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry in accordance with national law. Australia's obligations under Article 5.3 extend to new and emerging products, such as e-cigarettes and heated tobacco products.⁹

CONSULTATION

The TGA conducted two significant consultations in relation to the vaping reform measures. Between 30 November 2022 and 16 January 2023, the TGA undertook a public consultation on reforms to the regulation of nicotine vaping products in Australia. Close to 4,000 submissions were received from a range of organisations and individuals, including state and territory health departments, universities, health practitioner peak bodies, consumer groups, retailers, and suppliers. This included over 3,500 submissions from private individuals.

Following feedback from this consultation and advice received from public health experts at Tobacco Control Roundtables on 30 September 2022 and 17 April 2023, the TGA engaged in extensive consultation with the states and territories to assess the regulatory options and develop policy proposals. Consultations with the states and territories took place principally through the Health Ministers' Meeting and its subordinate National E-Cigarette Working Group, culminating in the Health Ministers' Meeting Communiqué dated 1 September 2023, which conveyed the Ministers' collective commitment to enhancing regulation of vapes.

A second targeted consultation was undertaken with stakeholders between 7 September 2023 and 21 September 2023 on the regulatory proposals developed in consultation with the states and territories, in addition to holding numerous webinars and stakeholder meetings. Submissions and survey responses to this consultation closed on 21 September 2023. The feedback to the consultation paper informed the deliberations of the Minister for Health and Aged Care on the regulatory measures to be implemented, including those in this Bill.

On 28 November 2023, the Minister announced the *Next steps on vaping reforms*, including the commencement of the first stage of the new vaping reforms on 1 January 2024. The TGA engaged in further updates with supply chain stakeholders, including manufacturers, suppliers, pharmacies and pharmaceuticals, healthcare professional and public health organisations, following the Minister's announcement.

On 12 January 2024, the TGA and the Office of Drug Control hosted a webinar to outline the impacts of the reforms to the medicinal cannabis industry. On 17 January 2024, the TGA hosted a further public webinar to outline the reforms. On 22 and 27 February 2024, the TGA held additional webinars with medical practitioners and pharmacists respectively.

On 1 March 2024, the TGA circulated draft provisions of the Bill to members of the National E-Cigarette Working Group, comprising representatives from the

⁹ See Australian Government Department of Health and Aged Care 'Guidance for public officials on interacting with tobacco industry' Available at: <https://www.health.gov.au/sites/default/files/2023-05/guidance-for-public-officials-on-interacting-with-the-tobacco-industry.pdf>

Commonwealth, states and territories for comment. Feedback from the exposure draft informed the final drafting of the Bill.

IMPACT ANALYSIS

An impact analysis was prepared on the proposed reforms to the regulation of vapes, based on the feedback received from stakeholders and the Australian public. The Office of Impact Analysis assessed the impact analysis and determined that it was consistent with good practice and met Australian Government best practice regulation requirements (**OBPR23-03933**).

The impact analysis supports this explanatory memorandum and has also been published on the Office of Impact Analysis website: www.oia.pmc.gov.au/.

FINANCIAL IMPACT STATEMENT

The Government will provide \$82.0 million over four years from 2023–24 to support the vaping reforms, awareness raising and enforcement activities. Funding includes:

- \$56.9 million over two years from 2023–24 to the Therapeutic Goods Administration to support regulatory development activities; and
- \$25.0 million over two years from 2023–24 to support the Australian Border Force’s regulatory and enforcement activities.

This measure builds on the 2023–24 Budget measure titled Vaping Regulation Reform and Smoking Cessation Package. The package committed to ban all vapes, other than therapeutic vapes imported, manufactured or supplied in accordance with the TG Act.

The regulatory reforms are part of the Government’s implementation of the National Tobacco Strategy and related initiatives on vaping and smoking prevention and cessation.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT (VAPING REFORMS) BILL 2024

The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Bill

The Bill will implement the second stage of the Government's vaping reform measures by amending the *Therapeutic Goods Act 1989* (the TG Act). The first stage of the Government's vaping reform measures comprised amendments to the *Therapeutic Goods Regulations 1990* (the TG Regulations), *Therapeutic Goods (Medical Devices) Regulations 2002* (the MD Regulations) and *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations). These amendments commenced operation on 1 January 2024.

In restricting the availability of, and access to, vaping goods in Australia, the Bill is intended to address the high levels of uptake of vaping among youth and young adults, the health risks that vapes pose to human health, the impacts of vaping on the initiation, continuation and cessation of tobacco product use, and the practice of dual use with conventional tobacco products. Despite the new restrictions and prohibitions applying to the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods, the Bill preserves legitimate patient access to therapeutic vaping goods for smoking cessation and the management of nicotine dependence under appropriate health practitioner supervision. All therapeutic vaping goods, including vaping goods that do not contain nicotine, are to be supplied in Australia, only by registered pharmacists, medical practitioners or nurse practitioners authorised to do so under state or territory law.

The public health problem

Vaping is rapidly increasing in Australia, particularly among youth and young adults. The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vaping goods.

The Australian Government introduced regulatory changes in October 2021 to clarify that persons require prescriptions from a health practitioner for the lawful supply of

products containing nicotine for human use except in certain circumstances, such as nicotine replacement therapies for oromucosal or transdermal administration for smoking cessation or tobacco smoking. These changes were intended to prevent youth and young adults from vaping, while allowing current smokers to access therapeutic vaping goods for smoking cessation under appropriate medical supervision. However, increasing rates of vaping among youth and young adults suggest that these reforms are not meeting their objectives. Normalisation of vaping is undermining population health and has the potential to disrupt the significant achievements Australia has made to date in tobacco control. Further measures were therefore needed to curb the increase in the rates of vaping, and to control the availability of vaping goods that are being accessed by young people.

The reforms implemented in the Bill align with the Government's broader objective to significantly reduce the use of tobacco and nicotine products in Australia by 2030, as outlined in the National Tobacco Strategy 2023-2030.

Objectives

The Bill provides for the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are imported into Australia, manufactured in Australia, supplied in Australia or exported from Australia. This is to address the health risks posed by vaping, while ensuring therapeutic vaping goods remain available, where clinically appropriate, to patients in pharmacy settings.

Human rights implications

The Bill engages the following human rights:

- the *right to health* under Article 12 of the International Covenant on Economic Cultural and Social Rights (ICESCR);
- the *right to life* under Article 6 of the International Covenant on Civil and Political Rights (ICCPR);
- the *obligation to ensure the survival and development of children* under Article 6(2) of the Convention of the Rights of the Child (CRC);
- the *obligation to protect children from illicit use of narcotic drugs and psychotropic substances* under Article 33 of the CRC;
- the *right to privacy* under Article 17 of the ICCPR;
- the *right to freedom of expression* under Article 19(2) of the ICCPR;
- the *right to a fair hearing* under Article 14(1) of the ICCPR;
- the *right to the presumption of innocence* under Article 14(2) of the ICCPR;
- the *right to be free from self-incrimination* under Article 14(3)(g) of the ICCPR;

- the right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted under Article 14(7) of the ICCPR.

The right to health

The Bill engages the right to health in Article 12 of the ICESCR. Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health and includes an obligation on state parties to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000)*, the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

Vaping has been associated with a range of short-term health risks, and its long-term health effects are still unknown. Marketing of vaping goods and use in the community has increased rapidly in recent years, particularly among young people, and pose a major risk to population health and Australia’s success in tobacco control.

The latest available trend data shows that among young people aged 14 years and over, current use of an e-cigarette, defined as used at least once in the month prior to being surveyed, increased from 2.5% to 8.9% between 2020 and 2023. The increase was even more marked among people aged 18-24 years old, increasing from 5.6% in 2020 to 19.8% in 2023. These findings reinforce a widespread and serious concern among public health policy makers and practitioners at the increasing marketing and use of vapes.

The health risks of vaping are substantial. A review of global evidence published in April 2022 found evidence that vaping by non-smokers results in dependence and conclusive evidence that vaping can cause respiratory disease, severe burns, poisoning and seizures. Further, there is strong and consistent evidence that adolescents and young adults who vape are up to three times more likely to take up smoking, compared to those who do not, and the long-term health risks of vaping are not yet known. Importantly, the long-term health effects of vaping are not known, and public health experts are concerned they could be of a similar magnitude to those resulting from smoking tobacco.

The Bill takes positive steps to promote the right to health by restricting access to vaping goods, except where clinically warranted through pharmacy (and medical) settings.

Bans on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods are intended to arrest and reverse the increasing uptake of recreational vaping, especially amongst youth and young adults by banning the domestic supply of vaping goods outside the pharmaceutical supply chain.

Allowing patient access to therapeutic vapes strikes an appropriate balance between the health concerns posed by vaping and the need to provide legitimate patient access to support Australians to quit smoking or manage nicotine dependence.

Ensuring vaping goods are only accessed under appropriate health practitioner supervision provides an opportunity for users to receive appropriate advice from a health professional on the appropriateness of therapeutic vaping goods in relation to the condition that is being treated, the availability of other therapeutic goods to treat the specified condition, the risks associated with their use and the benefits of not smoking. This will enable Australians to make informed decisions concerning their health.

In parallel to the introduction of the Bill, cessation services in Australia will be enhanced to ensure support for people who seek assistance to stop vaping.

The Bill promotes aspects of the right to health under Article 12 of the ICESCR that relate to recognising the right of everyone to enjoy the highest attainable standard of physical and mental health.

The right to life

By seeking to reduce the incidence of vaping, thereby reducing the associated health risks and controlling access to vapes, the measures contained in the Bill promote the right to life.

Nicotine, which is contained in most vapes and e-liquids, is highly poisonous and intentional or unintentional ingestion can lead to nicotine poisoning or death. An average 2-year-old child would experience potentially lethal effects by ingesting as little as 0.8 ml of a 100 mg/ml nicotine e-liquid.¹⁰

Vape use has been associated with a number of short-term health risks, including death from lung injury. The long term health consequences of vaping are unknown and public health experts are concerned that those risks could be of a similar magnitude to those resulting from smoking tobacco.

Further, vaping is a strong predictor of future tobacco use for youth and young adults, including for those who would otherwise be unlikely to take up conventional smoking.¹¹ Vaping also mimics behavioural and sensory aspects of smoking, which makes the transition to combustible smoking more likely.¹²

Tobacco use causes more deaths than any other behavioural risk factor. Up to two thirds of deaths in tobacco smokers can be attributed to smoking, and long-term

¹⁰ Morgan J and Kelso C, (2021) 'Nicotine Vaping Product Analysis: Evidence from the University of Wollongong'. Available at: .

¹¹ Department of Health and Aged Care, (2020) 'Notice of final decision to amend the current Poisons Standard – nicotine' Australian Government. Available at: <https://www.tga.gov.au/resources/publication/scheduling-decisions-final/notice-final-decision-amend-current-poisons-standard-nicotine#:~:text=Pursuant%20to%20regulation%2042ZCZR%20of,to%20be%20fitted%20in%20liquid>

¹² Baenziger ON et al. (2021) 'E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis,' *BMJ Open* 11(3). Available at: <https://pubmed.ncbi.nlm.nih.gov/33785493/>

smokers die an average of 10 years earlier than nonsmokers. Exposure to second-hand smoke is also a cause of preventable death and disability in both adults and children. Tobacco use and exposure among pregnant people and their babies is one of the most prevalent preventable causes of infant death and illness and of adverse pregnancy outcomes including preterm birth and still-birth.¹³

Tobacco smoking by youth and young adults has immediate adverse health consequences and accelerates the development of chronic diseases across the full life course. It can lead to nicotine dependence that causes young people to continue smoking for longer, causing increased physical damage. In addition, quitting smoking at any age reduces the risk of premature death and improves quality of life.

The Bill promotes the right to life by implementing measures to prohibit access to vaping goods unless clinically appropriate under health practitioner supervision.

Obligation to ensure the survival and development of children

Article 6(2) of the CRC requires state parties to take measures to ensure the survival and development of children to the greatest extent possible.

Vaping goods pose a particular risk to children. The variability in concentration and toxicity of active ingredients, particularly nicotine, but also other toxic substances, increases the risk that children who consume these ingredients may ingest a fatal dose or suffer severe adverse effects. In addition, vapes contain flavours designed to entice children, and for which the adverse effects are unknown. Although these flavours may be safe when ingested, their safety profile when inhaled directly into the lungs is not established.

Vapes can contain harmful chemicals that are known to cause irreversible lung damage and may also have chronic long-term effects. In addition, it appears that most products on the domestic market contain, or are likely to be used in conjunction with, nicotine. This is the case even where no nicotine is indicated on the label of the product, if any label exists.

Vaping goods are frequently designed to look like other innocuous and ubiquitous objects such as pens, USB devices, lip gloss, toys and sippy cups. The designs use colours, illustrations and cartoons that are deliberately attractive to children and may lead to misconceptions that vaping goods are harmless when this is not the case. To the extent that restricting the importation, domestic manufacture and supply of vaping goods may adversely affect the health of persons (including young persons) who are already addicted to nicotine, the prohibition in this amendment will not extend to those who are legitimately prescribed vaping substances that contain nicotine for the management of that dependence, in accordance with clinical guidelines, under appropriate health practitioner supervision.

In summary, the vaping reform will promote the survival and development of children to the greatest extent possible and where the measure may limit a child's rights, the

¹³ Dietz P, England L, Shapiro-Mendoza C, Tong V, Farr S and Callaghan W (2010) 'Infant morbidity and mortality attributable to prenatal smoking in the US' 39(1): 45–52, Am J Prev Med.

limitation is necessary in order to protect the Australian community, in particular children, from the risks to health that misuse can cause, and is reasonable and proportionate as access to vaping substances is still available where there is a legitimate medical need.

Obligation to protect children from illicit use of narcotic drugs and psychotropic substances

Article 33 of the CRC specifically requires state parties to take appropriate measures to protect children (up to the age of 18) from the illicit use of narcotic drugs and psychotropic substances. Although vapes are not specifically listed in the relevant international treaties banning narcotic drugs and psychotropic substances, the substances in unregulated vapes are not known and on occasion have been found to include a range of drugs. Further, the Committee on the Rights of the Child has recognised that Article 33 has a broad application and may impose obligations on state parties to protect children from the use of substances that are not listed in the Conventions, such as alcohol and tobacco. The Committee therefore urges state parties to regulate or prohibit information on and marketing of substances, such as alcohol and tobacco, particularly when the information or marketing targets children and adolescents.

The new controls on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods will promote the protection of children from exposure and easy access to addictive and unsafe vaping goods. Under the reforms, vaping goods are only intended to be accessed by legitimate patients through limited supply channels involving registered pharmacists, medical practitioners and nurse practitioners authorised under state or territory law to supply prescription medicines. This will reduce the potential for vapes to be supplied unlawfully to children.

The controls placed on the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods are therefore an important tool for promoting children's rights to be protected from nicotine dependence and exposure to other dangerous substances, including potentially narcotic drugs and psychotropic substances, in vaping goods. These measures, by restricting the importation, domestic manufacture and supply of untested and potentially dangerous substances contained in vaping goods will assist in preventing their supply to, and access by, youth and young adults.

These measures seek to promote the requirement to protect children from exposure to, and use of, narcotic drugs, psychotropic substances and other harmful substances that may be contained in vaping goods to the greatest extent possible. The limitation is reasonable and proportionate as access to vaping goods is still available where there is a legitimate therapeutic need under appropriate medical supervision.

The right to privacy

The Bill engages the protection against arbitrary or unlawful interference with privacy. Article 17 of the ICCPR prohibits arbitrary or unlawful interference with an individual's privacy, family, home or correspondence, and protects a person's honour

and reputation from unlawful attacks. The right to privacy can be limited to achieve a legitimate objective where the limitations are lawful and not arbitrary. For interference with the right to privacy to be permissible, the interference must be authorised by law, be for a reason consistent with the ICCPR and be reasonable in the circumstances. The United Nations Human Rights Committee has interpreted the requirement of ‘reasonableness’ as implying that any interference with privacy must be proportionate to a legitimate end and be necessary in the circumstances.

The Bill provides for the collection, use and disclosure of information, which may include personal information. These provisions engage and may limit the right to privacy. The proposed information gathering, reporting and release measures are reasonable, necessary and proportionate to a legitimate objective of supporting the effective implementation of the vaping reforms for a public health objective.

Consent scheme

The Bill amends the TG Act to introduce a consent scheme under section 41RC to allow persons who do not have a licence or authority under the TG Act or state and territory laws to lawfully manufacture, possess or supply vaping goods. Persons that can be granted consent may include:

- (a) persons transporting vaping goods within a state or from one state to another;
- (b) persons storing vaping goods for supply to a wholesaler or a pharmacist; and
- (c) pharmacists compounding or manufacturing different vaping goods.

A person who has been granted a consent under new section 41RC will be able to lawfully use the consent as a defence to the manufacturing, supply and possession offences or civil penalty contraventions under new Chapter 4A of the TG Act.

These provisions engage and may limit the right to privacy. The proposed information gathering and reporting measures are reasonable, necessary and proportionate to a legitimate objective of supporting the objects of the vaping reform to promote and support public health objectives.

If personal information is provided in a report to the Secretary, the collection, storage, use and disclosure of such personal information would be subject to the requirements and limitations in the *Privacy Act 1988*. The Department of Health takes seriously its obligations and compliance with requirements applying to personal information that it holds and collects under the *Privacy Act 1988*.

Investigations, entry to premises, investigations, seizure and forfeiture

The Bill introduces new offences and civil penalty contraventions in relation to the importation, manufacture, supply, commercial possession and advertisement of vaping goods. In addition, a new section 52AAA is introduced in the Bill in which vaping goods seized under a warrant under section 50 of the TG Act in specified circumstances are forfeited to the Commonwealth without any court order, and conviction or contravention of a civil penalty provision being established through court proceedings.

Although new offences and civil penalty contraventions are introduced in the TG Act by the Bill, individuals are protected against arbitrary interference with privacy. In general the entry, search and seizure powers cannot be exercised without the person affected being fully informed, a voluntary consent of the occupier of the premises being provided by the affected person, or the presence of a prior authorisation in the form of a warrant. There are exceptions to these in circumstances where an authorised person exercises entry and seizure powers in the interests of public health to avoid an imminent risk of death, serious illness or serious injury (refer to section 46B of the TG Act). The powers of an authorised person under Part 6-2 of the TG Act relating to entry, search and warrant remain unchanged.

The offence and civil penalty related warrants issued under section 50 of the TG Act are only issued by an issuing officer if satisfied, by information on oath that there are reasonable grounds for suspecting that there is, or there may be within the next 72 hours, in or on the premises evidential material in respect of an offence against the TG Act, in respect of a contravention of a civil penalty provision or in respect of both. An issuing officer must not issue a warrant unless the authorised person or some other person has given to the issuing officer, either orally or by affidavit, such further information as the officer requires concerning the grounds on which the issue of the warrant is being sought (subsection 50(3) refers). Such constraints on this power ensure adequate safeguards against arbitrary limitations on the right to privacy in the issuing of warrants.

If entry is authorised by warrant, the authorised person must provide a copy of the warrant to the occupier of the premises. This provides for the transparent utilisation of the powers and mitigates arbitrariness and risk of abuse.

Part 6-2 of Chapter 6 of the TG provides for constraints on the exercise of the powers by authorised persons and therefore limits the susceptibility to arbitrary use or abuse and ensures that their use is reasonable and proportionate in the circumstances.

Forfeiture of goods seized under specified circumstances for the purposes of section 52AAA will only be those seized under a warrant granted under current section 50 of the TG Act. This provision engages the right to privacy in Article 17 of the ICCPR. To the extent that it may limit this right, the limitation is provided for by law. The forfeiture of specified things or goods are subject to judicial review and can be challenged by the person who owns or possess the goods.

As such, any interference with an individual's privacy that may be said to be enabled under the TG Act to enforce the regulation of the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods would not be an arbitrary inference within the meaning of Article 17 of the ICCPR.

Accordingly, the amendments made in relation to the bans on importation, domestic manufacture, supply, commercial possession and advertisement are reasonable, necessary and proportionate to achieving the legitimate objective of the new regulatory framework applying to vaping goods in Australia.

The right to freedom of expression

The Bill contains prohibitions on the advertising of vaping goods (new Part 5-1A). Article 19(2) of the ICCPR engages the right to freedom of expression, which extends to any medium, including written and oral communications, the media, public protest, broadcasting and artistic works, and may include commercial advertising.

Article 19(3) of the ICCPR states that public health is a basis on which the right to freedom of expression can be limited. This right may be limited as provided for by law and when necessary for respect of the rights or reputations of others, for the protection of national security, public order, or of public health or morals. Limitations must be prescribed by legislation necessary to achieve the desired purpose and proportionate to the need on which the limitation is predicated.

The Bill contains prohibitions on the advertising of vaping goods in the new Part 5-1A. These prohibitions engage and may limit the right to freedom of expression, which is protected by Article 19(2) of the ICCPR. However, these restrictions are directed to the desired purpose of reducing illegitimate and non-therapeutic vaping and the related health risks. This is a legitimate public health objective and accordingly the prohibition is necessary to achieve the desired purpose and proportionate to the need on which the limitation is predicated.

Legitimate objective: measure is justified under a permitted limitation

The right to freedom of expression is not absolute. It carries special responsibilities and may be restricted on several grounds. Article 19(3) of the ICCPR expressly states that the right to freedom of expression may be subject to limitations necessary for the protection of public health. The limitation (if any) of the right to freedom of expression in the Bill aims to achieve a legitimate objective – the protection of public health – by contributing to efforts to reduce vaping rates and the associated health risks. This is of critical importance in relation to the advertising of vaping goods to youth and young adults by means of retail websites and social media. The Bill aims to achieve this by prohibiting the direct and indirect promotion of vaping goods subject to very limited exceptions, including patient consultations and authorisations given under new section 42DZC.

Reasonable: measure will be effective to achieve the desired ends

The proposed reforms include a comprehensive advertising ban of vaping goods in Australia. The ban would include a broad range of media platforms, extending to social media and other forms of advertising, promotion and sponsorship. It is important that the public's exposure to advertising and promotion of vaping goods, which pose a serious risk to population health, is limited to combat the sale and uptake of vapes.

Proportionate: measure does not impinge on freedom of expression to a greater degree than is necessary

The restrictions are central to achieving the aims and objectives of the advertising measure and are proportionate to the public health risk posed.

Vaping goods are widely marketed, available and accessible to youth and young adults in Australia. Evidence suggests that exposure to these advertisements increases the likelihood that youth and young adults will try vaping. Direct exposure to vaping promotions has contributed to decreased risk perceptions for vaping. Some marketing of vaping goods is also emulating successful tobacco advertising, presenting vaping as an enviable lifestyle choice, aligning the products with celebrities and influencers, and fashionable and youthful places and activities.

Marketing of vaping goods intentionally targets youth and young adults through its promotional activities and product features. Vapes are aggressively promoted via online advertising and other youth-focused media channels. Advertising spending is often focused on social media promotion, allowing for lower costs and wider reach, particularly to youth and young adults. The marketing messages promote perceptions among youth and young adults that vaping goods are fun, cool, healthier and safer than tobacco cigarettes, and often focus on the appeal of flavours.

Despite the general prohibition, advertising would still be allowed to persons involved in the legitimate supply of therapeutic vapes (such as health professionals and pharmaceutical wholesalers) and where advice is given directly to a patient by a health practitioner in the course of treatment. The Secretary is also conferred with a power to permit advertising in specified circumstances.

It is also important to note that the term *advertise* has a limited meaning and does not cover all communications in relation to vapes. The term ***advertise*** is defined in section 3 of the Act. In effect it provides that to advertise goods means to intend, either directly or indirectly, to promote the use or supply of those goods.

Necessary: no less restrictive means of achieving the desired ends

The prohibition on advertising will contribute to efforts to reduce vaping rates in Australia. Given the widespread impact of advertising vaping goods, particularly in relation to unlawful vaping goods with no therapeutic purpose, restrictions are necessary to arrest the uptake of illegitimate vapes and to protect public health.

Vaping is associated with a range of short-term health risks and the long-term health risk are unknown. Further, there is evidence that vaping is a strong predictor of future tobacco use, particularly among youth and young adults. There is strong and consistent evidence that youths and young adults who vape are up to three times as likely to take up smoking, compared to those who do not. Smoking is the leading cause of preventable disease and death in Australia. Smoking reduces a person's life expectancy and their quality of life and may increase the risk of many conditions and diseases such as lung cancer, chronic obstructive pulmonary disease, heart disease, stroke and cardiovascular disease. Smoking can also cause diabetes, dental problems, hearing and vision loss and fertility problems.

The Bill, however, allows the promotion of therapeutic vaping goods in limited circumstances. A general prohibition on the advertising of vaping goods, with limited, and necessary exceptions, is the only means by to effectively combat the danger that such advertising poses to the Australian community.

Although the advertising measures applying to prohibition of advertising of vaping goods affects and limits, the freedom of expression, they are necessary to achieve the desired public health purpose and are proportionate to the need on which the limitation is predicated.

The right to a fair hearing

The Bill engages the right to a fair hearing under Article 14(1) of the ICCPR. The right to a fair hearing is a fundamental part of the rule of law and the proper administration of justice. The essential right guarantees equality before courts and tribunals, and, in the determination of criminal charges, or any suit at law, the right to a fair and public hearing before a competent, independent and impartial court or tribunals established by law. Those charged with a criminal offence have the rights set out in Articles 14(2) to (7), including the presumption of innocence and the guarantees set out in Article 14(2). The Bill engages this right and at the same time ensures that a defendant is provided with a right to a fair hearing before the relevant court, whether under an offence provision or a civil penalty provision. No provision relating to any of these offences seeks to displace or modify defendants' fair hearing rights under Article 14.

Application of both criminal and civil penalties

The Bill's offence provisions contain both criminal penalties and civil penalties. These include fault-based offences, strict liability offences and civil penalties. The Commonwealth will decide in each case whether to prosecute a person for a fault-based or strict liability offence, or whether to bring proceedings for a civil penalty order. Division 2 of Part 5A-1 of Chapter 5A of the TG Act places restrictions on what kinds of proceedings can be brought against persons who are alleged to have contravened the TG Act. These limitations broadly mirror those seen in Division 3 of Part 4 of the *Regulatory Powers (Standard Provisions) Act 2014*. The provision in the TG Act relating to bringing criminal proceedings after civil penalty orders have been issued against a person is more restrictive than the provision that regulates the same situation in the *Regulatory Powers (Standard Provisions) Act 2014*. The limitations imposed by Division 2 of Part 5A-1 of Chapter 5A of the TG Act will apply to all new offences and civil penalty provisions introduced by the Bill.

Most relevantly:

- section 42YF provides that the Federal Court must not make a pecuniary penalty order against a person for a contravention of a civil penalty provision if the person has been convicted of an offence constituted by conduct that is substantially the same as the conduct constituting the contravention;
- section 42YG operates to stay civil proceedings if criminal proceedings commence or have commenced and relate to the same, or substantially the same, conduct. This is to prevent any information that arises during criminal proceedings prejudicing civil proceedings. If the criminal proceedings result in a conviction, civil proceedings related to the same, or substantially the same,

conduct will be dismissed. Civil proceedings may resume if the person is not convicted of the offence;

- section 42YH prevents criminal proceedings being brought against a person for conduct that is substantially the same as conduct constituting a contravention of a civil penalty provision if a pecuniary penalty order has been made against the person in respect of that conduct; and
- section 42YI provides that evidence given by an individual during proceedings for a civil penalty order cannot be used in any criminal proceedings, against the same individual relating to the same conduct. This ensures that information or documents produced during civil proceedings are not relied upon to support subsequent criminal proceedings, unless they are criminal proceedings relating to falsifying evidence in civil proceedings. While it is appropriate to allow criminal proceedings after civil proceedings have ended, given the overriding importance of the criminal justice system, criminal proceedings not related to falsifying evidence must rely upon evidence gathered during independent investigations, not evidence from prior civil proceedings.

Civil penalties

The Bill introduces, alongside criminal sanctions, civil penalty provisions relating to the importation, domestic manufacture, supply, commercial possession and advertisement of vaping goods. A civil penalty is a punitive sanction of a financial nature and provisions imposing civil penalties do not specify aggravating elements and fault elements. The penalties are imposed through civil court proceedings rather than through the criminal prosecution process. A civil penalty takes the form of a monetary penalty only and does not result in any criminal conviction. A criminal prosecution is a more appropriate sanction where a contravention is deliberate, where fraud may be involved, where the conduct demonstrates recklessness, where there is a serious pattern of continuous intentional contraventions, or where conduct has endangered lives or has caused death or serious injury.

A civil penalty is more appropriate to enable responsible persons to be fined for breaches of the TG Act where other sanctions, such as criminal prosecution, may not be as effective or appropriate in the circumstances. The civil penalty regime is also intended to act as a deterrent to behavior that breaches regulatory requirements, and also to act as an incentive for persons to establish systems designed to avoid breaches of regulatory requirements. In these ways, the civil penalty scheme is intended to prevent instances where public health and safety is, or could be, placed in jeopardy.

The focus of a civil penalty scheme is generally on the regulation of commercial activity. The inclusion of a civil penalty regime is proposed to strengthen enforcement options to deter non-compliance with regulatory requirements by persons whose main objective is monetary profit.

The levels of these penalties have been set having regard not just in relation to the significant impact on the health of the users of vaping goods but to the fact that the perpetrators stand to make significant financial gains from unlawful dealings with vaping goods. The potential monetary benefit of unlawful dealings with vaping goods

is significant. The objective is, for the benefit of good health outcomes for consumers, to incentivise those who have the most to gain by breaching the TG Act to comply with regulatory requirements.

Prescribing conduct that is subject to a civil penalty could engage criminal process rights if the imposition of civil penalties is classified as ‘criminal’ under international human rights law.

Guidance Note 2: Offence provisions, civil penalties and human rights (December 2014), which is published by the Parliamentary Joint Committee on Human Rights, states that civil penalty provisions may engage criminal process rights under Articles 14 and 15 of the ICCPR, regardless of the distinction between criminal and civil penalties in domestic law.

When a provision imposes a civil penalty, an assessment is required as to whether it amounts to a ‘criminal’ penalty for the purposes of the ICCPR. Determining whether penalties could be criminal under international human rights law requires consideration of the classification of the penalty provisions under Australian domestic law, the nature and purpose of the penalties, and the severity of the penalties.

The Bill seeks to create various civil penalty provisions, which will be expressly classified as civil penalties for the purposes of Australian domestic law and will not impose criminal liability. For several reasons, the civil penalty provisions are unlikely to be considered criminal for the purposes of human rights. These provisions are not classified and identified as criminal under the TG Act. Rather, they are alternatives to criminal prosecution and do not carry a sanction for imprisonment for non-payment. Further, a finding of breach will not lead to the creation of a criminal record. The provisions are part of an enforcement regime to incentivise those who would otherwise have much to gain by not complying with regulatory requirements to comply for the benefit of public health thus the high level of penalty. As such, the criminal process rights under Articles 14 and 15 of the ICCPR would be unlikely to apply.

The civil penalty provisions in the Bill are principally intended to provide an effective deterrent to non-compliance, and to reflect the serious potential impact on public health of non-compliance. Prosecution of a person for contravention of a civil penalty provision will generally only be considered after other available compliance measures have been considered. Those measures may include, for example, the giving of an infringement notice.

To provide effective deterrence, the penalties for individuals and bodies corporate are significant ranging from a maximum 5,000 penalty units for individuals to 50,000 penalty units for bodies corporate, to 7,000 penalty units for individuals to 70,000 penalty units for bodies corporate. These high penalties are commensurate to the public health risks associated with the use of vaping goods. The civil penalty contraventions are not directed to members of the public in general but only to those who are importing, manufacturing, supplying, commercially possessing and advertising illegal vaping goods. These penalties are comparable with existing civil penalty provisions under the TG Act and consistent with the penalties for similar conduct in comparable legislation, such as the *Corporations Act 2001* (section 1317G)

and pecuniary penalties under consumer law under *Competition and Consumer Act 2010*.

Thus, the civil penalties are classified as civil penalties and not criminal for the purposes of human rights law.

Further, a person who is the subject of a civil penalty proceeding has a right to a fair hearing before a competent, independent, and impartial court as provided for under the current Part 5A-1 (civil penalties) under Chapter 5A of the TG Act, which supports compatibility with the right to a fair hearing under Article 14(1) of the ICCPR.

The right to the presumption of innocence under Article 14(2)

Article 14(2) of the ICCPR provides that everyone charged with a criminal offence shall have the right to be presumed innocent until proven guilty according to law. The right to presumption of innocence is also a fundamental common law principle.

Strict liability offences

When strict liability applies to an offence, the prosecution is only required to prove the physical elements of an offence, not the fault elements, beyond reasonable doubt for the defendant to be found guilty. The defence of honest and reasonable mistake of fact is available to the defendant (see section 9.2 of the *Criminal Code*).

Strict liability is used in circumstances where there is a public interest in ensuring that regulatory schemes are observed, and it can be reasonably expected that the person was aware of their duties and obligations. Strict liability offences can be considered a limitation of the presumption of innocence because the defendant can be found guilty without the prosecution being required to prove fault.

The inclusion of strict liability offences for a contravention of the TG Act is a purposeful deterrence measure. A requirement for the prosecution to prove the existence of a fault element, such as intention or recklessness, would not adequately protect the public from the supply, and advertising for supply, of vapes, that are non-compliant with requisite regulatory obligations.

Strict liability offences are introduced because of the potential risk to public health arising from vapes, to strike an appropriate balance between deterrence and the right of the individual to be presumed innocent. The conduct involved in these offences is sufficiently serious that, if the defendant were convicted of an equivalent fault-based offence, a much higher penalty could be imposed including, in some cases, a significant term of imprisonment.

The strict liability provisions are compatible with Article 14(2) of the ICCPR, as the provisions pursue a legitimate objective in acting as a deterrent to behaviour that may otherwise represent a risk to public health, in particular, youth and young people, and are reasonable and proportionate in achieving that outcome. Where the prosecution that the defendant is culpable and the relevant fault elements such as intention and recklessness can be established, the normal fault-based offence could be pursued.

Reverse burden of proof

The primary offences in the Bill have offence and civil penalty specific defences, described in the Bill as exceptions. In effect, these defences reverse the burden of proof that would usually apply in an offence or civil penalty contravention, by requiring the defendant to discharge the evidential burden of proof for one or more elements. The reverse onus represents a departure from the ordinary principle of criminal law that a defendant is presumed to be innocent, and that the prosecution must prove every element of an offence relevant to the person's guilt.

The exceptions for relevant offences and civil penalty contraventions are set out in subsection 41Q(5) for importation, subsection 41QA(5) for manufacture, subsections 41QB(6), (7) and (8) operating in conjunction for wholesale supply, subsections 41QB(9), (10) and (11) operating in conjunction for retail supply, subsections 41QC(13) and (14) operating in conjunction for possession of a commercial quantity and subsections 41QD (7) and (8) operating in conjunction for possession of less than a commercial quantity. Under these exceptions, a person charged with the relevant offence will bear the evidential burden – that is, the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist (see subsection 13.3 of the *Criminal Code*). In each case, placing the evidential burden on the defendant is a reasonable and proportionate measure to ensure the effective regulation of vaping goods.

Although counter to the fundamental principle of the presumption of innocence, it is established practice that reversal of burden offences are reasonable and appropriate in circumstances in which relevant matters will ordinarily and peculiarly be within the defendant's knowledge while also be easily adduced by the defendant and where the conduct proscribed by the offence poses a grave danger to public health or safety. The existence of evidence relating to a particular licence, authorisation, approval, permission or exemption in relation to certain vaping goods or conduct is particularly within the knowledge of the defendant.

This approach is well established in Commonwealth and state and territory legislation. The presence of exceptions, for which the defendant must adduce or point to evidence that is peculiarly within their knowledge, can be seen in offence provisions under the TG Act (sections 19B and 41MI), the Criminal Code (sections 137.1 and 137.2), and state legislation such as the *Drug Misuse and Trafficking Act 1985* NSW (section 10).

The Bill introduces offences and civil penalty provisions that prohibit the import, manufacture, advertising, supply and commercial possession of vaping goods, subject to exceptions. Depending on the prohibited conduct, the exceptions include where the person has the appropriate licence, authority, approval or authorisation, the person was granted a consent by the Secretary of the Department to carry out those activities or the goods are supplied within the existing (lawful) pharmaceutical supply chain. The prohibited conduct and supply chain are made up of controls at the Commonwealth or state and territory levels, or both. The enforcement of these prohibitions is to be undertaken by both states and territories, as well as the Commonwealth. For this reason, the evidence to substantiate the lawful status of the

goods, or the specified activity will not rest with one government agency and is very likely to be split across many.

In contrast, the person seeking to rely on the exceptions will likely hold the evidence to substantiate the lawful status of the goods with respect to relevant importation, manufacture, supply or possession activities. The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the efficient regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. The Bill provides a list of the necessary evidence that a defendant needs to produce, such as an authority to prescribe a prescription only medicine in a state or territory or otherwise deal with vaping goods.

Thus, these provisions, despite reversing the evidential burden, are compatible with Article 14(2) of the ICCPR, as they pursue a legitimate objective in acting as a deterrent to behaviour and activities that may otherwise represent a risk to public health, and are reasonable and proportionate in achieving that outcome.

The right to be free from self-incrimination

Article 14(3)(g) of the ICCPR protects the right of an individual to be free from self-incrimination in the determination of a criminal charge by providing that a person cannot be compelled to testify against him or herself or confess guilt. The common law also recognises the privilege against self-incrimination, which applies unless expressly or impliedly overridden by statute. The privilege against self-incrimination may be subject to permissible limits but any such limitations must be for a legitimate objective and be reasonable, necessary and proportionate to that objective.

This Bill limits the right for an individual to be free from self-incrimination where the exercise of this right could seriously undermine the effectiveness of the regulatory scheme and prevent the identification of persons involved in the advertising, and potentially the supply, of vaping goods.

Sections 42DZD and 42DZE provide an offence and civil penalty where a person advertises or causes the advertising of vaping goods without authorisation or in a manner that does not comply with an authorisation that has been given. However, it may not be clear from the outset whether the person responsible for the advertisement was the person apparently responsible or a third party. Sections 42DZF, 42DZG, and 42DZH confer a power to require production, by a person apparently responsible for advertising vaping goods, of specified information relating to advertisements about vaping goods, which could be used to obtain information about the procurement of an advertisement, such as the identity of the procurer.

Without limiting the right to be free from self-incrimination, persons apparently responsible for advertising could withhold pertinent information that would seriously

undermine the Secretary's power to identify persons involved in the advertising, and potentially the supply, of vaping goods.

Section 42DZJ therefore removes the privilege against self-incrimination in relation to the requirement to provide specified information under sections 42DZF.

The abrogation of the privilege is acceptable in the circumstances because the specified information will generally only be within the knowledge of the person concerned and persons who may be acting unlawfully and would be unlikely to identify themselves. Further, the abrogation of the privilege is accompanied by immunity under subsection 42DZJ(2) from further criminal or civil proceedings against the individual to whom a requirement to produce specified information is directed, other than in a limited number of proceedings. These proceedings are those in relation to an offence for providing information or document in response to a notice and the information or document is false or misleading in a material particular (subsections 42DZG(3) and (4) refer), or a civil penalty contravention proceeding under subsection 42DZH where the person complying with the notice gives information or documents that are false or misleading in a material particular. The proceedings would be justifiable to ensure that the person complying with the notice provides relevant information or documents that are not false or misleading in a material particular.

Criminal offences and civil penalty provisions relating to the importation, manufacture, supply, commercial possession and advertisement of vaping goods, subject to exceptions

The Bill introduces the following offences and civil penalty contraventions, subject to exceptions:

- (a) section 41Q provides a fault-based offence (subsection 41Q(1) refers), an offence of strict liability (subsection 41Q(2) refers), and a civil penalty provision (subsection 41Q(3) refers) relating to the importation of vaping goods in Australia. Subsections 41Q(1), (2) and (3) do not apply if the importation of the vaping goods would not be prohibited under the CPI Regulations under the *Customs Act 1901* (the Customs Act);
- (b) section 41QA provides a fault-based offence, a strict liability offence and a civil penalty provision relating to the manufacture of vaping goods at premises in Australia. These offences and civil penalty contravention do not apply if the vaping goods are therapeutic goods and the person manufacturing the goods:
 - (i) is a holder of a manufacturing licence under Part 3-3 of the TG Act, or
 - (ii) holds a conformity assessment document that applies to the vaping goods; or
 - (iii) was granted a consent under subsection 41RC(1) to manufacture the vaping goods, or carry out the manufacture of the vaping goods at the premises and the manufacture, or the step was carried out in accordance with the consent;

- (c) section 41QB provides a fault-based offence, a strict liability offence and a civil penalty provision relating to the supply of vaping goods. Exceptions from the application of these provisions apply in relation to legitimate persons involved in the wholesale supply chain and the retail supply chain of therapeutic vapes respectively;
- (d) section 41QC provides fault-based offences, strict liability offences and civil penalty provisions relating to the possession of at least commercial quantities of vaping goods. Exceptions to the application of these provisions apply in relation to legitimate persons involved in the supply chain for therapeutic vapes. Absolute liability applies to the physical element of the fault-based offence in relation to the specified quantity of the kind of vaping goods;
- (e) section 41QD provides a fault-based offence, a strict liability offence and a civil penalty provision relating to the possession of less than a commercial quantity of vaping goods, subject to exceptions. Absolute liability applies to the physical element of the fault-based offence in relation to the quantity being less than a commercial quantity of that kind of vaping goods. Exceptions to the application of these provisions apply in relation to legitimate persons involved in the supply chain for therapeutic vapes. Importantly, there is also an exception if possession is for personal use or if a person possesses vaping goods on behalf of another person for whom the goods have been lawfully supplied;
- (f) section 42DZD provides a fault-based offence and a strict liability offence relating to the advertisement of vaping goods, which is not authorised, or if authorised does not comply with the authorisation;
- (g) section 42DZE provides a civil penalty provision relating to the advertisement of vaping goods, which are not authorised or if authorised does not comply with the authorisation;
- (h) section 42DZG provides fault-based offences and strict liability offences for the failure to comply with a notice under section 42DZF or provision of false or misleading information;
- (i) section 42DZH provides a civil penalty provision in relation to giving false or misleading information or document in compliance with a notice under section 42DZF;
- (j) section 42DZL provides offences for contravening a direction under section 42DZK; and
- (k) section 42DZM provides civil penalty provisions for contravening a direction under section 42DZK.

The right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted

Article 14(7) of the ICCPR provides that “no one shall be liable to be tried or punished again for an offence for which he has already been finally convicted or acquitted in accordance with the law and penal procedure of each country”. This prohibition on double jeopardy is also a fundamental safeguard in the common law of Australia. It means that a person who has been convicted or acquitted of a criminal charge is not to be re-tried for the same or substantially the same offence. This prohibition, as provided in Article 14(7), is limited to proceedings relating to a criminal charge. However, it is noted that whether a proceeding is civil or relates to a criminal charge under Article 14(7) is determined by the substance and the effect of the proceedings themselves, rather than their label under domestic law.

The right not to be twice tried or punished for the same offence may be engaged as the Bill permits both criminal and ‘civil’ proceedings to be brought against a person for the same conduct. However, the commencement and conduct of proceedings brought under the offences and civil penalty provisions introduced by the Bill are subject to the requirements under Division 2 of Part 5A-1 of Chapter 5A of the TG Act. Under Division 2 of Part 5A-1 criminal proceedings may not be commenced against a person after they have been ordered to pay a civil penalty for the same conduct. Similarly, criminal proceedings cannot be brought against a person for conduct that has already been the subject of civil penalty order. Finally, any civil proceedings for the same conduct for which criminal proceedings have commenced are stayed and can only be re-instated if the person is not convicted of the criminal offence.

Absolute liability

The Bill includes absolute liability fault element to specified physical elements set out in paragraphs 41QC(1)(b), 41QC(4)(b), 41QC(7)(b) and 41QD(1)(b) of the fault-based offences.

In relation to paragraph 41QC(1)(b), for example, the absolute liability fault element is proposed because it would be quite challenging and difficult to prove beyond reasonable doubt that a person was reckless that the quantity in their possession was at least a commercial quantity but less than 100 times the commercial quantity.

Similarly, it would be quite challenging for the prosecution to prove beyond reasonable doubt that a person was reckless that the quantity in their possession was at least a commercial quantity but less than 100 times the commercial quantity. Although recklessness is a lower threshold than knowledge or intention, the prosecution would still be required to point to some evidence that suggests the defendant was reckless as to the **specific** quantity. This includes recklessness as to what a commercial quantity is under the Regulations.

Requiring proof of fault of the relevant element to which strict or absolute liability applies would undermine deterrence in relation to the possession of a commercial quantity of vaping goods, and there are legitimate grounds for penalising persons lacking the necessary fault in respect of that element. The objective is to deter the

possession and subsequent supply of commercial quantities of vaping goods in Australia. At the same time, supply and possession of vaping goods for smoking cessation or the management of nicotine dependence would be permissible. The circumstances where possession of these goods are allowed or acceptable are set out in the exceptions to the offences.

The same reasoning applies to new paragraphs 41QC(4)(b), 41QC(7)(b), and 41QD(1)(b). By way of comparison, for drug offences under the *Criminal Code*, the fault element attached to the physical element relating to quantity (which is circumstance) is absolute liability (see s 6.2 of the Code). As such, there are no fault elements attributed to the physical element that the drugs are of a certain quantity.

An example of this approach can be found in s 307.5 of the Code:

“307.5 Possessing commercial quantities of unlawfully imported border controlled drugs or border controlled plants

- (1) A person commits an offence if:
 - (a) the person possesses a substance; and
 - (b) the substance was unlawfully imported; and
 - (c) the substance is a border controlled drug or border controlled plant; and
 - (d) the quantity possessed is a commercial quantity.

Penalty: Imprisonment for life or 7,500 penalty units, or both.

- (2) Absolute liability applies to paragraphs (1)(b) and (d).
- (3) The fault element for paragraph (1)(c) is recklessness.
- (4) Subsection (1) does not apply if the person proves that he or she did not know that the border controlled drug or border controlled plant was unlawfully imported.

Note: A defendant bears a legal burden in relation to the matter in subsection (4) (see section 13.4).”

The rationale behind this approach is discussed in the Explanatory Memorandum to the Law and Justice Legislation Amendment (Serious Drug Offences and Other Measures) Bill 2005:

“Applying absolute liability to the element of quantity...will markedly improve the enforceability of these offences [drug offences]. This approach was recommended by MCCOC in 2003 as a modification to the model offences originally proposed in its 1998 report and was also endorsed by the Standing Committee of Attorneys-General”.

The MCCOC refers to the Model Criminal Code Officers Committee of the Standing Committee of Attorneys-General, which was involved in the development of a national model criminal code for Australian jurisdictions.

Applying this approach to new draft 41QC(1), provided the prosecution can establish that the quantity is at least a commercial quantity but less than 100 times the commercial quantity, both the physical and fault elements will be satisfied. The same observations can be made for the other possession offences in the Bill. Note, however, that despite the inclusion of the absolute liability fault element, the human rights relating to presumption of innocence, the right to a fair trial and hearing, and the right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted all apply to the defendant.

The human rights identified in Article 14 of the ICCPR, are engaged by the Bill but the Bill does not limit those rights, and if it does there are legitimate reasons for doing so to ensure that access to vaping goods is appropriately restricted. In achieving that objective, any limitation to a particular human right is proportionate to that objective.

Conclusion

The Bill is compatible with human rights because it promotes and supports a number of rights and to the extent that it limits other rights, the limitations are reasonable, necessary and proportionate.

The Bill promotes and supports the following rights:

- the *right to health* under Article 12 of the ICESCR;
- the *right to life* under Article 6 of the International Covenant on Civil and Political Rights (ICCPR);
- the *obligation to ensure the survival and development of children* under Article 6(2) of the Convention of the Rights of the Child (CRC);
- the *obligation to protect children from illicit use of narcotic drugs and psychotropic substances* under Article 33 of the CRC.

The Bill engages a number of other rights, being:

- the *right to privacy* under Article 17 of the ICCPR;
- the *right to freedom of expression* under Article 19(2) of the ICCPR;
- the *right to a fair hearing* under Article 14(1) of the ICCPR;
- the *right to the presumption of innocence* under Article 14(2) of the ICCPR;
- the *right to be free from self-incrimination* under Article 14(3)(g) of the ICCPR;
- the *right not to be tried or punished again for an offence for which a person has already been finally convicted or acquitted* under Article 14(7) of the ICCPR.

However, to the extent that the Bill limits any of these rights the limitations are reasonable, necessary and proportionate to achieving the aim of protecting public health by limiting access to harmful vaping goods.

The Hon Mark Butler MP, Minister for Health and Aged Care

THERAPEUTIC GOODS AND OTHER LEGISLATION AMENDMENT (VAPING REFORMS) BILL 2024

NOTES ON CLAUSES

Clause 1 – Short Title

The clause provides for the short title of the TG Act, once enacted, to be the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024*.

Clause 2 – Commencement

This clause provides the timetable for the commencement of various provisions contained in the Bill as follows:

- Sections 1 to 3 commence on the day that the Bill receives the Royal Assent;
- Schedule 1 commences the later of 1 July 2024 and the day after the Bill receives Royal Assent;
- Schedule 2 commences the day after the Bill receives the Royal Assent; and
- Schedule 3 commences at the same time as Schedule 1.

Clause 3 – Schedules

This clause provides that each Act that is specified in a Schedule to this Bill is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item has effect according to its terms.

This is a technical provision which gives operational effect to the amendments contained in the Schedules.

Schedule 1 amends the *Therapeutic Goods Act 1989* (the TG Act).

Schedule 2 amends the *Customs Act 1901* (the Customs Act).

Schedule 3 amends other Acts, including the *Industrial Chemicals Act 2019* and the *Public Health (Tobacco and Other Products) Act 2023*.

SCHEDULE 1 — Amendment of the *Therapeutic Goods Act 1989*

Background

On 2 May 2023, the Minister for Health and Aged Care announced the Government's intention to address the significant generational harms posed by vaping in Australia by implementing a ban on all vaping goods, except vaping goods imported, manufactured, or supplied in accordance with the TG Act, and to strengthen the controls for therapeutic vapes, including by requiring therapeutic vapes to be supplied to patients through pharmacy settings.

At a general level, a 'therapeutic vape' is a shorthand expression for therapeutic vaping goods which are 'therapeutic goods' within the meaning of the TG Act and supplied within the existing (lawful) pharmaceutical supply chain.

The amendments in this Schedule will implement these measures by expanding the TG Act to regulate vaping goods that are not simply 'therapeutic goods'. This is intended to achieve a comprehensive, and nationally consistent, approach to the regulation of vapes by relying on the federal cooperative scheme for therapeutic goods. All states and territories have enacted corresponding laws to adopt the Commonwealth TG Act as amended from time, with Western Australia recently progressing their own corresponding law. The corresponding laws are designed to fill the gap in the Commonwealth's constitutional power to ensure appropriate coverage for the regulation of therapeutic goods.

Specifically, the measures in this Schedule are intended to:

- introduce key definitions, and related powers including the power for the Minister to, by legislative instrument, determine that specified goods are therapeutic goods, including when used, advertised or presented for supply in a particular way;
- prohibit the importation, manufacture, supply and commercial possession of vaping goods, with specified exceptions that are designed to reflect lawful dealings with therapeutic vaping goods and which include an exception for personal use in relation to the offences and civil penalties relating to the possession of less than a commercial quantity of vaping goods;
- enable the Secretary to consent to the manufacture, supply or commercial possession of vaping goods, with the effect that a person to whom such a consent is granted would be covered by an exception in relation to the relevant offences and civil penalties for such conduct – this measure is designed to ensure that persons who lawfully deal in therapeutic vaping goods will not be subjected to sanction for such dealings;
- introduce a new, tailored advertising framework for vaping goods, with requirements, and offences and civil penalties, designed to protect consumers from the advertising of vaping goods, including vulnerable audiences such as young Australians. Consistent with the existing advertising framework for therapeutic goods, the new framework will not apply to advertisements directed exclusively at health practitioners and other specified kinds of persons such as practice managers for health practitioners;
- introduce a number of new measures to enhance the compliance and enforcement framework for both vaping goods and therapeutic goods,

principally through powers for the Secretary to give enforceable directions to persons requiring them to do specified things in relation to particular products, such as to relabel the goods to bring them into compliance with the TG Act, or to deliver the goods for destruction or disposal, and through the introduction of new arrangements relating to the forfeiture and retention of products;

- allow for the delegation of certain powers of the Secretary to an officer of a Department of State of a state, a Department or administrative unit of the Public Service of a territory or an authority of a state or territory, in order to empower state and territory officials to carry out enforcement powers under the new vaping reforms, as part of measures to ensure a comprehensive and consistent approach to addressing unlawful vaping goods;
- ensure that the Secretary may release information about vaping goods to the public and to specified persons, bodies or authorities or kinds of persons, bodies or authorities, such as state and territory health departments and law enforcement bodies to support compliance and enforcement efforts and inform the public in relation to risks posed by particular vaping goods; and
- make a small number of more minor amendments, including updating the offences and civil penalties in the Act for breaching a condition of an exemption or approval for therapeutic goods. This will help ensure that therapeutic vapes supplied in Australia meet minimum benchmarks including the requirement for sponsors to notify the Secretary in relation to the compliance of their products with applicable quality standards.

The amendments complement the recent amendments to:

- the CPI Regulations to ban the importation of non-therapeutic and disposable single use vapes (subject to certain exceptions) and to require a licence and permit to import non-disposable therapeutic vapes; and
- the TG Regulations and MD Regulations to strengthen the regulatory controls for therapeutic vapes that are exempt from the requirement to be included in the Australian Register of Therapeutic Goods (the Register).

Part 1—Definitions and objects of Act

Therapeutic Goods Act 1989

Item 1 – Subsection 3(1) (after paragraph (b) of the definition of therapeutic goods)

This item amends the definition of ‘therapeutic goods’ in subsection 3(1) of the TG Act to insert new subparagraph 3(1)(ba), consequential to the introduction of new section 7AAA.

New subparagraph 3(1)(ba) has the effect that the definition of ‘therapeutic goods’ in subsection 3(1) of the TG Act includes goods determined to be therapeutic goods under new section 7AAA.

Item 2 - Subsection 3(1) (paragraphs (e) and (f) of the definition of therapeutic goods)

This item makes a minor amendment to paragraphs (e) and (f) of the definition of ‘therapeutic goods’ in subsection 3(1) of the TG Act consequential to the introduction of new section 7AAA.

Item 3 – At the end of subsection 4(1)

This item amends subsection 4(1) of the TG Act to include the regulation of vaping goods. The amendment makes it clear that the objects of the TG Act include the establishment and maintenance of a national system of controls relating to the regulation of vaping goods that are imported, manufactured, supplied in Australia or exported from Australia.

Item 4 - After section 7

This item inserts new subsections 7AAA(1) and (2) into the TG Act.

New subsection 7AAA(1) provides that the Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods (other than goods declared not to be therapeutic goods under an order in force under section 7 and goods covered by a determination under subsection 7AA(1) or (2) (excluded goods)):

- (a) are therapeutic goods; or
- (b) when used, advertised, or presented for supply in a particular way, are therapeutic goods.

New paragraph 7AAA(2)(a) sets out the matters that the Minister must have regard to before making a determination under new subsection 7AAA(1). These matters include whether:

- (a) it is likely that the specified goods, if not regulated under this Act, might harm the health of members of the public;

- (b) it is appropriate in all the circumstances to apply the national system of controls relating to the quality, safety, efficacy and performance of therapeutic goods established by this Act to regulate the specified goods;
- (c) the kinds of risks from the specified goods to which members of the public might be exposed could be more appropriately dealt with under another regulatory scheme.

New paragraph 7AAA(2)(b) provides that the Minister may have regard to any other relevant matter before making a determination under new subsection 7AAA(1).

Allowing the definition of therapeutic goods to be broadened in delegated legislation will enable rapid amendments to cater for novel and unanticipated products that it is desired should be regulated as therapeutic goods. Despite the broad definition of therapeutic goods, the importation, manufacture, supply, export and advertising of goods in novel and unanticipated forms that should be regulated as ‘therapeutic goods’ may not readily fit within the current definition is still a possibility and may pose a risk to public health. This is intended to be a broad power for the Minister to specify any good to be a therapeutic good.

Allowing the Minister to determine specified goods to be therapeutic goods through delegated legislation is important, as that definition could be readily amended to capture a new range of goods that for public health reasons should be regulated as therapeutic goods under the TG Act.

Subsection 57(1) of the TG Act allows the Minister to delegate this power to a broad class of delegates. This ensures that those with the most relevant expertise in regulating new and emerging therapeutic goods can participate in the decision-making process. It is also important to note that any amendments to the defined term in delegated legislation would be subject to Parliamentary scrutiny and disallowance.

Item 5 - After paragraph 8(1)(b)

This item amends subsection 8(1) of the TG Act to insert new paragraph 8(1)(ba). In effect, this amendment broadens the classes of person from whom the Secretary may, by giving written notice, request information under subsection 8(1).

The amendment broadens the classes of person to include a person who has imported into Australia, or supplied in Australia, goods in relation to which the Minister is considering making a determination under the new section 7AAA(1) (goods that are therapeutic goods).

This will allow the Secretary to collect relevant information of the kind referred to above which can then be provided to the Minister for the purposes of making such a determination.

Part 2—Regulation of vaping goods

Division 1—Main amendments

Therapeutic Goods Act 1989

Item 6 – Subsection 3(1)

This item inserts two definitions in subsection 3(1) of the TG Act. The definitions provide that ‘commercial quantity’ of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations, and ‘evidential burden’, in relation to a matter means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist. The definition of ‘evidential burden’ reflects the definition in section 13.3 of the Commonwealth *Criminal Code*.

Definition of commercial quantity

It is necessary and appropriate for a quantity of a kind of vaping goods that would amount to a commercial quantity (item 6 of Schedule 1) to be prescribed in delegated legislation, noting the importance of this definition to the offence provisions proposed to be inserted by the Bill.

This definition applies to both the offence and civil penalty provisions proposed to be inserted by the Bill relating to possession. However, the definition has greater significance to the offence provisions due to the cascading maximum penalties that apply under clause 41QC (possession of a commercial quantity of vaping goods). This is because the applicable offence provision and maximum penalty depends on the quantity of vaping goods found in a person’s possession.

Necessary and appropriate

It is necessary and appropriate for a quantity of a kind of vaping goods that would amount to a commercial quantity to be prescribed in regulations to:

- ensure flexibility to change the quantity in line with prescribing practices of health professionals with respect to therapeutic vapes for personal use;
- ensure the commercial quantity is adaptive to new and emerging design specification, which could affect the types of vaping substance used, the delivery of vaping substance, the volume and concentration capacity of the vaping device and the number and types of vaping accessories available for use with vaping devices and substances;
- allow quantities to be amended efficiently, if necessary, in response to illicit trade of vapes to ensure that the criminal offences continue to act as a sufficient deterrent; and
- maintain a workable connection between a commercial quantity of vaping goods and acceptable or legitimate volumes or quantities of therapeutic vaping goods.

The vaping reforms are not intended to prohibit the possession of vaping goods for personal use, provided the vapes in a person’s possession are appropriately less than a

commercial quantity. Accordingly, the phrase ‘commercial quantity’ serves as a marked distinction between commercial possession and possession for personal use.

The medical advice as to the appropriate quantity of vaping goods for personal use is evolving and differs significantly depending on the patient’s individual circumstances. This makes it difficult to specify with certainty where the relevant line is between a quantity that could reasonably be for personal use, and where that line is clearly crossed, and the possession is for commercial purposes.

By allowing for the quantities to be prescribed in the regulations, the government can more easily and quickly respond as the medical and public health advice evolves. Flexibility will be important in ensuring that by the prohibitions on commercial possession by unlawful actors in Australia are fit for purpose and achieve the regulatory objective of these measures.

The reasoning behind the proposed approach with respect to the meaning of a commercial quantity would, of course, be included in the explanatory statement to the regulations and would be based on expert public health and medical advice and the broader compliance and enforcement experience.

Analogous approach – commercial quantity of serious drugs and precursors

An example of an analogous approach where a commercial quantity of a substance has been prescribed in regulations made under primary legislation is the commercial quantity of a serious drug, controlled precursor or border-controlled precursors in the *Criminal Code Act 1995*.

Section 301.10 of the *Criminal Code Act 1995* provides that the quantity of a serious drug, controlled precursor or border-controlled precursor is prescribed. These quantities are set out in the *Criminal Code Regulations 2019* (the *Criminal Code Regulations 2002* at the time the provision was introduced).

The reason provided for this approach similarly related to the need for flexibility in the face of evolving markets and emerging products. It was felt that any delay in updating quantities would be exploited by ‘entrepreneurial criminals and organised crime groups’. The same arguments apply in relation to vaping goods. Further, the regulations would remain subject to parliamentary scrutiny and disallowance.

Item 7 – Section 3(1) (definition of *manufacture*)

This item amends the definition of ‘manufacture’ in the TG Act to provide that the term relates to the manufacture of vaping goods, as well as therapeutic goods.

Item 8 – Subsection 3(1)

This item inserts three definitions in section 3(1) of the TG Act, for ‘medical practitioner’, ‘nurse practitioner’, and ‘pharmacist’. These terms are defined as meaning a person who is registered, licensed or authorised (as relevant) under a law of

a state or internal territory that provides for such registration, licensing or authorisation.

Item 9 – Subsection 3(1) (paragraph (c) of the definition of *supply*)

This item amends the definition of ‘supply’ in subsection 3(1) of the TG Act to provide that the term also relates to vaping goods.

Item 10 – Subsection 3(1)

This item inserts new definitions in subsection 3(1) of the TG Act. It inserts the new definition of ‘unit’ of vaping goods, which has the meaning prescribed by the regulations.

This item also inserts new definitions for ‘vaping accessory’, ‘vaping device’, ‘vaping goods’ and ‘vaping substance’, all of which are defined in new section 41P of the TG Act. The scope of each of these definitions are discussed in relation to the operation of section 41P.

Definition of a “unit” of vaping goods

The concept of a ‘unit’ of vaping goods has no application to the criminal offence provisions proposed to be inserted by the Bill. Rather, it is a matter central only to the enforceability, and application, of the civil penalty provisions in the proposed new Chapter 4A relating to the importation, manufacture, supply and commercial possession of vaping goods in subclauses 41Q(3), 41QA(3), 41QB(3), 41QC(10) and 41QD(4).

The concept is intended to provide an appropriate mechanism for calculating the number of contraventions of a civil penalty provision, as an alternative to the prosecution of corresponding criminal conduct.

As a public health measure directed to discourage unlawful conduct relating to vaping goods to ultimately discourage the uptake of vaping, the definition of a ‘unit’ needs to be flexible and adaptable as appropriate in the circumstances. It is proposed that a unit of vaping goods is prescribed in regulations made under the TG Act.

The regulations would be subject to appropriate parliamentary scrutiny and disallowance. This supports an approach that is adaptive to evolving public health issues, contemporary clinical and scientific evidence and changes in technology and the market more generally.

Necessary and appropriate

The intention of the new offences and civil penalty provisions is to deter unlawful conduct, arrest the alarming increase in the use of vapes in Australia, particularly among youth and young adults, and to prevent a new generation of persons being exposed to dangerous chemicals and developing nicotine dependence.

It is necessary and appropriate for the definition of a ‘unit’ of vaping goods (in item 10 of Schedule 1) to be prescribed by regulations having regard to:

- the design, development and marketing of unlawful vaping goods, which will continue to evolve following the vaping reforms; this is because the market has consistently sought to evade compliance efforts in recent years through product design and concealment; successful regulation must remain responsive to industry changes;
- the scientific, medical and public health understanding in relation to vaping goods, which will continue to mature, as the health impact of unlawful vapes is determined particularly with reference to nicotine concentrations and toxicities;
- matters specified in other delegated legislation made under the *Therapeutic Goods Act 1989* (TG Act), such as standards, which may change from time to time and materially impact the determination of a ‘unit’ of vaping goods.

Given the need for adaptability, it is appropriate for a ‘unit’ of vaping goods to be prescribed in the regulations having regard to changing scientific, medical, and public health understanding. Any incongruence with acceptable or legitimate volumes or quantities of therapeutic vaping goods would create serious difficulties for compliance and enforcement efforts.

Prescribing a ‘unit’ of vaping goods in delegated legislation would provide for necessary flexibility and agility to ensure that the public health risks from vaping are expeditiously managed and enforced in response to an aggressive and changing illicit market. The public health risks are significant and are explained at pages 3 to 5 of the explanatory memorandum to the Bill.

The reasoning behind the proposed approach with respect to a ‘unit’ of vaping goods would be included in explanatory material to the regulations. and based on further consultation, medical advice and the broader compliance and enforcement experience.

Responsive to the evolution of the illicit market

The government’s experience in enforcing the existing regulatory framework has demonstrated that the illicit market is quick to adapt to the changing regulatory settings, including making alterations to the manufacturing of vaping goods.

Examples include the removal of all references to nicotine on the label of vaping goods being imported and subsequently supplied in Australia, and the deliberate mischaracterisation of vaping goods as perfume atomisers or the like.

Such steps significantly frustrate the ability for the Australian Border Force and the Therapeutic Goods Administration (TGA) to take appropriate regulatory action to prevent these goods entering Australia and making their way to retailer stores for the purpose of direct supply to the public.

Flexibility in determining a unit of vaping goods will ensure that any changes to the way that vaping goods are designed, manufactured, promoted or characterised can be appropriately responded to by ensuring that a unit of vaping goods reflects the reality of the evolving illicit market.

Responsive for public health reasons

Clause 41P provides that vaping goods are to be defined as including all their various permutations: vaping accessories, devices, and vaping substances. Vaping goods can be one, or a combination of these different permutations, and there can be different characteristics, which distinguish the goods from each other, and the objective harm of each permutation of the goods themselves.

Flexibility in determining a unit of vaping goods is critical in ensuring that the harms of the different permutations of vaping goods are internally consistent and correspond to the objective harms of each kind of vaping good.

For example, the objective harm of 20 vaping accessories could be said to correspond to the objective harm of 200ml of vaping substance. However, this assessment may change as over time, and require amendment to ensure consistency, depending on the relevant concentration or toxicity.

There may be circumstances where the objective harm may be linked to the nicotine concentration in the vaping substance, rather than the volume itself. Determining a ‘unit’ of each of the permutations may be complex and is anticipated to evolve as the scientific and medical knowledge about, vaping goods develops and matures.

Relevance of other delegated legislation

Standards, which are disallowable legislative instruments, made under the TG Act set maximum volumes for vaping substances. These volumes are subject to change from time to time and will be relevant to determining a ‘unit’ of vaping goods. Prescribing ‘units’ in the regulations allows flexibility to amend this concept if maximum volumes in the standards are changed.

Example – traveller’s exemption

An example of an analogous approach, which has been specified in delegated legislation, is the prescription of the quantity allowable under the traveller’s exemption in regulation 5A of the *Customs (Prohibited Imports) Regulations 1956*.

This exemption allows a person travelling to Australia to bring a small quantity of vaping goods with them for use in their treatment, or someone they are caring for, who is entering Australia on the same ship or aircraft. The current maximum allowable quantity is no more than 2 vapes, 20 vaping cartridges and 200 ml of vaping liquid.

While no explanation was provided in the explanatory statement for the *Customs Legislation Amendment (Vaping Goods) Regulations 2023*, the volumes and quantities specified in the traveller’s exemption are relatively modest and considered to be reasonable in the circumstances for the personal use of a traveller to Australia.

Item 11 – After Chapter 4

This item inserts new Chapter 4A in the TG Act. This Chapter is titled ‘Vaping goods’ and principally deals with the regulation of vaping goods under the TG Act.

Division 1 in Part 4A-1 deals with introductory matters. Division 1 contains new section 41N which provides the simplified outline of this Chapter.

New section 41NA provides that an offence provision or civil penalty provision in Chapter 4A does not limit the generality of an offence provision or civil penalty provision in any other Chapter, and those provisions in other Chapters do not limit the generality of offence provisions or civil penalty provisions in Chapter 4A.

Division 2—Interpretation

Therapeutic Goods Act 1989

Division 2 in Part 4A-1 provides definitions for relevant terms.

Division 2 contains new subsection 41P(1) which provides a definition for *vaping accessory*, *vaping device*, *vaping goods* and *vaping substance*. These definitions would broadly mirror the definitions inserted into the CPI Regulations by the *Customs Legislation Amendment (Vaping Goods) Regulations 2023*. Where the proposed definitions materially differ from those already present in the CPI Regulations, explanation of this difference is provided below.

The term *vaping goods* is defined to mean a vaping substance, vaping accessory or vaping device, as well as goods the presentation of which includes an express or implied representation that the goods are such goods, or that they are included in a class of goods that are determined to be vaping goods under subsection (3). This definition captures goods in relation to which the name, labelling, packaging, or any advertising or informational material associated with the goods, includes an express or implied representation that the goods are either a *vaping substance*, *vaping accessory* or *vaping device*. In relation to a *vaping device*, one example where this may arise would include a good that is included in the same package as a *vaping substance* and/or *vaping accessory*, making it apparent that it is intended to be used as a *vaping device*. Similarly, a substance may be characterised as a *vaping substance* where it is labelled as an ‘e-juice’ or an ‘e-liquid’, as it will be apparent that it is for use in, or with, a *vaping device*.

Paragraph (e) of the definition of *vaping goods* would also have the effect that the definition of vaping goods would include goods that are, or are included in a class of goods that are, determined to be *vaping goods* by the Minister under subsection 41P(3). This is a broad power that allows the Minister to determine any good to be a vaping good where regulation under Chapter 4A is desirable.

The term *vaping device* is defined to mean:

- (a) a device (whether or not filled with a vaping substance) that generates or releases, or is designed or intended to generate or release, using a heating

element and by electronic means, an aerosol, vapour or mist for direct inhalation by its user; or

- (b) a device to which paragraph (a) would apply if the device were not temporarily or permanently inoperable, incomplete, damaged, or unfinished.

The note to the definition of *vaping device* provides that humidifiers, diffusers, nebulisers and inhalers are not vaping devices.

Devices that release vapour or mist into the air, including devices such as humidifiers, diffusers and some steam inhalers, do not meet the definition of a vaping device because the vapour or mist is not for direct inhalation by the user. Devices that release vapour, aerosol or mist into the air, and direct that air towards the user through a mask, such as some inhalers and nebulisers do not meet the definition of a vape. Devices that do not produce vapour or mist using a heating element, such as nebulisers and most inhalers, do not meet the definition of a vape because they do not generate the vapour or mist using a heating element.

A heat not burn device, which heats, using a heating element and by electronic means, processed tobacco without combustion and produces a vapour for direct inhalation, meets the definition of a *vaping device*. An e-hookah device that vaporises vaping substances for direct inhalation will meet the definition of a *vaping device*, but a traditional non-electronic shisha device will not be a *vaping device* because it does not use electronic means.

A *vaping device* includes both a finished a device (such as a fully assembled device that is either pre-filled with a vaping substance or simply requires the addition of a vaping substance or vaping accessory in order to be operable) and a device that is incomplete, damaged, temporarily or permanently inoperable or unfinished. It should be noted that the words ‘incomplete, damaged, temporarily or permanently inoperable, or unfinished’ refer to goods that are not yet in full working order, but which could be converted to full working order with some additional parts or by assembly of the parts. This would include goods such as mouthpieces, coils and casements that are intended to be attached to other parts, whether as part of further manufacture or for self-assembly by a consumer. It would also include parts that are intended to be attached to vape accessories, such as batteries intended for use with vape cartridges. Other than the CPI Regulations referring to a *vape*, rather than a *vaping device*, the definition of vaping device to be inserted in the TG Act is not materially different to that definition in the CPI Regulations.

The term *vaping accessory* is defined to mean a cartridge, capsule, pod or other vessel that is for use in, or with, a *vaping device*, and whether or not the cartridge, capsule, pod or other vessel contains a *vaping substance* or is designed or intended to be refilled. This definition would not include a good that would meet the definition of a *vaping device*. In practice this definition intends to capture goods that are vape cartridges, whether or not they are filled with a *vaping substance* or are refillable. A *vaping accessory* would also include a vape cartridge that is integrated with components that would otherwise be considered parts of a *vaping device*, such as a mouthpiece and heating coil. It is not uncommon that vape cartridges are supplied

already integrated with both mouthpieces and coils. It is intended that these goods would be captured by the definition for a *vaping accessory*.

The primary difference between this definition of *vaping accessory* and the definition of vape accessory in the CPI Regulations is that this definition is limited in scope to vape cartridges and other vessels that are intended to be used with, or in, vaping devices. By contrast, the definition of vape accessory in the CPI Regulations is broader and is designed to capture any container of vaping substances, including dripper bottles of e-liquid. This proposed definitional difference is attributable to the differing purposes of the TG Act and the CPI Regulations. The CPI Regulations seek to provide definitions which are most readily identifiable and enforceable by border officials.

In the context of vaping goods, having a definition that captures any small or handheld containers of vaping substances (rather than large vats of liquid for further manufacture) enables border officials to readily identify a class of vaping goods. The definition of *vaping accessory*, as inserted by the new 41P definition into the TG Act, needs to be able to effectively interact with the therapeutic goods framework maintained under the TG Act. As such, the proposed definitions would need to account for the qualitative difference between a filled vape cartridge and filled dripper bottle despite being similar in size and containing vaping substances. Due to the potential inclusion of medical device-like elements, such as a heating coil, in a vape cartridge, it would be regulated differently to a therapeutic good that is (for example) a dripper bottle containing a vaping substance.

The term *vaping substance* is defined to mean nicotine in solution in any concentration (including in a salt or base form) or any liquid or other substance for use in, or with, a vaping device, and includes a container, or part of a container (other than a vaping accessory or vaping device), in which such a liquid or other substance is present.

Vaping substance means a liquid or other substance for use in, or with, a *vaping device* or nicotine in solution in any concentration, including in salt or base form. This definition would extend to the container holding the vaping substance unless the container is a *vaping accessory* or *vaping device*. In practice this means a dripper bottle containing e-liquid would be considered a *vaping substance*. The substances referred to in this definition would include, but are not limited to, a liquid, gel, solid or salt that is intended for use in a *vaping device*. This also applies to bulk *vaping substances*, irrespective of the quantity.

It should be noted that there is no unique chemical or substance that is used only in vaping liquids, gels, solids. Vaping substances can vary greatly in their component ingredients, and may include ingredients that are dangerous chemicals in their own right, as well as ingredients that have a significant range of ‘ordinary’ uses such as in the manufacture of cosmetics, pharmaceuticals, foods and industrial goods (for example, glycerine, propylene glycol, essential oils and vitamins). Where these ingredients that are in widespread use in the community for ordinary purposes are not intended or presented for use for vaping, they will not be affected by this definition.

Finished goods that contain nicotine as an ingredient, but are not nicotine in solution, and are not for use in or with a *vaping device*, such as nicotine patches and nicotine gum, do not meet the definition of a *vaping substance*. However, nicotine in solution, including as a raw material or finished good, will meet the definition of a *vaping substance* even if the solution is not for use with a *vaping device*. All substances for use with a *vaping device* that contain nicotine (as well as substances for use with a *vaping device* that do not contain nicotine in solution), will meet the definition of a *vaping substance*.

Substances made from dried plants, including but not limited to heat-sticks made of tobacco intended for use in a heat not burn *vaping device*, meet the definition of *vaping substance*. Substances for use with e-hookah devices will meet the definition of *vaping substance*, but shisha tobacco is not generally considered to be for use with an electronic shisha device and therefore will not ordinarily meet the definition of a *vaping substance*.

New subsection 41P(2) provides that for paragraph (d) of the definition of ‘vaping goods’ in subsection (1), the presentation of goods includes matters relating to the name of the goods, labelling and packaging of the goods, and any advertising or informational material associated with the use or supply of the goods. New subsection 41P(2) also provides that the goods are taken to be presented as being a particular kind of goods even if the presentation is capable of being misleading or confusing as to the content or proper use or identification of the goods, or suggests that the goods have ingredients, components or characteristics that they do not have.

In practice, subsection 41P(2) will enable the offences in the new Chapter 4A to operate even if goods have inaccurate claims or are the subject of misleading marketing. Subsection 41P(2) is intended to prevent persons from evading the regulatory controls in Chapter 4A by:

- modifying the components or ingredients of vaping goods; or
- designing the vaping goods to make them difficult to identify or detect; or
- describing the goods in a way that conceals their purpose to an uninformed observer but signals the intended use to the user.

Marketing can make individuals believe these goods are safe for human consumption when they are not. Vaping goods are frequently designed to look like other ubiquitous objects such as pens, USB devices, toys, lip glosses and sippy cups, reinforcing the idea that vaping goods are safe for children when this is not the case. For adults using vaping goods, the variability in concentration of the ingredients and potential toxicity of the goods, increases the risk of harm, particularly when the label is misleading.

The effect of subsection 41P(2) would be that there is no requirement for testing or identification by an expert to determine whether a good is a *vaping good*. Goods can be *vaping goods* solely on the basis of express or implied representations made through the presentation of the goods, including the name, labelling, packaging and any advertising or informational material associated with the goods.

Examples of terms that, when used in the presentation of goods, would ordinarily have the effect that those goods are taken to be *vaping goods* include: vapes, e-cigarettes, e-cigs, e-smoke, e-pens, e-sticks, vape pens, vape sticks, pv (personal vaporiser), ENDS (electronic nicotine delivery system), doubler, shortfills, e-liquid and e-juice.

Examples of terms that may, in particular contexts, imply that a good is for vaping include tanks, pods, capsules, cartridges, doubler, shortfills, flavour or cloud, as well as references to nicotine and derivatives of the word nicotine, such as nic, and reference to the type of nicotine such as salt or freebase.

Some vaping goods are designed with colours and cartoons to be attractive to children and their presentation does not include terms commonly associated with vaping. Similarly, vaping goods aimed at adults may have no terms on the label or packaging that explicitly relate to vaping and may have associated informational material and advertising that is explicitly designed to avoid references to vaping. These may nonetheless be *vaping goods* if they are designed or intended for vaping, or the overall presentation indicates that they are a *vaping substance*, a *vaping accessory*, a *vaping device*, or a good determined to be a vaping good under subsection 41P(3).

New subsection 41P(3) provides that the Minister may, by legislative instrument, determine that, for the purposes of this Act, specified goods or a specified class of goods are or are not vaping goods or, when used, advertised, or presented for use or supply in a particular way, are or are not vaping goods. This power will enable the Minister to respond to a rapidly evolving market that has repeatedly sought to evade regulation since the Commonwealth Government first regulated nicotine vaping products in 2021.

The ability to determine that things are not vaping goods is broadly analogous to section 7AA of the TG Act. Section 7AA enables the Minister to exclude goods that would otherwise be therapeutic goods from the therapeutic goods regulatory framework. This power also enables exclusion based on how goods are used, advertised or presented for supply. Determining that goods are not vaping goods would have a similar effect to section 7AA in that it would exclude those goods from the regulatory framework for vaping in the new Chapter 4A. Goods excluded from the new Chapter 4A under subsection 41P(3), would, however, still be subject to the other Chapters of the TG Act (as applicable) if they are therapeutic goods.

The power to exclude vaping goods from the operation of the new Chapter 4A is also similar to the power found in subregulation 5A(5) of the CPI Regulations. This subregulation enables the Minister to approve, by legislative instrument, the importation of vaping goods without an import licence or permit. Like the 7AA power, this in effect excludes certain goods from the operation of regulation 5A of the CPI Regulations.

The subsection 41P(3) is intended to allow the Minister to determine that goods are vaping goods despite those goods not otherwise meeting the definition of vaping goods provided in 41P(1). Such a power is crucial if the Government is to maintain parity with an ever-evolving market.

A principal purpose of subsection 41P(3) will be to capture vape-like products. In 2021, when the Commonwealth Government first addressed the growing vaping problem by changing the scheduling status of nicotine found in vapes in the *Poisons Standard*, the market immediately pivoted to supplying vaping goods that were silent on their nicotine content. This hampered enforcement efforts domestically, as well as at the border, as officers were unable to ascertain the lawfulness of goods in the absence of lab testing for nicotine content.

With respect to the present reforms, a sufficiently precise definition for vaping goods is needed so as to avoid inadvertent capture of unrelated goods such as nebulisers or humidifiers. The Government is already aware of products that are being branded as non-vape, but vape-like, alternatives to vaping. These goods may have systems of direct inhalation but do not heat substances by electronic means and may technically evade the definition of vaping goods. Subsection 41P(3) will enable the Minister to determine such goods to be vaping goods. However, the power is not limited to including vape-like goods. It is a broad power to include or exclude any goods from the definition of a vaping good.

Part 4A-2—Offences and civil penalty provisions relating to vaping goods

Division 1 – General

Division 1 in Part 4A-2 creates a number of offences and civil penalties for importing, manufacturing, supplying and commercially possessing vaping goods. Division 1 contains new sections 41Q to 41QD.

These provisions ban certain activities unless permitted by the TG Act, the Customs Act and by state and territory medicine and poisons laws, as the case may be.

In relation to possession, the intent is not to criminalise or otherwise prohibit the personal possession of vaping goods. It is only commercial possession that is intended to be prohibited or possession other than for personal use.

The sponsor defence will not be available for these offences and civil penalty provisions. This is because the bans are intended to apply to all persons in the supply chain and ensure that supply is through the legitimate pathways.

The intent of the bans is to ensure that vaping goods are only supplied through the same supply chains that apply to goods containing substances included in Schedule 4 to the Poisons Standard (prescription medicines). This will give effect to the policy intention of ensuring that nicotine vapes are only supplied to consumers under medical supervision with a prescription at a pharmacy, subject to very limited exceptions.

Overview of penalties for the prohibitions

The TG Act includes a tiered penalty regime for most offences, with two fault-based offences (one with an aggravated factor) and a strict liability offence. There is also usually a corresponding section which makes the relevant physical conduct a contravention of a civil penalty provision.

This is an example of dual track regulation where the legislation gives regulators a choice of responses in respect of the same physical conduct and a range of enforcement options. Examples include sections 19B and 19D of the TG Act. Providing these options will enable the utilisation of a range of regulatory tools, including the issuing of an infringement notice, commencing civil penalty proceedings or criminal prosecution with a view to specifically and generally deterring the proscribed conduct.

Criminal offences

A criminal offence conviction is considered to be the ultimate sanction for breaching the law. According to the Australian Law Reform Committee Report No 95 – *Principled Regulation* at paragraph 2.9:

The main purpose of criminal law is traditionally considered to be **deterrence and punishment**. Central to the concept of criminality is the notation of individual culpability and the criminal intention for one's actions.

Where the proscribed conduct involves considerable harm to the public health of Australians and requisite mental elements relating to the conduct can be established, the TGA will generally pursue criminal prosecutions through the Director of Public Prosecutions. This is particular the case where the level of culpability of the person warrants criminal sanction.

Conviction of a crime however carries with it a range of serious consequences beyond the immediate penalty, whether the conviction results in imprisonment or a pecuniary penalty, including ineligibility to hold public office or be a director, principal officer or auditor of a company, or to travel to certain countries, and disqualification from being accredited under various legislation. Therefore, the TGA would generally elect to deal with breaches by way of a criminal prosecution where there is an element of culpability. This is particularly so where there is an organised crime element to the offending. Where culpability and criminality of the conduct are not apparent but there is a need to address breaches of the Act and deter future non-compliance, it would be appropriate for the TGA to opt for a civil penalty fine, or other enforcement mechanism such as the giving of an infringement notice, accepting an enforceable undertaking or issuing a forfeiture direction.

A criminal prosecution is considered to be a more appropriate sanction where a contravention is deliberate, where fraud may be involved, where the conduct demonstrates recklessness, where there is a serious pattern of continuous intentional contraventions, or where conduct has endangered lives or has caused death or serious injury.

For the vaping offences, it is proposed that there would be a single fault and strict liability offences, with the fault-based offence considered similar to the existing counterfeit provisions in s 42E of the TG Act. This is because:

- the health risks of vaping are substantial. The widespread supply of vaping goods in the community represents a serious risk of harm to the health of the population, especially among youth and young adults; and
- vape use is increasing, with research undertaken by Cancer Council Victoria showing that 77,200 Victorians who had previously never smoked had used e-cigarettes in the past year.¹⁴

The Guide to Framing Commonwealth Offences at page 39 provides that '[a] penalty should be consistent with penalties for existing offences of a similar kind or of a similar seriousness. This should include a consideration of existing offences within the legislative scheme and other comparable offences in Commonwealth legislation such as the *Criminal Code*'.

Set out below is a table of maximum penalties for comparable offences relating to therapeutic goods and illicit tobacco which serve as a helpful comparator which determined the appropriate maximum penalties for vaping goods.

Offence	Description	Maximum penalty – imprisonment	Maximum penalty – financial
s 19B(1) of the TG Act (aggravated offence)	unlawful importation, exportation, manufacture, supply of therapeutic goods by the sponsor of the goods	5 years	4,000 penalty units (or both)
s 19B(2) of the TG Act (fault-based offence)	unlawful importation, exportation, manufacture, supply of therapeutic goods by the sponsor of the goods	12 months	1,000 penalty units (or both)
s 19B(3) of the TG Act (strict liability)	unlawful importation, exportation, manufacture or supply of therapeutic goods by the sponsor of the goods	Nil	100 penalty units
s 42DL(1) of the TG Act (aggravated offence)	unlawful advertisement of therapeutic goods	5 years	4,000 penalty units (or both)
s 42DL(1) of the TG Act (fault-based offence)	unlawful advertisement of therapeutic goods	12 months	1,000 penalty units (or both)
s 42DL(1) of the TG Act (strict liability)	unlawful advertisement of therapeutic goods	Nil	100 penalty units

¹⁴ [Alarming rise in e-cigarette usage and purchasing... | Quit Victoria](#)

Offence	Description	Maximum penalty – imprisonment	Maximum penalty – financial
s 42E of the TG Act (fault-based offence)	importation, exportation, manufacture or supply of counterfeit therapeutic goods	7 years	2,000 penalty units (or both)
s 308-10 of Schedule 1 to the <i>Taxation Administration Act 1953</i>	possession of tobacco (500 kilograms or above)—reasonable suspicion offence	5 years	1,000 penalty units or both 5 years and the greater of 1,000 penalty units or 5 times the excise duty
s 308-15 of Schedule 1 to the <i>Taxation Administration Act 1953</i>	possession of tobacco (100 kilograms or above)—reasonable suspicion offence	2 years	500 penalty units or both 2 years and the greater of 5 times the excise duty
s 308-20 of Schedule 1 to the <i>Taxation Administration Act 1953</i>	possession of tobacco (5 kg or above)—reasonable suspicion offence	Nil	200 penalty units or the greater of 5 times the excise duty
s 320.2 of the <i>Criminal Code</i>	importation of psychoactive substances	5 years	300 penalty units (or both)

In this context, the maximum penalties for offences relating to the importation, manufacture and supply of vaping goods are considered appropriate, being 7 years imprisonment for fault-based offences and 200 penalty units for strict liability offences. Equally, the sliding scale maximum penalties for offences relating to the possession of vaping goods are also appropriate. Depending on the quantity of vaping goods possessed, a maximum penalty of 7 years, 5 years, 2 years or 12 months will apply for fault-based offences and 420 penalty units, 240 penalty units, 120 penalty units or 60 penalty units will apply for strict liability offences.

Civil penalty provisions

A civil penalty is a punitive sanction of a financial nature, with no aggravating element and no-fault element, imposed through civil court proceedings rather than through the criminal prosecution process. It takes the form of a monetary penalty only and does not result in any criminal conviction.

The focus of a civil penalty is generally the regulation of commercial activity and is directed against corporate or white collar wrongdoing. Therefore, civil penalties are appropriate in regulating commercial activities involving the importation, manufacture, supply and possession of a commercial quantity of vaping goods. This is

particularly so where the relevant activities are undertaken by incorporated bodies, including subsidiaries of multinational companies engaged in commercial operations in Australia. The financial disincentive that a civil penalty regime provides to address and deter breaches of the TG Act is likely to be more effect than criminal sanctions in appropriate circumstances.

A civil penalty regime is intended to strengthen the TGA's enforcement options to deter non-compliance with the bans with respect to vaping goods designed to protect public health and safety. A civil penalty is an appropriate measure where other sanctions may not be as effective or appropriate in the circumstances.

For the civil penalty provisions relating to the import, manufacture, supply and possession of vaping goods, consistent with existing approaches to framing commonwealth civil penalty provisions, each unit of vaping good will constitute a separate contravention. A unit of vaping goods will be prescribed in the regulations. This will ensure that there is clarity in the proscribed conduct in these provisions and avoid ambiguity and unintended consequences such as the treating of a 500000ML gallon of vaping liquid as a single contravention in the same way as 100ML would be. The conduct in each case is not equal and the penalty that is warranted to deter such conduct differs significantly.

As an example, the importation of 1000 unlawful vaping goods may attract a theoretical maximum penalty in the hundreds of millions, or even over a billion dollars. However, the penalty imposed by the court will very likely be much lower than this amount. There are well established principles applied by the courts to ensure that penalties imposed are proportionate to the conduct in such circumstances, without being overly oppressive. While the per unit approach could result in significant theoretical penalty maximum amounts, on a mathematical basis, it is important to note that the court takes several factors into account to ensure that the total penalty does not exceed what is proper for deterrence for the entire contravening conduct.

It is not unusual for civil penalty provisions to attract very significant numbers of contraventions. For example, section 81 of the *Anti-Money Laundering and Counter-Terrorism Financing Act 2006* attracts contraventions for each designated service provided by a reporting entity during the period a risk management program is not compliant. The number of contraventions is often unquantifiable. Similarly, civil penalty provisions involving false or misleading conduct under the Australian Consumer Law can also attract large or unquantifiable contraventions. In the Act itself, the advertising prohibitions, such as section 42DLB can attract thousands of contraventions as can the prohibitions relating to supply of therapeutic goods in section 19D.

Framing the civil penalty contraventions in this way, on a per unit approach will also allow the Secretary to give a person an infringement notice(s) as an alternative to having the penalty determined by the court and provides greater flexibility for the Secretary to decide an appropriate penalty amount.

Higher civil penalties than the existing penalties in the TG Act are also warranted for the same reasons as provided for above in relation to criminal penalties. It is anticipated that the level of civil penalties will act as an effective financial

disincentive against non-compliance with regulatory requirements, especially for corporations for whom imprisonment is not available.

The current civil penalty provisions in the TG Act for importation, manufacture and supply of unlawful therapeutic goods provide for a corporate multiplier of 10 times the penalty for the individual. That is the 5,000 penalty units for an individual and 50,000 for a body corporate. The new civil penalty provisions relating to vaping goods adopt the same approach due to the seriousness of the conduct and the public health harms associated with vaping goods. However, given the need to curb a large black-market in vapes and to effectively deter non-compliance given high profit margins associated with illicit vape supply, a higher maximum penalty of 7,000 penalty units for an individual and 70,000 for a body corporate is considered appropriate and proportionate to the proscribed conduct.

A summary table of the new offences and civil penalty provisions is provided below with the relevant maximum penalties.

Provision	Offence	Maximum penalty (fault-based offence)	Maximum penalty (strict liability offence)	Maximum penalty (civil penalty)
41Q	Importation of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QA	Manufacture of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QB	Supply of vaping goods	For an individual—imprisonment for 7 years and/or 5,000 penalty units. For a body corporate—25,000 penalty units.	For an individual—200 penalty units. For a body corporate—1000 penalty units.	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.
41QC	Possession of commercial quantity of vaping goods	For an individual— At least the commercial quantity – 2 years imprisonment/1,000 penalty units. At least 100 times the commercial quantity – 4 years imprisonment/3,000 penalty units. At least 1000 times the commercial quantity – 7 years imprisonment/5,000 penalty units. For a body corporate—	For an individual— At least the commercial quantity – 120 penalty units. At least 100 times the commercial quantity – 240 penalty units. At least 1000 times the commercial quantity – 420 penalty units. For a body corporate —	For an individual—7,000 penalty units. For a body corporate—70,000 penalty units.

Provision	Offence	Maximum penalty (fault-based offence)	Maximum penalty (strict liability offence)	Maximum penalty (civil penalty)
		At least the commercial quantity – 5,000 penalty units. At least 100 times the commercial quantity – 15,000 penalty units. At least 1000 times the commercial quantity – 25,000 penalty units.	At least the commercial quantity – 600 penalty units. At least 100 times the commercial quantity – 1,200 penalty units. At least 1000 times the commercial quantity – 2,100 penalty units.	
41QD	Possession of less than commercial quantity of vaping goods	For an individual—Imprisonment for 12 months and/or 500 penalty units. For a body corporate—2,500 penalty units.	For an individual—60 penalty units. For a body corporate—300 penalty units.	For an individual—1,000 penalty units. For a body corporate—10,000 penalty units.

Banning the importation of unlawful vaping goods

Section 41Q establishes offences and a civil penalty provision for importing vaping goods into Australia, with exceptions in certain circumstances. Importation is not defined and will be given its ordinary meaning.

Subsection 41Q(1) provides that a person commits an offence if the person imports vaping goods into Australia, with an associated maximum penalty of imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the importation of vaping goods into Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41Q(2) provides an offence of strict liability for importing vaping goods into Australia, with an associated maximum penalty of 200 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

A strict liability offence has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41Q(3) provides a civil penalty for importing vaping goods into Australia, with a maximum civil penalty of 7,000 penalty units for an individual and 70,000 penalty units for a body corporate.

Subsection 41Q(4) provides that a person who contravenes the civil penalty provision in subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods imported by the person into Australia. The note to this subsection references subsection 3(1) for the definition of unit of vaping goods.

Subsection 41Q(5) provides an exception to the application of these offence and civil penalty provisions if the importation would not be prohibited under the Customs Act. The note to subsection 41Q(5) provides that the person bears an evidential burden in relation to the matter in subsection (5), in accordance with section 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Section 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

The import offences and civil penalty provisions in this part are intended to complement the Customs Act.

Explanation of exception

A licence and permit would likely be the evidence a person would need to produce to avail themselves of the exception. Whether a person has an import licence and permit is a matter peculiarly within their knowledge.

There is also a traveller's exemption for persons bringing vaping goods into the country in connection with their visit to Australia. Whether the person has in their possession vaping goods under the maximum allowable traveller's limit is a matter peculiarly within their knowledge and control and would be easily produced.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this element than for the defendant to establish the matter. Whether a person is relying on a traveller's exemption will be a matter peculiarly within their knowledge.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the effective regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Licence and permit

The importation of vaping goods is subject to regulation 5A of the CPI Regulations which requires the importer to hold a licence and permit. The importer will need to meet certain criteria to be granted a licence or a permit to import vaping goods into Australia. A permit to import each specific type of vaping good is required.

Before an import permit can be granted under a vaping good import licence, the vaping good must either be entered on the Register, or a notice must be given to the Secretary which complies with applicable requirements under the TG Act (sponsor notice). Exceptions to this requirement apply to vaping goods imported for medical or scientific research, and vaping goods of a kind or for a purpose specified in a legislative instrument made by the Secretary. No such legislative instrument has been made at this time.

A sponsor notice (other than a sponsor notice for a vaping device used to administer medicinal cannabis) requires a sponsor to state that a vaping good complies with applicable standards and that the only indications of the vaping good are for smoking cessation or the management of nicotine dependence. If a sponsor notice is required but cannot be given because the goods do not comply with applicable standards or the indications are broader than smoking cessation or the management of nicotine dependence, importation and supply of the goods will be unlawful.

A sponsor notice for a vaping device used to administer medicinal cannabis requires a sponsor to state that the vaping device complies with the essential principles or is imported with the consent of the Secretary under section 41MA or 41MAA of the Act. This notice is required for a vaping device or vaping device accessory that is intended to be used *only* to contain or administer medicinal cannabis. If a sponsor notice is required but cannot be given because the goods do not comply with the essential principles and consent has not been granted, or the goods are not intended to be used *only* to contain or administer medicinal cannabis, importation and supply of the goods will be unlawful.

A sponsor notice is not required for a vaping good in relation to which a licence and permit under regulation 5 of the CPI Regulations has been granted, for example, a disposable single use vape or a pod or cartridge containing medicinal cannabis that has been imported in accordance with a permit given under regulation 5 of those regulations.

The TGA will publish a list of vaping goods in relation to which sponsor notices have been given (other than sponsor notices for cannabis vaping devices) and that can be made available for lawful supply.

Traveller's exemption

Under regulation 5A of the CPI Regulations, there is also traveller's exemption which allows persons entering Australia to carry no more than 2 vapes, 20 vape accessories and 200mL of vaping substance in liquid form. This exemption gives effect to the intention not to criminalise possession of vaping goods for personal use.

Banning the manufacture of unlawful vaping goods

Section 41QA establishes offences and a civil penalty provision for manufacturing vaping goods in Australia, where the manufacturer does not have a relevant licence, certificate, exemption or consent in certain circumstances.

Subsection 41QA(1) provides that a person commits an offence if the person manufactures, or carries out a step in the manufacture of, vaping goods in Australia, with an associated maximum penalty of imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of

their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the manufacture of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Manufacture, in relation to vaping goods, will have the same meaning as subsection 3(1) or section 41BG depending on the nature of the vaping goods.

Subsection 41QA(2) provides an offence of strict liability for manufacturing, or carrying out a step in the manufacture of, vaping goods in Australia, with an associated maximum penalty of 200 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice(s) as an alternative to criminal prosecution.

Subsection 41QA(3) provides a civil penalty for manufacturing vaping goods in Australia with a maximum civil penalty of 7,000 penalty units for an individual and 70,000 penalty units for a body corporate.

Subsection 41QA(4) provides that a person who contravenes the civil penalty provision in subsection (3) commits a separate contravention of that subsection in respect of the manufacture, or the carrying out of the step in the manufacture, by the person of each unit of vaping goods manufactured in Australia. The note to this subsection references subsection 3(1) for the definition of unit of vaping goods.

Subsection 41QA(5) provides an exception to the application of these offence and civil penalty provisions if the vaping goods are therapeutic goods and one of the following applies:

- (i) the person is the holder of a licence in force under Part 3-3 that authorises the manufacture of the vaping goods, or the carrying out of the step in the manufacture of the vaping goods, at the manufacturing site where the manufacture, or the step, was carried out;
- (ii) the person is the holder of a conformity assessment document that applies to the vaping goods;
- (iii) the Secretary has given the person a consent under subsection 41RC(1) to manufacture the vaping goods, or carry out a step in the manufacture of the vaping goods and the manufacture, or the step, is carried out in accordance with the consent.

The note to subsection 41QA(5) provides that the person bears an evidential burden in relation to the matter in subsection (5), in accordance with subsection 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Subsection 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Explanation of exception

Australian manufacturers of vaping goods must obtain a Part 3-3 licence from the TGA, unless a relevant exemption applies. In relation to vaping devices they may also hold a conformity assessment document under Chapter 4 of the TG Act, that relates to the manufacture of vaping goods.

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

Whether a manufacturer has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the efficient regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia.

Banning the supply of unlawful vaping goods

Section 41QB establishes offences and a civil penalty provision for supplying vaping goods in Australia, with exceptions in certain circumstances.

Subsection 41QB(1) provides that a person commits an offence if the person supplies vaping goods in Australia, with an associated maximum penalty of imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to

prevent the breaches. There is significant public harm from the supply of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QB(2) provides an offence of strict liability for supplying vaping goods in Australia, with an associated maximum penalty of 200 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QB(3) provides a civil penalty for supplying vaping goods, with a maximum civil penalty of 7,000 penalty units for an individual and 70,000 penalty units for a body corporate.

Subsection 41QB(4) provides that a person who contravenes the civil penalty provision in subsection (3) commits a separate contravention of that subsection in respect of each unit of vaping goods supplied by the person in Australia. The note to this subsection references subsection 3(1) for the definition of unit of vaping goods.

Subsection 41QB(5) provides exceptions to the application of these offence and civil penalty provisions if subsections (6) to (8) or subsections (9) to (11) apply to the supply of the vaping goods by the person. The note to subsection 41QB(5) provides that the person bears an evidential burden in relation to the matters in subsections (6) to (8) or (9) to (11), in accordance with section 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Section 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Wholesale supply exception

Subsections (6), (7) and (8) have the effect of providing an exception to these offences and civil penalty provisions for supply if the supply was part of the wholesale supply chain for prescription medicines. The wholesale supply chain for prescription medicines is intended to be the primary lawful pathway for the supply of vaping goods in Australia. This supply chain is made up of controls at both the Commonwealth and state and territory levels.

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

The exception in subsections (6), (7) and (8) is directed to persons who are supplying vaping goods to persons who are not the ultimate consumer of the goods. For a person to avail themselves of the exception they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the effective regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Subsection (6) is directed to the status of the vaping goods. Subsection (7) is directed to the identity of the person supplying the vaping goods. Subsection (8) is directed to the identity of the person receiving the vaping goods.

Subsection 41QB(6) provides that this subsection applies in relation to the supply of the vaping goods by the person if the vaping goods are:

- (a) therapeutic goods that are entered on the Register; or
- (b) both:
 - (i) exempt under subsection 18(1) or 41HA(1) of the TG Act and the sponsor has given a notice in compliance with the exemption; and
 - (ii) the vaping goods are not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or
- (c) covered by a determination made by the Minister under section 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QB(6)(b). It

is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

The type of evidence that a person is likely to produce to make out this subsection includes a current certificate of registration of the vaping goods on the Register, a sponsor notification provided to the Secretary, evidence from the Department's website that the vaping good is not the subject of a determination or a current determination applicable to the vaping goods made by the Minister.

These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(7) provides that this subsection applies in relation to the supply of vaping goods by the person if:

- (a) the person holds a licence or a permission granted under regulations made for the purpose of section 50 of the Customs Act, to import the vaping goods, or is otherwise approved to import the vaping goods under those regulations; or
- (b) the person is the holder of a licence in force under Part 3-3 of the TG Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is a holder of a conformity assessment document that applies to the vaping goods; or
- (d) the person is a wholesaler who is the holder of a licence or is otherwise authorised to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occurs, and the supply occurs in accordance with the licence or authority;
- (e) the Secretary has given the person a consent under subsection 41RC(1) to supply the vaping goods, and the supply is in accordance with the consent; or
- (f) where the goods are covered by a determination made under section 41R—the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods, and the supply occurs in accordance with the determination.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters within the persons' knowledge.

Subsection 41QB(8) provides that this subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the person to whom the vaping goods are supplied, i.e. the recipient, is the holder of a Part 3-3 licence in force under the TG Act that authorises a step in the manufacture of the vaping goods; or
- (b) the recipient is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence or is otherwise authorised to supply one or more substances in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the recipient carries on a business, practises or is employed; or
- (c) the Secretary has given the recipient a consent under subsection 41RC(1) to supply the vaping goods; or
- (d) in the case of vaping goods covered by a determination made under section 41R—the recipient is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters within the persons' knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Retail supply exception

Subsections (9), (10) and (11) have the effect of providing an exception to these offences and civil penalty provisions for supply as part of a retail supply chain.

The exception in subsections (9), (10) and (11) is directed to persons who are supplying vaping goods to persons who are the ultimate consumer of the goods. For a person to avail themselves of the exception, they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Subsection (9) is directed to the status of the vaping goods. Subsection (10) is directed to the identity of the person supplying the vaping goods. Subsection (11) is directed to the identity of the person receiving the vaping goods.

Subsection 41QB(9) provides that this subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered on the Register; or
- (b) both the following apply:

- (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption; and
 - (ii) the vaping goods are not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or
- (c) the vaping goods are covered by a determination under section 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QB(9)(b). It is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

The type of evidence that a person is likely to produce to make out this subsection includes a current certificate of registration of the vaping goods on the Register, a sponsor notification provided to the Secretary, evidence from the Department's website that the vaping good is not the subject of a determination or a current determination applicable to the vaping goods made by the Minister.

These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(10) provides that this subsection applies in relation to the supply of the vaping goods by the person if the person is a:

- (a) pharmacist; or
- (b) medical practitioner or nurse practitioner who is the holder of a licence or is otherwise authorised to supply one or more substances in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the supply occurs.

The type of evidence that a person is likely to produce to make out this subsection includes evidence of current registration as a pharmacist, medical practitioner or nurse practitioner and, if applicable, their authorisation or licence. These are all matters that can be easily produced by a person if required and are matters within the persons' knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(11) provides that this subsection applies in relation to the supply of the vaping goods by the person if:

- (a) the supply is:
 - (i) to another person for use by that person for smoking cessation or management of nicotine dependence, or for another indication determined by the Minister under section 41RA; or
 - (ii) to another person, who is the carer of a third person, for use by the third person for smoking cessation or management of nicotine dependence, or for another indication determined by the Minister under section 41RA; and
- (b) if the vaping goods are, or contain, a vaping substance—the vaping substance is in final dosage form; and
- (c) the supply is:
 - (i) in accordance with this Act (apart from this section); and
 - (ii) consistent with the person’s authority to supply the vaping goods under a law of the state or territory in which the supply occurs.

It is anticipated that a determination would be made by the Minister under section 41RA that would determine indications appropriate for medicinal cannabis vapes.

The type of evidence that a person is likely to produce to make out this subsection includes a prescription for the supplied vaping good, a tax invoice and product specification or some other material which indicates that the good is in final dosage form. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters peculiarly within the persons’ knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings to disprove this if it was an element than for the defendant to establish the matter. Further, given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Subsection 41QB(12) provides that for the purposes of paragraph (11)(b), a vaping substance is in final dosage form if the vaping substance is in a form that can be administered to a person without any change or modification (other than vaporisation).

Banning the possession of at least a commercial quantity of unlawful vaping goods

Section 41QC establishes offences and civil penalties for possessing commercial quantities of a kind of vaping goods, with exceptions in certain circumstances.

Subsection 3(1) provides that ‘commercial quantity’ of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

Subsections (1), (2) and (3) relate to commercial quantities that are less than 100 times the commercial quantity, subsections (4), (5) and (6) relate to quantities of 100 times the commercial quantity but less than 1,000 times the commercial quantity, and subsections (7), (8) and (9) relate to 1,000 times the commercial quantity or more.

Subsection 41QC(1) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods. The maximum penalty for this offence is imprisonment for 2 years or 1,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the possession of a commercial quantity of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QC(2) provides that absolute liability applies to paragraph (1)(b), that is that the quantity is at least the commercial quantity, but less than 100 times the commercial quantity, of that kind of vaping goods. This applies to a physical element of the offence. Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person’s state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QC(3) provides an offence of strict liability for the same conduct, with an associated maximum penalty of 120 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not

established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QC(4) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least 100 times the commercial quantity, but less than 1000 times the commercial quantity, of that kind of vaping goods. The maximum penalty for this offence is imprisonment for 4 years or 3,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the possession of a commercial quantity of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QC(5) provides that absolute liability applies to paragraph (4)(b), that is that the quantity is at least 100 times the commercial quantity, but less than 1000 times the commercial quantity, of that kind of vaping goods. This applies to a physical element of the offence. Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person's state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QC(6) provides an offence of strict liability for the same conduct, with an associated penalty of 240 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QC(7) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least 1,000 times the commercial quantity or more of that kind of vaping goods. The maximum penalty for this offence is imprisonment for 7 years or 5,000 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the possession of a commercial quantity of vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41QC(8) provides that absolute liability applies to paragraph (7)(b), that is that the quantity is 1,000 times the commercial quantity, or more, of that kind of vaping goods, of that kind of vaping goods. This applies to a physical element of the offence. Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person's state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QC(9) provides an offence of strict liability for the same conduct, with an associated penalty of 420 penalty units. Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QC(10) provides a civil penalty where a person possesses a quantity of a kind of vaping goods in Australia and the quantity is at least the commercial quantity of that kind of vaping goods. The maximum civil penalty is 7,000 for an individual and 70,000 for a body corporate.

A person is only liable for a civil penalty contravention of subsection (10) if they are in possession of a kind of vaping goods of at least a commercial quantity and the exceptions do not apply to them. Each contravention also takes into consideration each kind of vaping good in the possession of a person which is at least of a commercial quantity.

Subsection 41QC(11) provides that a person who contravenes subsection (10) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia.

It is intended that the per unit is to apply to each individual unit of vaping goods in the person's possession. For example, each vaping device, accessory or substance or

combination thereof, would comprise of one unit for the purposes of calculating the number of contraventions.

By way of example, if commercial quantity is 10 vaping devices, and a person is in possession of 11 vaping devices then this will be 11 contraventions of the civil penalty provision in subsection (10). If the person is in possession of 9 vaping devices, they will not contravene the civil penalty provision in subsection (10). These are only examples and for illustrative purposes. Commercial quantity for each kind of vaping goods will be prescribed in the regulations.

Another example is if a person is found in possession of a large shipment of vaping goods and the shipment contains 5,000 vaping devices, 5,000 vaping substances and 5,000 vaping accessories (each of which exceed the prescribed commercial quantity), there will be 15,000 contraventions of subsection (10) in relation to the shipment; 5,000 contraventions in respect of each kind of vaping good.

This approach to the civil penalty provision is justified to achieve consistency across the other civil penalty prohibitions for import, manufacture and supply of vaping goods.

Tiered maximum penalties for criminal offences

Tiered penalties depending on the quantity of the vaping goods involved is appropriate in circumstances where there will be a wide spectrum of conduct captured under these offences. Tiered penalty structures also appear in other legislation such as Schedule 1 to the *Taxation Administration Act 1953* for possession of illicit tobacco and various offences under the *Criminal Code*.

Exception

Subsection 41QC(12) provides an exception to the application of the offence and civil penalty provisions in subsections (1) to (10) if subsections (13) and (14) apply to the possession of the vaping goods by the person. The note to subsection 41QC(12) provides that the person bears an evidential burden in relation to the matters in subsections (13) and (14), in accordance with subsection 13.3(3) of the *Criminal Code* and section 41QE of the TG Act. Section 13.3 of the *Criminal Code* provides that evidential burden, in relation to a matter, means the burden of adducing or pointing to evidence that suggests a reasonable possibility that the matter exists or does not exist.

Subsections (13) and (14) have the effect of providing an exception to these offences and civil penalty provision for the possession of vaping goods if the possession occurs as part of the wholesale supply chain or retail supply chain for prescription medicines. These supply chains are made up of controls at both the Commonwealth and state and territory levels. The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

For a person to avail themselves of the exception they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Subsection (13) is directed to the status of the vaping goods. Subsection (14) is directed to the identity of the person in possession of the vaping goods.

Subsection 41QC(13) provides that this subsection applies in relation to the possession of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered on the Register; or
- (b) the vaping goods are:
 - (i) therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption; and
 - (ii) not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or
- (c) the vaping goods are covered by a determination under section 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QC(13)(b).

It is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

The type of evidence that a person is likely to produce to make out this subsection includes a current certificate of registration of the vaping goods on the Register, a sponsor notification provided to the Secretary, evidence from the Department's website that the vaping good is not the subject of a determination or a current determination applicable to the vaping goods made by the Minister.

These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods. The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

For a person to avail themselves of the exception they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying. The Bill provides a list of the necessary evidence that a defendant needs to produce, such as an authority to prescribe a prescription only medicine in a state or territory or otherwise deal with vaping goods.

Subsection 41QC(14) provides that this subsection applies in relation to the possession of the vaping goods by the person if:

- (a) the person is the holder of a licence and a permission granted under regulations made for the purposes of section 50 of the Customs Act to import the vaping goods or is otherwise approved under those regulations to import the vaping goods;

- (b) the person is the holder of a licence in force under Part 3-3 of this Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
- (d) both of the following apply:
 - (i) the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the person possesses the goods; and
 - (ii) the possession of the goods is in accordance with the licence or authority; or
- (e) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods and the possession is in accordance with the consent; or
- (f) in the case of vaping goods that are covered by a determination made by the Minister under section 41R—the person is specified in the determination, or is included in a class of persons that is specified in the determination, in relation to those goods, the possession is in accordance with the determination.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination, or a prescription for the supplied vaping good. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters peculiarly within the persons' knowledge.

It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying. Given the seriousness of the public health harms associated with vaping in Australia, the reversal of onus in this regard is justified.

Banning the possession of less than a commercial quantity of unlawful vaping goods

Section 41QD establishes offences and civil penalties for possessing a quantity of vaping goods less than the commercial quantity of that kind of vaping goods, with exceptions in certain circumstances including when the vaping goods are for personal use. The intention of these provisions is to deter persons possessing vaping goods less than a commercial quantity other than for personal use, including retailers or vendors who may be in possession of less than a commercial quantity of vaping goods in a retail setting not for personal use.

Subsection 3(1) provides that 'commercial quantity' of a kind of vaping goods means the quantity of that kind of vaping goods prescribed by the regulations.

Subsection 41QD(1) provides that a person commits an offence if the person possesses a quantity of a kind of vaping goods in Australia and the quantity is less than the commercial quantity of that kind of vaping goods.

The penalty for this offence is imprisonment for 12 months or 500 penalty units, or both. The note to this subsection references sections 54B and 54BA in relation to liability of an executive officer of a body corporate.

Subsection 41QD(2) provides that absolute liability applies to paragraph (1)(b), that is that the quantity is less than the commercial quantity of that kind of vaping goods of that kind of vaping goods. This applies to a physical element of the offence.

Subsection 6.2(2) of the *Criminal Code* provides that there are no fault elements for this physical element and the defence of mistake of fact under section 9.2 is unavailable in relation to this physical element.

Applying absolute liability to the element of quantity will ensure the enforceability of these offences in circumstances where it may be difficult to establish a person's state of mind with respect to the quantity of vaping goods possessed.

Subsection 41QD(3) provides an offence of strict liability for possessing a quantity of vaping goods less than the commercial quantity of that kind of vaping goods, with an associated penalty of 60 penalty units.

Section 9.2 of the *Criminal Code* provides that a person will not be criminally responsible if the person was under a mistaken but reasonable belief about those facts and if those facts had existed, the conduct would not have constituted an offence.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41QD(4) provides a civil penalty where a person possesses a quantity of a kind of vaping goods in Australia and the quantity is less than the commercial quantity of that kind of vaping goods. The maximum civil penalty is 1,000 for an individual and 10,000 for a body corporate.

A person is only liable for a civil penalty contravention of subsection (4) if they are in possession of a kind of vaping goods of less than a commercial quantity and the exceptions do not apply to them. The commercial quantity for each kind of vaping goods will be different depending on the kind of vaping goods in question, for example whether it is a device, accessory or substance, or combination.

Exceptions apply in relation to vaping goods possessed for personal use for smoking cessation or management of nicotine dependence, or another indication determined by the Minister under section 41RA. It is anticipated that a determination would be made by the Minister under section 41RA that would determine indications appropriate for medicinal cannabis vapes.

Subsection 41QD(5) provides that a person who contravenes subsection (4) in relation to a kind of vaping goods commits a separate contravention of that subsection in respect of each unit of the quantity of vaping goods of that kind possessed by the person in Australia. The note to this subsection references section 3(1) for the definition of unit of vaping goods.

It is intended that the per unit is to apply to each individual unit of vaping goods in the person's possession. For example, each vaping device, accessory or substance or combination thereof, would comprise of one unit for the purposes of calculating the number of contraventions.

By way of example, if commercial quantity is 10 vaping devices, and a person is in possession of 9 vaping devices then this will be 9 contraventions of the civil penalty provision in subsection (4). This is only an example and for illustrative purposes. Commercial quantity for each kind of vaping goods will be prescribed in the regulations.

This approach to the civil penalty provision is justified to achieve consistency across the other civil penalty provisions relating to the importation, manufacture and supply of vaping goods.

Exception – authorised persons

Subsection 41QD(6) provides an exception to the application of the offence and civil penalty provisions in section 41QD for authorised persons, if subsections (7) and (8), or subsection (9) apply to the possession of the vaping goods by the person. The note to subsection 41QD(6) provides that the person bears an evidential burden in relation to the matters in subsections (7) and (8), or subsection (9), in accordance with subsection 13.3(3) of the *Criminal Code* and section 41QE of the TG Act.

Subsection (7) is directed to the status of the vaping goods. Subsection (8) is directed to the identity of the person in possession of the vaping goods.

Subsection 41QD(7) provides that this subsection applies in relation to the possession, or custody, of the vaping goods by the person if:

- (a) the vaping goods are therapeutic goods that are entered in the Register; or
- (b) the vaping goods are:
 - (i) the vaping goods are therapeutic goods that are exempt goods under regulations made for the purposes of subsection 18(1) or an exempt device under regulations made for the purposes of subsection 41HA(1), and the sponsor has given the Secretary a notice in compliance with the exemption; and
 - (ii) the vaping goods are not the subject of a determination by the Secretary, published on the Department's website, that the supply of the goods be stopped or should cease because the Secretary is satisfied that the supply

of the goods compromises public health and safety or the goods do not conform with a standard applicable to the goods; or

(c) the vaping goods are covered by a determination under subsection 41R.

Medicinal cannabis vapes are not generally subject to an exemption requiring a sponsor notice, and as such would not meet the exception in paragraph 41QD(7)(b). It is anticipated that a determination would be made by the Minister under section 41R that would apply to medicinal cannabis vapes as appropriate.

Subsection 41QD(8) provides that this subsection applies in relation to the possession, or custody, of the vaping goods by the person if:

- (a) the person is the holder of a licence or a permission granted under regulations made for the purpose of section 50 of the Customs Act, or is otherwise approved to import the vaping goods under those regulations; or
- (b) the person is the holder of a licence in force under Part 3-3 of the TG Act that authorises a step in the manufacture of the vaping goods; or
- (c) the person is the holder of a conformity assessment document that applies to the vaping goods; or
- (d) the person is a wholesaler, pharmacist, medical practitioner or nurse practitioner who is the holder of a licence, or is otherwise authorised, to supply one or more substances included in Schedule 4 to the current Poisons Standard under a law of the state or territory in which the person possesses the goods, and the possession of the goods is in accordance with the licence or authority; or
- (e) the Secretary has given the person a consent under subsection 41RC(1) to possess the vaping goods, and the possession is in accordance with the consent; or
- (f) where the goods are covered by a determination made under subsection 41R—the person is specified in the determination, or is included in a class of persons specified in the determination, in relation to those goods, the possession is in accordance with the determination.

The type of evidence that a person is likely to produce to make out this subsection includes the relevant licence, permission, authority, consent or determination, or a prescription for the supplied vaping good. These are all matters that can be easily produced by a person if required to substantiate the nature of the vaping goods and are matters peculiarly within the persons' knowledge.

The investigation and enforcement of these offences and civil penalty provisions will be undertaken by a combination of Commonwealth, state and territory agencies and may involve federal and state police. For this reason, the evidence to substantiate the lawful status of the goods, or the specified activity will not rest with any one agency and is very likely to be split across many.

For a person to avail themselves of the exception, they must adduce or point to evidence that suggests a reasonable possibility that the relevant matter in each subsection exists, or does not exist, as the case may be.

Whether the person has a relevant licence, consent, exemption or certificate, and whether the vaping good is covered by the exception, is a matter within the person's knowledge. That evidence will be able readily accessible to persons who can avail themselves of the exception.

The burden on the defendant is evidential only, meaning that the defendant must adduce or point to evidence that suggests a reasonable possibility that the matter exists or does not exist. If that burden is discharged, the prosecution must disprove the matters in the exception beyond reasonable doubt, or in civil penalty proceedings on the balance of probabilities.

Reversing the burden of proof is justified because of the public interest in the regulation of vaping goods, noting the seriousness of the public health harms associated with vaping in Australia. It would be significantly more difficult, costly and burdensome for the prosecution, or the Secretary in civil penalty proceedings, to prove these matters in their totality as an element of the offence or civil penalty provision rather than the defendant to establish the reasonable possibility of the exception applying.

Exception—personal use or possession on behalf of another person

Subsection 41QD(9) provides that this subsection applies in relation to the possession, or custody, of the vaping goods by the person if:

- (a) the vaping goods are for use by the person personally; or
- (b) the person possesses the vaping goods on behalf of another person for whom the vaping goods have been lawfully supplied.

This exemption gives effect to the intention not to criminalise possession of vaping goods less than a commercial quantity for personal use. The context and surrounding circumstances in which the vaping goods are possessed will likely be the primary factor which will determine whether this exception is available, such as whether the possession is in a retail setting. The type of evidence that a person is likely to produce to make out this subsection includes, but is not limited to, a prescription or written authority to possess the vaping goods. However, such evidence is not necessary.

Subparagraph (b) has been included to protect persons who may be possessing vaping goods on behalf of someone who requires the vaping goods in connection with treatment for smoking cessation or the management of nicotine dependence, including carers and nurses in a hospital or nursing home setting.

Exception to civil penalty provisions – burden of proof

Division 2 in Part 4A-2 contains section 41QE which provides that if, in proceedings for a pecuniary penalty order against a person for contravention of a civil penalty provision in this Chapter, the person wishes to rely on any exception, exemption, excuse, qualification or justification that applies in relation to the civil penalty provision, then the person bears an evidential burden in relation to that matter.

Part 4A3—Other provisions

Division 1—Determinations by Minister

Section 41R provides that the Minister may, by legislative instrument determine that specified goods, or a specified class of vaping goods can be supplied or possessed in Australia by a specified person, or a specified class of persons, and in certain circumstances and subject to any conditions. The note to this section provides an example of the conditions that may be imposed, for example conditions relating to the value or amount of specified vaping devices, or the manner in which specified vaping goods may be supplied.

The purpose of this provision is to provide a mechanism by which the Minister can authorise the possession or supply of specified vaping goods by certain people in circumstances where they may not be authorised under other relevant statutory provisions. The Minister does not need to receive an application to decide whether to make a determination, however, there is nothing preventing a person from requesting that the Minister consider exercising the power in a particular circumstance.

A determination made under this section is not subject to merits review. This is because determinations are not intended to be directed towards the circumstances of particular persons. Rather they are proposed to apply generally.

Section 41RA provides that the Minister may, by legislative instrument, determine for the purposes of paragraph 41QB(11)(a), other indications for which vaping goods may be used. It is anticipated that a determination would be made by the Minister under section 41RA that would determine indications appropriate for medicinal cannabis vapes.

Division 2—Consent of Secretary

Section 41RB creates an application provision to allow the Secretary to provide consent to the manufacture, supply or possession of vaping goods.

Subsection 41RB(1) provides that a person may apply to the Secretary for consent to manufacture, supply or possess vaping goods.

Subsection 41RB(2) provides that an application under subsection (1) must be in accordance with a form approved by the Secretary.

Subsection 41RB(3) provides that the Secretary may, by notice in writing given to the applicant, require the applicant to give to the Secretary, within such reasonable time

as is specified in the notice, such further information concerning the application as is specified in the notice.

Subsection 41RB(4) provides that an approval of a form referred to in subsection (2), or a notice referred to in subsection (3), may require or permit an application or information to be given in accordance with specified software requirements including on a specified kind of data processing device or by way of a specified kind of electronic transmission.

Section 41RC provides that the Secretary may give consent in certain circumstances.

Subsection 41RC(1) provides that the Secretary must decide whether to give, or refuse to give the consent if the person has applied to the Secretary under section 41RB, and the applicant has complied with any requirements made by the Secretary under subsection 41RB(3) in relation to the application.

Subsection 41RC(2) provides that the Secretary may give consent under subsection (1) unconditionally or subject to conditions or in respect of particular vaping goods or classes of vaping goods. The note to this subsection provides that a person may commit an offence or be liable to a civil penalty if the person does an act or omits to do an act and the act or omission breaches a condition of consent given under subsection (1). The note further directs to section 41RD in this regard.

Subsection 41RC(3) requires the Secretary to cause particulars of the decision to be published on the Department's website as soon as practicable after making a decision to give consent under subsection (1).

Subsection 41RC(4) provides that if the Secretary decides to refuse to give consent under subsection (1), the Secretary must, within 28 days after making the decision, notify the applicant in writing of the decision and the reasons for the decision.

Section 41RD creates offences and civil penalty provisions for breaching a condition of a consent given under subsection 41RC(1).

Subsection 41RD(1) creates a fault-based offence with an aggravating element. The subsection provides that a person commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1) and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

The maximum penalty is 2,000 penalty units.. The note to this subsection refers to section 54AB and 54BA with respect to the liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from breaching a condition of

consent to undertake activity in relation to vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Subsection 41RD(2) creates a fault based offence and provides that a person commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1). The maximum penalty is 500 penalty units.

Subsection 41RD(3) creates an offence of strict liability and provides that a person commits an offence if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1). The maximum penalty is 100 penalty units.

An offence of strict liability has been included to ensure that this conduct is criminalised to protect consumers from vaping goods even where fault is not established. The inclusion of an offence of strict liability will also provide the option for the giving of an infringement notice as an alternative to criminal prosecution.

Subsection 41RD(4) creates a civil penalty provision and provides that a person contravenes this subsection if the person does an act or omits to do an act and the act or omission breaches a condition of a consent given to the person under subsection 41RC(1). The maximum penalty for an individual is 3,000 penalty units and 30,000 penalty units for a body corporate.

Division 2—Other amendments

Therapeutic Goods Act 1989

Item 12 – Paragraph 14B(a)

This item amends paragraph 14B(a) to add a reference to subsections 41Q(1) or (2).

Item 13 – Paragraph 14B(a)

This item amends paragraph 14B(a) to add a reference to subsection 41Q(3).

Item 14 – Subsection 19(9)

This item repeals subsection 19(9) of the TG Act.

Item 15 – Subsection 30EK(6)

This item repeals subsection 30EK(6) of the TG Act.

Item 16 – Subsection 30EL(1)

This item omits the subsection number for subsection (1) in section 30EL(1).

Item 17 – Subsection 30EL(2)

This item repeals subsection 30EL(2) of the TG Act.

Item 18 – Subsection 32CM(8)

This item repeals subsection 32CM(8) of the TG Act.

Item 19 – At the end of section 41BG

This item adds a note to section 41BG to provide that this section applies in relation to vaping goods that are a medical device.

Item 20 – Subsection 41HC(7)

This item repeals subsection 41HC(7) of the TG Act.

Item 21 – Section 53A (after table item 33)

This item introduces item 33AA in the table in section 53A to include reference to subsection 41RD(1) and subsection 41RD(2).

Item 22 – Section 54BA (after table item 43)

This item adds new items 43AA to 43AF to the table in section 54BA.

Item 23 – After subsection 56A(4A)

This item introduces subsection 56A(4B) to provide that, in proceedings for an offence against section 41QA, 41QB, 41QC or 41QD, or the contravention of subsection 41QA(3), 41QB(3), 41QC(10) or 41QD(4), which are civil penalty provisions, a certificate by the Secretary to the effect that the Secretary did not consent to the manufacture, supply or possession that is the subject of the proceedings, or consented to that manufacture, supply or possession subject to conditions specified in the certificate, is prima facie evidence of the matters specified in the certificate.

Although this power, in effect, reverses the onus of proof, this reversal is considered reasonable in the circumstances. The existence of a consent is a matter of fact, that, outside of the Secretary's belief as expressed in a certificate, is peculiarly within the knowledge of the defendant. If the Secretary is of belief that the consent did, or did not exist, it is reasonable that only the defendant would be aware of the counter position. Adducing evidence to that effect would be most easily adduced by the defendant and would likely exist in the form of documentary evidence. The defendant need only meet an evidential burden of proof to rebut the certificate issued under 56A.

Item 24 – Subsection 57(10)

This item amends subsection 57(10) to include a reference to subsection 41P(3). Subsection 57(10) limits the power of the Minister to be delegated to:

- the Secretary;
- an SES employee, who holds or performs the duties of, an SES Band 3 position in the Department; or
- a person who is registered, in a state or internal territory, as a medical practitioner and who holds or performs the duties of, a position that is equivalent to or higher than, an SES Band 2 position in the Department.

The making of these instruments under 41P(3) may be time-critical, to respond to a rapidly evolving market that has repeatedly sought to evade regulation since the Commonwealth Government first regulated nicotine vaping products in 2021. As such, it is important to have a sufficient number of delegates, at a senior level available to make such an instrument.

Item 25 – Subsection 60(1) (after paragraph (k) of the definition of *initial decision*)

This item amends subsection 60(1) to introduce paragraph 60(1)(ka), which provides that refusing to give a consent under subsection 41RC(1), or giving such a consent subject to conditions under subsection 41RC(2), is an initial decision.

Division 3—Application and transitional provisions

Item 26 – Application of amendments

This item provides that the amendments of the TG Act made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 3—Advertising relating to vaping goods

Division 1—Main amendments

Therapeutic Goods Act 1989

Item 27 – After Part 5-1

This item introduces new Part 5-1A to Chapter 5 of the TG Act. Part 5-1A sets out the requirements relating to advertising of vaping goods.

Part 5-1A—Vaping Goods

Division 1—Preliminary

This Part not to apply to advertisements directed at health professions etc. (new section 42DZ)

New subsection 42DZ(1) provides that Part 5-1A does not apply to advertisements directed exclusively to:

- (a) health practitioners included in a class of health practitioners specified for the purposes of this paragraph under subsection (2); or
- (b) persons who are practice managers for a health practitioner covered by paragraph (a); or
- (c) persons who are engaged in the business of wholesaling vaping goods and are included in a class of persons specified for the purposes of this paragraph under subsection (2); or
- (d) a class of persons specified for the purposes of this paragraph under subsection (2).

New subsection 42DZ(2) provides that the Minister may, by legislative instrument, specify any or all of the following:

- (a) a class of health practitioners for the purposes of paragraph (1)(a);
- (b) a class of persons who are engaged in the business of wholesaling vaping goods for the purposes of paragraph (1)(c);
- (c) a class of persons for the paragraph (1)(d).

New subsection 42DZ(3) provides that Part 5-1A does not apply to advice or information given directly to a patient by a health practitioner covered by paragraph (1)(a) in the course of treatment of that patient.

This Part not to apply to certain advertisements for exported goods (new section 42DZA)

New section 42DZA provides that Part 5-1A does not apply to advertisements that are solely for vaping goods that have been exported, or are intended exclusively for export, if the advertisements are not available to consumers in Australia.

Definitions (new section 42DZB)

New section 42DZB introduces a definition of ‘generic information’ for the purposes of new Part 5-1A.

The term *generic information* in relation to vaping goods, includes any statement, pictorial representation or design, however made, about the composition, properties or other characteristics of the vaping goods, but does not include:

- (a) an advertisement about the goods;
- (b) generic information included in an advertisement about the goods; or
- (c) bona fide news.

Division 2—General provisions about advertising vaping goods

Authorised advertisement etc (new section 42DZC)

This section provides for authorisation of advertising of vaping goods.

Secretary may authorise advertising—general

Advertising of vaping goods are absolutely prohibited in view of the health risks associated with vaping and the significant increase in the uptake of vaping in the last few years, in particular, by young people. However, there may legitimate reasons where advertising may in limited circumstances could be justified. For example, advertising for participants in a possible clinical trial, or advertising to discourage the use of vaping goods due to particular presence of an additive. The authorisation is not intended to be granted to a particular individual and there is no application process.

New subsection 42DZC(1) provides that the Secretary may, by writing, authorise the advertising, or a class of advertising, of specified vaping goods.

New subsection 42DZC(2) provides that an authorisation under subsection (1) may authorise specified representations or information to be included in an advertisement of specified vaping goods.

Secretary may authorise specified representation on label or package etc.

New subsection 42DZC(3) provides that the Secretary may, by writing, authorise the use of specified representations:

- (a) on the label of specified vaping goods; or
- (b) on the package in which specified vaping goods are contained; or
- (c) on any material included with the package in which specified vaping goods are contained;

if the Secretary is satisfied that the representations are necessary for the appropriate use of the vaping goods.

Conditions

New subsection 42DZC(4) provides that an authorisation under this section may be subject to conditions specified in the authorisation.

Authorisation not a legislative instrument

New subsection 42DZC(5) provides that an authorisation under this section is not a legislative instrument. The authorisation deals with the administrative matter of specifying representations that may be authorised as part of the advertisement and does not determine or alter the law.

Publication

New subsection 42DZC(6) provides that as soon as practicable after giving the authorisation under this section, the Secretary must cause the authorisation to be published on the Department's website.

Division 3—Offences and civil penalty provisions

Offences—no authorisation or conditions of authorisation not complied with (new section 42DZD)

New section 42DZD provides offences for unauthorised advertising of vaping goods. A person will commit an offence if the person advertises by any means, or causes the advertising, by any means, of vaping goods and there is no authorisation under section 42DZC in relation to the advertising, or where an authorisation is in force, the advertisement is not in accordance with that authorisation.

New subsection 42DZD(1) provides that a person commits an offence if:

- (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods; and
- (b) either:

- (i) no authorisation under section 42DZC is in force in relation to the advertising; or
- (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representation or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

The maximum penalty for an offence under subsection 42DZD(1) is imprisonment for 7 years or 5,000 penalty units, or both. As supply and access of vaping goods are significantly influenced by advertising (including online advertising) and prohibition of advertising is an effective way of curbing and stopping supply, the high penalties are justified and are consistent with the maximum civil penalties in relation to the supply, importation, manufacture and possession of vaping goods. In assessing the level of penalties to be imposed it is considered that advertisements directed to minors (under 18's), advertisements of vaping goods close to schools and facilities, and advertisements indicating safety of vaping goods would attract the maximum penalty.

The note to subsection (1) references sections 54B and 54BA for the liability of an executive officer of a body corporate. Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from breaching a condition of consent to undertake activity in relation to vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

New subsection 42DZD(2) provides that a person commits an offence of strict liability if:

- (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods; and
- (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or
 - (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representation or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

The maximum penalty for an offence under subsection 42DZD(2) is 200 penalty units.

Continuing offences

New subsection 42DZD(3) provides that a person who contravenes subsection (1) or (2) commits a separate offence in respect of each day (including a day of conviction for the offence or any later day) during which the contravention continues.

New subsection 42DZD(4) provides that the maximum penalty for each day that an offence against subsection (1) or (2) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

Civil penalty—no authorisation of conditions of authorisation not complied with (new section 42DZE)

New section 42DZE sets out corresponding civil penalty provision for unauthorised advertising of vaping goods.

New subsection 42DZE(1) provides that a person contravenes this subsection if:

- (a) the person:
 - (i) advertises, by any means, vaping goods; or
 - (ii) causes the advertising, by any means, of vaping goods; and
- (b) either:
 - (i) no authorisation under section 42DZC is in force in relation to the advertising; or
 - (ii) an authorisation under section 42DZC is in force in relation to the advertising, but the advertising does not include representation or information as specified in the authorisation, or the advertising is not otherwise in accordance with the authorisation, or the advertising does not comply with a condition to which the authorisation is subject.

Contravention of this provision attracts a maximum penalty of 7,000 penalty units for an individual, and 70,000 penalty units for a body corporate. These levels of penalties are consistent with the levels of penalties for the contravention of civil penalties applying to vaping goods in new Chapter 4A.

Continuing contraventions

New subsection 42DZE(2) provides that a person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each day during which the contravention continues (including the day the relevant order under subsection 42Y(2) is made or any later day)

New subsection 42DZE(3) provides that the maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Division 4—Secretary may require information or documents

Secretary may require information or documents (new section 42DZF)

Advertisements

New section 42DZF introduces a new information gathering power in relation to the advertisements of vaping goods. This notice is referred to as a ‘substantiation’ notice. The approach in section 42DZF is consistent with existing provisions in the TG Act, including section 42DR which relates to the advertising of therapeutic goods.

New subsection 42DZF(1) provides that the Secretary may, by written notice given to a person apparently responsible for advertising vaping goods, or for causing the advertising of vaping goods, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the advertisement.

Generic information

New subsection 42DZF(2) provides that the Secretary may, by written notice given to a person apparently responsible for disseminating, or for causing the disseminating of, generic information in relation to vaping goods to the public or a section of the public, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the dissemination.

Manner of compliance

New subsection 42DZF(3) provides the manner of compliance including that the person must give the information, or produce the documents to the Secretary within a period of not less than 14 days after the day the notice is given and in the form specified in the notice.

The note to subsection 42DZF(3) makes it clear that a person may commit an offence under section 42DZG for failing to comply with the notice or giving false or misleading information or documents and may be liable to a civil penalty under section 42DZH for giving false or misleading information or documents.

New subsection 42DZF(4) provides that the form may require or permit the information to be given, or the documents to be produced, in accordance with specified software requirements:

- (a) on a specified kind of data processing device; or
- (b) by way of a specified kind of electronic transmission.

Notice not a legislative instrument

New subsection 42DZF(5) makes it clear that a notice under subsection (1) or (2) is not a legislative instrument. Notices given under subsections 42DZF(1) and (2) are administrative in character as they are directed to a specific person (that is the person apparently responsible), and have no general application.

Offences—failing to comply with a notice etc. (new section 42DZG)

New section introduces offences for failing to comply a notice under section 42DZF. The approach in section 42DZG is consistent with existing provisions in the TG Act, including section 42DS.

New subsection 42DZG(1) provides a fault-based offence if the person is given a notice under subsection 42DZF(1) or (2) and the person fails to comply with the notice.

The maximum penalty is 500 penalty units.

New subsection 42DZG(2) is the equivalent strict liability offence of subsection 42DZG(1) and attracts a maximum penalty of 100 penalty units.

New subsection 42DZG(3) provides a fault-based offence if the person is given a notice under subsection 42DZF(1) or (2) and the person gives information or produces a document in compliance or purported compliance with the notice and the information or document provided by the person is false or misleading in a material particular.

The maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

New subsection 42DZG(4) is the equivalent strict liability offence of subsection 42DZG(3) and attracts a maximum penalty of 100 penalty units.

Civil penalty—giving false or misleading information or document in compliance with a notice (new section 42DZH)

New section 42DZH introduces a civil penalty provision for providing information or documents, in purported compliance with a notice given under subsection 42DZF(1) or (2), that are false or misleading in a material particular. The approach in section 42DZH is consistent with existing provisions in the TG Act, including section 42DT.

Contravention of this provision attracts a maximum penalty of 5,000 penalty units for an individual, and 50,000 penalty units for a body corporate.

Self-incrimination (new section 42DZJ)

New section 42DZJ abrogates the privilege against self-incrimination in relation to the giving of information or producing a document under section 42DZF. The approach in section 42DZJ is consistent with existing provisions in the TG Act, including section 42DU.

Without abrogating the privilege against self-incrimination, a person would withhold pertinent information that could seriously undermine the Secretary's power to investigate possible contraventions of the TG Act or regulations and the ability to take timely regulatory action, criminal prosecutions or civil penalty proceedings in relation to such contraventions. While in some cases it may be feasible to obtain information by other means or from other persons, there will be occasions where the relevant information is only known by that person or it is not feasible or timely to do so, which could significantly increase the risk of harm or injury to consumers particularly where the information or documents relate to unlawful vaping goods.

This information could potentially be critical to preventing a serious threat to public health or could lead to a finding of serious safety concerns that pose a significant risk to the health and wellbeing of Australian consumers. The ability to enforce and undertake effective and timely post-market monitoring of the safety of vaping goods under the therapeutic goods regulatory scheme would be compromised and this could have serious public health risks. As such, the public benefit of the abrogation of this privilege outweighs the loss of personal liability.

Any information given in response to such a notice cannot be used as evidence against the person in criminal proceedings or civil proceedings, except for the following:

- (a) proceedings for an offence against subsections 42DZG (3) or (4) due to giving false or misleading information or document in compliance with a notice; or
- (b) proceedings for a civil penalty contravention under section 42Y for a contravention of section 42DZH due to giving false or misleading information or document in compliance with a notice.

New subsection 42DZJ(1) provides that a person is not excused from giving information or producing a document under section 42DZF on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

New subsection 42DZJ(2) provides that in the case of an individual:

- (a) the information given or the document produced; and
- (b) giving the information or producing the document; and
- (c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

- (d) in criminal proceedings, except proceedings for an offence against subsection 42DZG(3) or (4); or
- (e) in civil proceedings, except proceedings under section 42Y for a contravention of section 42DZH.

Division 5—Directions about advertisements or generic information

Directions about advertisements of generic information (new section 42DZK)

New section 42DZK empowers the Secretary to direct a person apparently responsible for advertising vaping goods or disseminating generic information about vaping goods to take certain actions. The approach in section 42DZK is consistent with existing provisions in the TG Act, including section 42DV.

Advertisements

New subsection 42DZK(1) empowers the Secretary to direct, in writing, a person who is apparently responsible for advertising vaping goods, or for causing the advertising of the vaping goods to do one or more of the following:

- (a) cease the advertisement;
- (b) make a retraction;
- (c) make a correction;
- (d) recover any advertisement that is still in circulation;
- (e) destroy the advertisement;
- (f) cease making a particular claim or representation made by the advertisement.

In making a decision to issue a direction, the Secretary must be satisfied that there has been a contravention of the TG Act or regulations.

Generic information

New subsection 42DZK(2) empowers the Secretary to direct, in writing, a person who is apparently responsible for the dissemination, or for causing the dissemination of generic information in relation to the vaping goods to do one or more of the following:

- (a) withdraw the generic information;
- (b) make a retraction;
- (c) make a correction;
- (d) recover any generic information that is still in circulation;
- (e) destroy the generic information;
- (f) cease making a particular claim or representation made by the generic information.

In making a decision to issue direction the Secretary must be satisfied that there has been a contravention of the TG Act or regulations.

Conditions

New subsection 42DZK(3) provides that a direction under subsection (1) or (2) may be subject to conditions specified in the direction.

New subsection 42DZK(4) provides that without limiting subsection (3), the conditions may relate to one or more of the following:

- (a) the period for doing a thing the subject of the direction;
- (b) in relation to the making of a retraction or correction, either or both of the following:
 - (i) the form and manner of the retraction or correction;
 - (ii) the period for which the retraction or correction must be made publicly available;
- (c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

New subsection 42DZK(5) makes it clear that a direction under subsection (1) or (2) is not a legislative instrument within the meaning of subsection 8(1) of the *Legislation Act 2003*. Directions given under subsections 42DZK(1) and (2) are administrative in character as they deal with the administrative matter of issuing directions to a specific person, where the Secretary is satisfied there has been a contravention of the TG Act or regulations. The direction is given to a particular person to comply with the action specified in the direction, and is not directed to the public in general. In addition, the decision to issue a direction under subsection 42DZK(1) or (2) is a reviewable decision under section 60 of the TG Act.

Publication

New subsection 42DZK(6) imposes the requirement for the Secretary to cause the direction to be published on the Department's website as soon as practicable after giving a direction.

Offences—contravening direction under section 42DZK (new section 42DZL)

New section 42DZL introduces fault-based offence (new subsections 42DZL(1) and (2) refer) and a strict liability offence (new subsection 42DZL(3)) for contravening a direction given to a person under subsection 42DZK(1) or (2) of the TG Act in relation to vaping goods. The approach in section 42DZL is consistent with existing provisions in the TG Act, including section 42DW.

New subsection 42DZL(1) provides that a person commits an offence if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2) in relation to vaping goods; and
- (b) the person does an act or omits to do an act;
- (c) and the act or omission contravenes the direction or a condition of the direction;
- (d) either:
 - (i) the use of the vaping goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or
 - (ii) the use of the vaping goods, if the vaping goods were used, would result in, or would be likely to result in, harm or injury to any person; and
- (e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

The maximum penalty is imprisonment for 5 years or 4,000 penalty units, or both.

Note 1 to subsection (1) provides that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (2) instead, with reference to section 53A.

Note 2 to subsection (1) references sections 54B and 54BA for the liability of an executive officer of a body corporate. Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches.

There is significant public harm from breaching a condition of consent to undertake activity in relation to vaping goods in Australia caused by corporate offending and the liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

New subsection 42DZL(2) provides that a person commits an offence if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

The maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

New subsection 42DZL(3) provides that a person commits an offence of strict liability if:

- (a) a direction is given to a person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

The maximum penalty is 100 penalty units.

Civil penalty—contravening direction under section 42DZK (new section 42DZM)

New section 42DZM introduces a civil penalty provision for contravening a direction given to a person under subsection 42DZK(1) or (2) of the TG Act in relation to vaping goods. The approach in section 42DZM is consistent with existing provisions in the TG Act, including section 42DX.

New section 42DZM provides that a person contravenes this section if:

- (a) the Secretary has given a direction to the person under subsection 42DZK(1) or (2); and
- (b) the person does an act or omits to do an act; and
- (c) the act or omission contravenes the direction or a condition of the direction.

Contravention of this provision attracts a maximum penalty of 5,000 penalty units for an individual, and 50,000 penalty units for a body corporate.

Division 6—Public warning notices

Secretary may issue a public warning notice (new section 42DZN)

New section 42DZN empowers the Secretary to issue a public warning notice. The approach in section 42DZN is consistent with existing provisions in the TG Act, including section 42DY.

New subsection 42DZN(1) provides that the Secretary may issue to the public a written notice containing a warning about vaping goods if:

- (a) the Secretary reasonably suspects that there has been a contravention of this Act or the regulations in relation to:
 - (i) the advertising of the vaping goods; or

- (ii) the dissemination of generic information in relation to the vaping goods to the public or a section of the public; and
- (b) the Secretary is satisfied that it is in the public interest to issue the notice.

New subsection 42DZN(2) provides that if:

- (a) the Secretary has given a person a notice (the *substantiation notice*) under subsection 42DZF(1) or (2); and
- (b) the person fails to comply with the substantiation notice; and
- (c) the Secretary is satisfied that it is in the public interest to issue a notice under this subsection;

the Secretary may issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related.

New subsection 42DZN(3) provides that subsection (2) does not limit subsection (1).

New subsection 42DZN(4) makes it clear that a notice under subsection (1) or (2) is not a legislative instrument within the meaning of subsection 8(1) of the *Legislation Act 2003*. Notices given under subsections 42DZN(1) and (2) are administrative in character.

Division 2—Other amendments

Therapeutic Goods Act 1989

Item 28 – Subsection 3(1) (definition of *advertise*)

This item amends the definition of ‘advertise’ in subsection 3(1) of the TG Act to provide that term also relates to vaping goods.

Item 29 – Section 5A

This item amends section 5A of the TG Act to provide that section 15.2 of the *Criminal Code* applies to offences against new subsection 42DZD(1) and (2) and new sections 42DZG and 42DZL.

Item 30 – Subparagraph 25(1)(fa)(ii)

This item amends subparagraph 25(1)(fa)(ii) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 31 – Paragraphs 30(1)(f) and (fa)

This item amends paragraphs 30(1)(f) and (fa) of the TG Act to include a reference to subsection 42DK(1).

Item 32 – Paragraph 30(1)(fb)

This item amends paragraph 30(1)(fb) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 33 – Paragraphs 30(2)(eaa) and (eab)

This item amends paragraphs 30(2)(eaa) and (eab) of the TG Act to include a reference to subsection 42DK(1).

Items 34 to 37 (amendments to subparagraph 30(2)(ea)(ii), subparagraph 31(1)(h)(ii), subparagraph 31(2)(gaa)(ii), and subparagraph 41FD(h)(ii))

These items amend subparagraphs 30(2)(ea)(ii), 31(1)(h)(ii), 31(2)(gaa)(ii) and 41FD(h)(ii) of the TG Act to include a reference to new Part 5-1A consequential to the introduction of that part above.

Item 38 – Paragraphs 41GL(g) and (ga)

This item amends paragraphs 41GL(g) and (ga) of the TG Act to include a reference to subsection 42DK(1).

Item 39 – Paragraph 41GL(h)

This item amends paragraph 41GL(h) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 40 – Paragraphs 41GN(1)(i) and (j)

This item amends paragraphs 41GN(1)(i) and (j) of the TG Act to include a reference to subsection 42DK(1).

Items 41 and 42 (Amendments to subparagraph 41GN(1)(k)(ii) and subparagraph 41JA(1)(h)(ii))

These items amend subparagraphs 41GN(1)(k)(ii) and 41GN(1)(k)(ii) of the TG Act to include a reference to new Part 51A consequential to the introduction of that part above.

Item 43 – After section 42AC

This item amends the TG Act to insert new section 42AD.

New subsection 42AD(1) provides that Part 5-1 of the TG Act does not apply in relation to advertisements about vaping goods.

New subsection 42AD(2) provides that new Part 5-1A applies in relation to advertisements about vaping goods.

Item 44 – After subsection 42DLB(10)

This item amends the TG Act to insert new subsections 42DLB(10A) and (10B) to provide for continuing contraventions for civil penalties relating to advertisements.

New subsection 42DLB(10A) provides that a person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each of day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

New subsection 42DLB(10B) provides that the maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Item 45 – After subsection 42DMA(2)

This item amends the TG Act to insert new subsections 42DMA(2A) and (2B) to provide for continuing contraventions for civil penalties relating to non-compliance with the Therapeutic Goods Advertising Code.

New subsection 42DMA(2A) provides that a person who contravenes subsection (1) commits a separate contravention of that subsection in respect of each of day during which the contravention continues (including the day the order under subsection 42Y(2) is made or any later day).

New subsection 42DMA(2B) provides that the maximum civil penalty for each day that a contravention against subsection (1) continues is 10% of the maximum civil penalty that can be imposed in respect of the contravention.

Item 46 – Section 53A (after table item 33D)

This item inserts new table item 33E into the table in section 53A of the TG Act. Section 53A provides for alternative verdicts for various offences.

Item 47– Section 45BA (after table item 43D)

This item inserts new table items 43E and 43F into the table in section 45BA of the TG Act. Section 45BA sets out offences to which the chief executive officer of a body corporate has personal liability.

Item 48 – Subsection 60(1) (at the end of the definition of *initial decision*)

This item amends subsection 60(1) of the TG Act to make it clear that a decision made by the Secretary under subsection 42DZK(1) or (2) is an initial decision and therefore subject to merits review (comprising internal reconsideration and external review by the AAT) under section 60 of the TG Act.

Division 3—Application and transitional provisions

Item 49 – Application of amendments

This item provides that the amendments made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 4—Enforceable directions and forfeiture

Forfeiture and destruction

These amendments create new forfeiture provisions which overcome the limitations of the existing forfeiture provisions in the TG Act and expand the circumstances in which forfeiture may occur. The existing forfeiture (and related) provisions are set out below:

- under section 54 of the TG Act, forfeiture orders can only be obtained following a criminal conviction, an order under section 19B of the *Crimes Act 1914*, or a finding by a court that the person has contravened a civil penalty provision;
- under section 48H of the TG Act, seized goods may be required to be returned to the owner if they are no longer needed for evidentiary purposes, regardless of whether it is lawful for the owner to possess or deal with the goods.

These enhanced forfeiture powers will enable the TGA to disrupt the trafficking of unlawful goods more efficiently, as well as address potential storage and destruction issues where large quantities of unlawful vapes are seized.

These new powers only apply where goods have been seized pursuant to a search warrant. The intention is that the Secretary would be empowered to initiate a process for the goods to be forfeited to the Commonwealth where there is a *reasonable belief* the goods have been unlawfully imported, manufactured, supplied or are otherwise non-compliant with the TG Act including in relation to possession.

Once the goods have been forfeited, the Secretary should have a broad power to dispose of the goods.

Enforceable directions

An emerging issue with vaping goods is that they are costly to destroy because component parts such as plastics, batteries, and hazardous nicotine need to be separated and appropriately disposed of.

To manage waste issues associated with enforcement of vaping laws, but also to give the Secretary a broad range of compliance and enforcement tools to manage unlawful vapes and therapeutic goods generally, these amendments include a new power which permits the Secretary to make directions to a person to take one or more steps, within the time specified in the notice, to comply with the TG Act if the Secretary believes, on reasonable grounds, that:

- a person is not complying with the TG Act; and
- it is necessary to exercise this power to protect the health and safety of humans.

This power allows directions to be made requiring one or more of the following:

- to relabel or label goods in compliance with the requirements under the TG Act;
- to repackage goods in compliance with the requirements under the TG Act; or
- to destroy or dispose of goods at their own cost, including by delivering the goods to specific service providers who will dispose of the goods responsibly.

Warrants

Sections 49 and 50 of the TG Act require warrants to be issued by a magistrate. The TGA often experiences operational when seeking timely access to magistrates to issue warrants. This is problematic when there is urgency in the obtaining and execution of a warrant.

Consequently, these amendments extend the authority to issue monitoring, offence and civil penalty related warrants in relation to premises to court registrars and other legislative officers of a court of a state or territory.

Such an approach is not unprecedented, with the *Crimes Act 1914* providing for the issuing of warrants by an ‘issuing officer’ which means:

- a magistrate; or
- a justice of the peace or other person employed in a court of a state or territory who is authorised to issue search warrants or warrants for arrest, as the case may be.

Amendments to sections 49 and 50 of the TG Act allow for a registrar of the court or other officers employed in a court of a state or territory to issue monitoring, offence or civil penalty related search warrants in relation to premises.

Therapeutic Goods Act 1989

Item 50 - Subsection 3(1) (paragraph (b) of the definition of *authorised person*)

This item amends the definition of ‘authorised person’ in subsection 3(1) of the TG Act to include a reference to new Part 6-2A.

Item 51 - At the end of Chapter 5A

This item introduces Part 5A-5 in Chapter 5A of the TG Act. Part 5A-5 includes provisions relating to enforceable directions.

New section 42YS provides a simplified outline for Part 5A-5 of the TG Act.

New section 42YT provides that the Secretary may give directions if the TG Act or an instrument is not being complied with. Subsection 42YT(1) provides that this section applies if the Secretary believes, on reasonable grounds, that a person is not

complying with this Act or an instrument made under the TG Act in relation to particular goods and it is necessary to exercise powers under this section to protect the health and safety of humans.

The note to subsection 42YT(1) provides that paragraph 42YT(1)(b), which requires the Secretary to believe on reasonable grounds that it is necessary to exercise powers under this section to protect the health and safety of humans, covers protecting the health and safety of humans in relation to the environment.

Subsection 42YT(2) provides that the Secretary may, by written notice, give directions to the person requiring the person to do any of the following, within the period specified in the notice and at the person's own cost:

- (a) relabel, or label, the goods in compliance with this Act or the instrument;
- (b) repackage the goods in compliance with this Act or the instrument;
- (c) destroy or otherwise dispose of the goods;
- (d) deliver the goods to a specified person to be destroyed or otherwise disposed of in an appropriate manner;
- (e) any other thing prescribed by the regulations in relation to the goods.

The note to this subsection references, in relation to variation and revocation of the directions, subsection 33(3) of the *Acts Interpretation Act 1901*.

Subsection 42YT(3) provides that a period specified in a notice given under subsection (2) must be reasonable having regard to the circumstances.

Subsection 42YT(4) provides that a person commits an offence if the person is given a notice under subsection (2) and the person fails to comply with the notice within the period specified in the notice, with an associated penalty of imprisonment for 12 months or 1,000 penalty units, or both.

Subsection 42YT(5) provides for civil penalties for the same conduct, with the maximum civil penalty for an individual of 5,000 penalty units and for a body corporate of 50,000 penalty units.

Item 52 - At the end of section 48H

This item introduces a note at the end of section 48H, which provides that section 48H does not apply in relation to the thing if section 52AAB applies in relation to the thing (in accordance with subsection 52AAB(2)).

Item 53 - At the end of section 48J

This item introduces a note at the end of section 48J, which provides that section 48J does not apply in relation to the thing if section 52AAB applies in relation to the thing (in accordance with subsection 52AAB(2)).

Item 54 - After Part 6-2

This item introduces Part 6-2A to the TG Act, which includes provisions relating to forfeiture of things seized.

New section 52AAA provides for the forfeiture of things seized under search warrants in certain circumstances.

Subsection 52AAA(1) provides that if an authorised person seizes a thing under a warrant issued under section 50, and the Secretary believes on reasonable grounds that the thing has been imported, manufactured or supplied, or been in the possession, custody or control of a person, in contravention of this Act or an instrument made under this Act or a requirement under this Act or such an instrument has not been complied with in relation to the thing, the thing is forfeited to the Commonwealth.

Subsection 52AAA(2) provides that the Secretary must give a written notice, i.e. a forfeiture notice, in accordance with subsection (3) to the owner of the thing or, if the owner cannot be identified after reasonable inquiry, the person who had possession, custody or control of the thing immediately before it was seized.

Subsection 52AAA(3) provides that the forfeiture notice must identify the thing, and state a number of matters, including the day it was seized, that it was seized under warrant, the grounds on which it was seized, and that the owner or person who had possession, custody or control of the thing may, within 2 months of the forfeiture notice being given, commence proceedings against the Commonwealth for a declaration that the thing is not forfeited to the Commonwealth. Subsection 52AAA(4) provides that the owner of the thing, or person who had possession, custody or control of the thing, may commence proceedings for a declaration that the thing is not forfeited to the Commonwealth. Subsection 52AAA(5) provides that proceedings may be commenced under subsection (4) even if the forfeiture notice has not been given and may only be commenced before the end of the period of 2 months beginning on the day the forfeiture notice is given.

Subsection 52AAA(6) provides that, if the owner or person who has possession custody or control of the thing does not commence such proceedings within 2 months specified in the forfeiture notice, or commences such proceedings but a court has not made a declaration, then the thing is condemned as forfeited to the Commonwealth, and the Secretary may cause notice of the forfeiture of the thing to be published on the Department's website and the Secretary may either retain the thing for the purpose of proceedings in respect of which the thing may afford evidence or cause the thing to be disposed of in such manner as the Secretary directs. The note to subsection (6) references section 54 dealing with offences and forfeiture.

Section 52AAB provides for the return or retention of a thing that is declared not to be forfeited to the Commonwealth.

Subsection 52AAB(1) provides that this section applies in relation to a thing if the thing was forfeited to the Commonwealth under subsection 52AAA(1) and a court has

made a declaration that the thing is not forfeited to the Commonwealth under that subsection.

Subsection (2) provides that sections 48H and 48J do not apply in relation to the thing.

Subsection (3) provides that at the end of 120 days after a court has made a declaration that the thing is not forfeited, an authorised person must take reasonable steps to return the thing to the person from whom it was seized unless:

- (a) proceedings in which the thing may afford evidence were commenced before the end of the 120 day period and have not been completed;
- (b) an authorised person may retain the thing because of an order under subsection (6); or
- (c) an authorised person is otherwise authorised by a law or order of a court of the Commonwealth, a state or a territory, to retain, destroy or dispose of the thing.

Subsection 52AAB(4) provides that the thing may be returned either unconditionally or on such terms and conditions as the Secretary sees fit.

Subsection 52AAB(5) provides that the secretary may apply to an issuing officer for an order that an authorised person may retain the thing for a further period. The application must be made before the end of the 120 day period or, if an order is made under subsection (6), before the end of the period specified in the most recent order.

Subsection 52AAB(6) provides that if the issuing officer is satisfied that it is necessary for an authorised person to continue to retain the thing for one of the following purposes, the issuing officer may order that an authorised person may retain the thing for a period specified in the order not exceeding 3 years:

- (a) for the purposes of an investigation as to whether an offence against this Act has been committed;
- (b) to enable evidence of an offence against this Act to be secured for the purposes of a prosecution;
- (c) for the purposes of an investigation as to whether a civil penalty provision has been contravened;
- (d) to enable evidence of a contravention of a civil penalty provision to be secured for the purposes of civil proceedings.

Subsection (7) provides that before making an application to an issuing officer for an order that an authorised person may retain the thing for a further period, the Secretary must take reasonable steps to discover who has an interest in the retention of the thing and, if it is practicable to do so, notify each person who the Secretary believes to have such an interest of the proposed application.

Item 55 – Application of Amendment

This item provides that Part 6-2A of the TG Act, as inserted by this Part, applies in relation to a thing that is seized under a warrant issued under section 50 of the TG Act on or after the commencement of this Part.

Item 56 – Subsection 54(3)

This item amends subsection 54(3) to include a reference to vaping goods.

Item 57 – At the end of section 54

This item introduces a note at the end of section 54, which provides a reference to Part 6-2A which deals with forfeiture of things seized under a warrant in certain circumstances.

Part 5—Entry, searches and warrants

Therapeutic Goods Act 1989

Background

These amendments extend the power to issue warrants and extension of time to retain seized goods to a registrar and other officers of the state or territory court who are authorised under a state or territory law to issue search warrants. These officers are not carrying out judicial powers. These amendments allow additional flexibility for authorised officers to apply for a warrant from other officers of the state or territory court or a Registrar. Thus, an authorised person can apply for a warrant even when the court is not sitting and the Magistrate is not available.

Details of the amendments

Item 58 - Subsection 3(1)

This item inserts a new definition in the TG Act for *issuing officer*, who is defined as a magistrate or a registrar or other officer of a state or territory court who is authorised under a state or territory law to issue search warrants.

Item 59 - Paragraphs 46A(1)(b) and (2)(b)

This item amends paragraphs 46A(1)(b) and 2(b) of the TG Act to insert “or vaping goods” after “therapeutic goods” (wherever occurring).

Item 60 - Before subparagraph 46A(4)(a)(ia)

This item inserts a new subparagraph 46A(4)(a)(iaa) in the TG Act and provides that subsection 46A(4) applies to premises of a person who is required to comply with a condition of an exemption of vaping goods under sections 18 or 41HA of the TG Act.

Item 61 - Paragraph 48(1)(b)

This item amends paragraph 48(1)(b) of the TG Act to insert “or vaping goods” after “therapeutic goods” (wherever occurring).

Item 62 – Subsection 48A(3)

This item amends subsection 48A(3) of the TG Act to omit the term “magistrate” and substitute it with “issuing officer”.

Item 63 - Subparagraph 48AA(2)(b)(ii)

This item amends subparagraph 48AA(2)(b)(ii) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 64 - Subparagraph 48AA(3)

This item amends subsection 48AA(3) of the TG Act to omit the term “a magistrate” and substitutes it with “an issuing officer”.

Item 65 – Subsection 48AA(5)

This item amends subsection 48AA(5) of the TG Act to omit the term “A magistrate” and substitute it with “An issuing officer”.

Item 66 - Paragraph 48AA(5)(b)

This item amends paragraph 48AA(5)(b) of the TG Act to omit the term “magistrate” and substitute it with “issuing officer”.

Item 67 - Subsections 48BA(7) and 48C(7)

This item amends subsections 48BA(7) and 48C(7) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 68 - Section 48J (heading)

This item amends the heading in section 48J of the TG Act to omit the term “Magistrate” and substitute it with “Issuing Officer”.

Item 69 - Subsection 48J(1)

This item amends subsection 48J(1) of the TG Act to omit the term “a magistrate” (wherever occurring) and substitute it with “an issuing officer”.

Item 70 - Subsection 48J(2)

This item amends subsection 48J(2) of the TG Act to omit the term “a magistrate” (wherever occurring) and substitute it with “an issuing officer”.

Item 71 - Subsection 49(1)

This item amends subsection 49(1) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 72 - Subsections 49(2) and (3)

This item amends subsections 49(2) and (3) of the TG Act to omit the term “magistrate” (wherever occurring) and substitute it with “issuing officer”.

Item 73 - Subsection 50(1)

This item amends subsection 50(1) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 74 – Subsections 50(2) and (3)

This item amends subsection 50(2) and (3) of the TG Act to omit the term “a magistrate” (wherever occurring) and substitute it with “an issuing officer”.

Item 75 – Subsection 51(1)

This item amends subsection 51(1) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 76 - Subsections 51(4) to (9)

This item amends subsections 51(4) to (9) of the TG Act to omit the term “magistrate” (wherever occurring) and substitute it with “issuing officer”.

Item 77 - Subsection 51(10)

This item amends subsection 51(10) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 78 - Paragraph 51B(2)(a)

This item amends paragraph 51B(2)(a) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 79 - Paragraph 51B(2)(a)

This item amends paragraph 51B(2)(a) of the TG Act to omit the term “that magistrate” and substitute it with “that issuing officer”.

Item 80 - Paragraph 51B(2)(b)

This item amends paragraph 51B(2)(b) of the TG Act to omit the term “magistrate” and substitute it with “issuing officer”.

Item 81 - Subparagraphs 51B(2)(c)(i) and (ii)

This item amends subparagraphs 51B(2)(c)(i) and (ii) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 82 - Paragraph 51B(2)(d)

This item amends paragraph 51B(2)(d) of the TG Act to omit the term “a magistrate” and substitute it with “an issuing officer”.

Item 83 - After section 51B

This item inserts new section 51C in the TG Act, which provides that a power conferred on an issuing officer by Part 6-2 of the TG Act is conferred on the officer in a personal capacity and not as a court or as a member or an officer of a court. An issuing officer is not required to accept the powers conferred on them by Part 6-2 of the TG Act.

Further, an issuing officer exercising a power under Part 6-2 of the TG Act has the same protection and immunity as if the officer were exercising the power as the court of which it is a member or officer, or as a member or an officer of the court of which the issuing officer is a member or an officer.

Part 6—Delegation and authorised persons

Therapeutic Goods Act 1989

Background

The vaping reforms are intended to achieve a timely and nationally consistent approach for the regulation of vaping goods by relying on the federal cooperative scheme for therapeutic goods. All states and territories have enacted corresponding laws to adopt the Commonwealth TG Act as amended from time, with Western Australia having recently progressed their own corresponding law. The corresponding laws fill the gap in the Commonwealth's constitutional power to ensure appropriate coverage for the regulation of therapeutic goods.

To empower state and territory officials to carry out enforcement powers under the new reforms, the Bill allows for the delegation of the powers of the Secretary under Chapter 5A, new section 52AA and new section 52AAB to an officer of a Department of State of a state, a Department or administrative unit of the Public Service of a territory or an authority of a state or territory. The Department, unit or authority must have functions relating to therapeutic goods, health or law enforcement. Section 7 of the TG Act already provides for the Secretary to authorise these officers to exercise powers under a specified provision of the TG Act. State and territory officers authorised by the Secretary under section 7A exercise powers and functions under Part 6-2 (Entry, searches and warrants) of Chapter 6 of the TG Act.

In practice, the Secretary only provides authorisation and delegation of powers to officers who have the relevant skills and experience in relation to enforcement powers such as entry to premises, execution of search, monitoring and investigation warrants, testing of things and samples, and the seizing of evidential materials. Current delegates and authorised officers range from APS 5 to SES officers. Although delegation and authorisation are given to APS officers, they are generally accompanied by high level APS officers, and depending on the risks associated with the search and seizure, will be accompanied by law enforcement officers. In addition, these officers are given appropriate training and must adhere to standard operating procedures developed by the Department of Health. It is intended that the same criteria will be applied by the Secretary in the making of delegation and authorisation for state and territory officers.

To ensure consistency in the application of enforcement powers under the Commonwealth therapeutic goods legislation and applied laws, authorised officers and delegates must comply with any directions of the Secretary or of the person who delegated the function or power. The binding directions could relate to compliance with standard operating procedures developed by the Department of Health.

Details of specific amendments

Item 84 - Section 7A

This item makes an editorial amendment to section 7A to provide for subsection (1)

Item 85 - At the end of section 7A

This item amends section 7A of the TG Act to introduce subsection 7A(2), which provides that in exercising a power under a provision of this Act under an authorisation under subsection (1), the authorised person must comply with any directions of the Secretary.

Item 86- After subsection 57(1)

This item inserts a new subsection 57(1A) in the TG Act, which provides that the Secretary may, in writing, delegate all or any of the Secretary's powers and functions under Chapter 5A (enforcement), section 52AAA (forfeiture of things seized under search warrant) or section 52AAB (return of retention of a thing declared not to be forfeited) to an officer of:

- a Department of State of a state; or
- a Department or administrative unit of the Public Service of a territory; or
- a state or territory authority;

being a Department, unit or authority that has functions relating to therapeutic goods, health or law enforcement.

The new subsection 57(1A) does not limit the delegations set out under subsection 57(1) of the TG Act.

Delegation of powers to state and territory officers

The intended formulation of the delegation in subclause 57(1A) is to officers of a department, unit or authority that have functions relating to therapeutic goods, health or law enforcement. It is not intended that the delegation be limited to the head of the relevant departments and administrative units.

This is because it is not practical or appropriate for enforcement related functions, such as entry, search and seizure powers to be only delegated to heads of relevant departments and administrative units. It is expected that significant enforcement activities will be required by the Commonwealth, states and territories. This will require a number of persons with varying technical skills due to the significant amount of seizures of illicit goods that are likely to be executed. Such powers are appropriately delegated to experienced and skilled persons who undertake investigations and related regulatory functions. It is anticipated that there may be a number of persons with different technical skills, including forensic data analysts, health officials and police officers, who will have jurisdiction to exercise powers under the applied laws.

The approach to delegation of these powers is an extension of the current regulatory framework, which enables state and territory officers to exercise the powers of authorised officers under the TG Act. The enforcement of controls on therapeutic goods (and proposed under this Bill, vaping goods) is carried out under a national system of controls; essentially, a federal cooperative scheme between the

Commonwealth, states and territories. Consistent with the scheme, the Commonwealth will take responsibility for enforcing importation, manufacture, sponsor supply and advertisement. The states and territories will take responsibility for enforcing wholesale supply, retail supply and commercial possession.

The national approach to the regulation of vaping goods is a centrepiece of the vaping reforms and will be critical to the success of the measures to achieve the public health objectives. By extending the power to delegate the powers and functions of the Secretary to state and territory officers, the Bill would complement existing arrangements in relation to authorised officers and therefore further enhance the compliance and enforcement effort in Australia.

Finally, it is intended that the delegation of these powers and functions would be subject to a binding direction that officers must adhere to standard operating procedures created by the Secretary to ensure consistency for the carrying out of enforcement powers (refer to Item 87 below regarding the addition of new subsection 57(12)).

Item 87 - At the end of section 57

This item introduces new subsection 57(12), which provides that in exercising any powers or performing any functions under a delegation under section 57, the delegate must comply with any directions of the person who delegated the power or function.

Item 88 - Subsection 61A(4) (at the end of paragraph (c) of the definition of protected person)

This item amends the definition of *protected person* in subsection 61A(4) of the TG Act and adds “(1A)” after “subsection 57(1)”.

Part 7—Release of information

Therapeutic Goods Act 1989

Section 61 of the TG Act principally provides for powers to release certain kinds of information to specified persons or the public, in certain circumstances. While these powers are not exhaustive of the ways in which the Department may use or release the kinds of information specified in section 61, they are an important mechanism by which the Department may inform the public, health departments, law enforcement bodies and others of certain information, including critical safety and regulatory information, in a timely manner and in accordance with specified requirements.

Most of the information release powers in section 61 permit the release of ‘therapeutic goods information’, which is defined in subsection 61(1) as being information relating to therapeutic goods that is held by the Department and that relates to the performance of the Department’s functions.

The amendments contained in this Part would create new powers to release information relating to vaping goods which mirror existing information release powers relating to therapeutic goods, and make consequential amendments to expand the application of section 61 to vaping goods.

Items 89 – Subsection 61(1)

This item inserts a new definition in subsection 61(1) of the TG Act for *vaping goods information*, which refers to information in relation to vaping goods that is held by the Department and relates to the performance of the Department’s functions.

This definition is intended to include a wide range of information concerning vaping goods and aligns with the definition of ‘therapeutic goods information’ contained in subsection 61(1).

Consistent with the definition of ‘therapeutic goods information’, the Department’s functions to which information may relate in order to be within the definition of ‘vaping goods information’ is not limited to functions under the TG Act. It may include, for example, functions under other legislation administered by the Department, such as the *National Health Act 1954*.

It is anticipated that some kinds of information may be simultaneously ‘vaping goods information’ and ‘therapeutic goods information’, such as information about a vaping device included in the Register. Such information is intended to be able to be released under one or more existing information release powers relating to therapeutic goods, one or both of the information release powers relating to vaping goods proposed in Item 137, or both.

Item 90 - After subsection 61(7)

This item inserts new subsections 61(7A), (7B), (7C) and (7D) in the TG Act.

Subsection 61(7A) will permit the Secretary to release vaping goods information of a kind specified under subsection 61(7B) to one or more persons, bodies or authorities (or one or more kinds of persons, bodies or authorities) specified under that subsection, for one or more purposes specified under that subsection.

The new subsection 61(7B) of the TG Act empowers the Minister to specify, by legislative instrument, one or more of the following:

- a person, body or authority, such as the World Health Organisation or the Department of Home Affairs;
- kinds of persons, bodies or authorities, such as state or territory health departments, or Australian law enforcement agencies;
- kinds of vaping goods information, such as information about enforcement action taken in relation to vaping goods, or all information within the meaning of ‘vaping goods information’;
- purposes, such as to support cooperation in relation to the enforcement of border controls relating to vaping goods, to promote industry awareness, or for any purpose related to the Department’s functions.

Subsections 61(7A) and (7B) reflect the existing information release powers concerning therapeutic goods contained in subsections 61(5AA) and (5AB) of the TG Act.

Subsection 61(7C) will permit the Secretary to release vaping goods information of a kind specified under subsection 61(7D) to the public. The new subsection 61(7D) of the TG Act empowers the Minister to specify, by legislative instrument, the kinds of information that the Secretary may release to the public. Subsections 61(7C) and (7D) are modelled on the existing information release powers concerning therapeutic goods contained in subsections 61(5C) and (5D) of the TG Act.

The amendments will provide flexibility for the release of a wide range of information relating to vaping goods. This may include, for example:

- providing safety alerts to the public about the dangers associated with the use of particular vaping goods (e.g. instances of vaping goods being contaminated with high levels of toxic substances), to ensure that users are informed about such risks and are able to take steps to avoid a threat to their health by not using products for which such alerts are made;
- informing Commonwealth, state and territory health authorities or law enforcement bodies about vaping goods which have been, or are suspected of having been, imported, manufactured or supplied in contravention of the TG Act; or
- informing the public about decisions or actions taken under the TG Act or its regulations in relation to vaping goods, such as information about enforcement action taken against the suppliers of prohibited vaping goods.

Items 91 to 94 (Amendments to subsection 61(8), paragraphs 61(8)(a) and (b), subsection 61(8) (note) and subsection 61(9))

Subsection 61(8) of the TG Act provides that, subject to the data protection regimes for medicines in sections 25A and 26AF of the TG Act, therapeutic goods information (as defined in subsection 61(1) of the TG Act) provided to the Department in relation to a matter may be:

- used by the Department in the consideration of another matter that relates to therapeutic goods; or
- given to a committee appointed to advise the Minister or Secretary on matters relating to therapeutic goods.

Items 91 and 92 are principally intended to expand the operation of subsection 61(8) so that it also applies to vaping goods information (as intended to be defined in subsection 61(1) of the TG Act). Together, these items would amend subsection 61(8) so that vaping goods information or therapeutic goods information may be:

- used by the Department in consideration of another matter that relates to therapeutic goods or vaping goods; or
- given to a committee appointed to advise the Minister or Secretary on matters relating to therapeutic goods or vaping goods.

These amendments are primarily intended to ensure that information held by the Department in relation to a particular vaping-related matter (for example, intelligence about the kinds of prohibited vaping goods attempted to be illegally imported into Australia), may be used in relation to other functions, such as broader public health policy.

Item 91 also replaces the phrase ‘... information provided to the Department...’ with ‘... information held by the Department...’. This amendment will align subsection 61(8) with the description of information being ‘held by’ the Department in the definition of ‘therapeutic goods information’ (and the proposed definition of ‘vaping goods information’) in subsection 61(1).

This amendment is intended to clarify, for the avoidance of doubt, that the information to which subsection 61(8) applies includes information which is created or generated by the Department, and is not limited to information ‘provided to’ the Department.

It is the Department’s position that subsection 61(8) already applies to information created or generated by the Department. However, this amendment is intended to provide certainty about the application of the provision. For example, information provided to the TGA by a person when applying for the inclusion of a vaping device in the Register would be information ‘provided to’ the Department, and therefore would be within the scope of subsection 61(8). However, it may be less clear whether the TGA’s report which evaluated that application is also information ‘provided to’ the Department.

This amendment is intended to put beyond doubt that information like an evaluation report (or the results of testing conducted by the TGA's laboratories of a vaping substance) is information to which subsection 61(8) applies.

Item 93 makes a minor amendment to the note in subsection 61(8) of the TG Act to clarify that, pursuant to section 132C of the *National Health Act 1953* (the NH Act), the Secretary of the Department may disclose therapeutic goods information 'held by' the Department to the Chief Executive Medicare for the purpose of certain data matching.

Currently, the note says that information 'provided to' the Department may be disclosed for the purpose of data-matching. However, subsection 132C(1) of the NH Act does not include the words 'provided to'. That provision instead states that the Secretary may disclose 'therapeutic goods information (within the meaning of subsection 61(1))' of the TG Act, which is relevantly defined as information 'held by' the Department. Consequently, item 139AA is intended to ensure that the note to subsection 61(8) aligns more closely with subsection 132C(1) of the NH Act.

Item 94 makes a minor, technical amendment to subsection 61(9) of the TG Act, to provide that an instrument made under the proposed subsections 61(7B) or (7D) may apply, adopt or incorporate, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time. In relation to vaping goods, an instrument made under those subsections might incorporate, for example, a matter contained in a standard concerning the quality or safety of vaping devices.

The current subsection 61(9) already makes this allowance in relation to the other instrument-making powers contained in section 61, namely subsections 61(5AB) and (5D).

Item 95 - Application of amendments

This item provides that the amendments made by Part 6 of the Bill apply in relation to the release, disclosure or use of information on or after the commencement of Part 6, whether the information started to be held, or was obtained or created, before or after that commencement.

Part 8—Laboratory testing

Therapeutic Goods Act 1989

This Part contains amendments to the regulation-making powers in section 63 of the TG Act. These amendments are intended to expand existing regulation-making powers concerning the testing of therapeutic goods to include the testing of vaping goods (or any kind of goods, to ascertain whether the goods are vaping goods or therapeutic goods).

Item 96 - Paragraph 63(2)(d)

Paragraph 63(2)(d) of the TG Act provides that regulations may provide for the procedures to be followed by the Department in the sampling and testing of therapeutic goods.

This item repeals and substitutes paragraph 63(2)(d) to provide that the regulations may provide for the procedures to be followed in the sampling and testing of:

- therapeutic goods;
- vaping goods;
- any kind of goods, for the purpose of ascertaining whether the goods are therapeutic goods or vaping goods.

This amendment is intended to ensure that the regulations may make appropriate provision for the procedures to be followed by the Department or others (such as commercial testing laboratories engaged by the Department) in relation to the sampling and testing of vaping goods.

The new paragraph 63(2)(d) also enables the making of regulations to prescribe procedures for the sampling and testing of any kind of goods for the purpose of ascertaining whether or not they are therapeutic goods or vaping goods (or both). The phrase ‘any kind of goods’ is intended to capture a broad array of things, including physical possessions and digital possessions (like software).

This amendment is intended to expressly permit the making of procedures related to obtaining and testing samples of kinds of goods where, for example, it is not apparent that the goods are therapeutic goods or vaping goods until after they have been sampled and tested, or where sampling and testing would be preferable to confirm a suspicion that the goods are therapeutic goods or vaping goods.

Consistent with the current paragraph 63(2)(d), it is not intended for paragraph 63(2)(d), or regulations made under this paragraph, to exhaustively provide for:

- the ways that the Department may sample or test therapeutic goods, vaping goods, or any kind of goods for the purpose of determining whether the goods are vaping goods or therapeutic goods; or

- the procedures that the Department may or must follow when sampling or testing those kinds of goods.

Item 97 – Saving of regulations

This item provides that regulations made for the purposes of paragraph 63(2)(d) of the TG Act, which are in force immediately before the commencement of this item, continue in force for the purposes of that paragraph as in force after that commencement. This will notably include regulations contained in Part 5 of the *Therapeutic Goods Regulations 1990*.

Item 98 – Paragraph 63(2)(g)

Paragraph 63(2)(g) of the TG Act provides that the regulations may make provision for:

- the testing of therapeutic goods;
- the inspection of manufacturing operations; or
- the evaluation of data concerning therapeutic goods,

by the Department at the request of persons.

This item expands paragraph 63(2)(g) to expressly provide that the regulations may make provision for the testing of vaping goods, or the evaluation of data concerning vaping goods, by the Department at the request of persons.

Part 9—Approvals for certain Part 3-2 exempt goods

Therapeutic Goods Act 1989

Item 99 - Subsection 19(1)

This item amends subsection 19(1) of the TG Act to enable the Secretary to grant approvals under that provision—i.e., Special Access Scheme Category B (“SAS B”) and clinical trial approvals—in relation to the importation, exportation or supply of exempt goods.

Under subsection 18(1) of the TG Act, the regulations may, subject to any conditions, exempt specified therapeutic goods, or a specified class of therapeutic goods, from the operation of Part 3-2 of the TG Act (save for a small number of provisions in that Part). The effect of this provision is to enable the regulations to specify therapeutic goods, or classes of therapeutic goods, that may be imported into, manufactured in, and supplied in Australia, despite the goods not being included in the Register.

Relevantly, therapeutic vaping goods are exempt from the operation of Part 3-2 of the TG Act if, among other things:

- the only indications (i.e., therapeutic uses) of the goods are for smoking cessation or the management of nicotine dependence; and
- the sponsor of the goods, and any other person involved in the wholesale or retail supply of the goods, intend for the goods to be supplied to the ultimate consumer in accordance with an approval or authority under section 19 of the TG Act.

However, subsection 19(1) of the TG Act currently precludes the Secretary from granting SAS B and clinical trial approvals in relation to therapeutic goods that are exempt goods. As such, sponsors wishing to import, manufacture or supply unregistered therapeutic vaping goods in Australia can only do so if they intend for the goods to be supplied to the ultimate consumer in accordance with an authority granted under the TG Act (namely, under the Authorised Prescriber Scheme, which is established by subsection 19(5) of the TG Act).

This impacts the flexibility of the exemption for therapeutic vaping goods, as it establishes a barrier to legitimate patient access to such goods for smoking cessation, and the management of nicotine dependence, under appropriate clinical supervision.

Consequently, this item amends subsection 19(1) of the TG Act by omitting “registered goods, listed goods or exempt goods” and substituting “registered goods or listed goods”. This amendment ensures that the lawful supply of therapeutic vapes under the relevant exemption can operate in conjunction with SAS B and clinical trial approvals granted by the Secretary under subsection 19(1).

Part 10—Offences and civil penalty provisions for breach of condition of certain exemptions or approvals

Therapeutic Goods Act 1989

Item 100 - Section 22(5A)

This item creates a new fault-based offence with an aggravating factor if a person does an act, or omits to do an act and the act or omission results in the breach of a condition of an exemption applicable under regulations made for the purposes of subsection 18(1) or a condition of approval under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A) or a condition of an approval under section 19A and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

The maximum penalty is imprisonment for 5 years or 4,000 penalty units or both. The notes for this subsection provide that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A and refers to section 54B and 54BA in relation to the liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the supply of unapproved therapeutic goods which do not comply with a condition of an unapproved supply pathway under the TG Act in Australia caused by corporate offending. Such unapproved therapeutic goods may include vaping goods. The liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

Item 101 - At the end of subsection 22(7)

This item amends this subsection by adding that the maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

Item 102 - Subsection 22(7AA)

This item repeals the existing subsection and substitutes with an offence of strict liability if a person does an act, or omits to do an act and the act or omission results in the breach of a condition of an exemption applicable under regulations made for the purposes of subsection 18(1) or a condition of approval under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A) or a condition of an approval under section 19A. The maximum penalty is 100 penalty units.

Item 103 – Section 22AA (heading)

This item omits “a condition of an exception” and substitutes it with “conditions”.

Item 104 – Section 22AA

This item inserts “(1)” before “A person”.

Item 105 – Section 22A

This item omits “this section” and substitutes it with “subsection”.

Item 106 – At the ed of section 22AA

This item creates a civil penalty provision if a person does an act, or omits to do an act and the act or omission results in the breach of a condition of an exemption applicable under regulations made for the purposes of subsection 18(1) or a condition of approval under section 19 or a condition applicable under regulations made for the purposes of subsection 19(4A) or a condition of an approval under section 19A. The maximum penalty for an individual is 5,000 penalty units and 50,000 penalty units for a body corporate.

Item 107 - Subsection 41HA(2) (note)

This item omits “subsection 41MN(9)” and substitutes it with “subsections 41MN(9), (9A) and (9B)”.

Item 108 - Subsection 41HB(2) (note)

This item omits “subsection 41MN(9)”, substitutes it with “subsections 41MN(9), (9A) and (9B)”.

Item 109 - Subsection 41HB(7) (note)

This item omits “subsection 41MN(9)”, substitutes it with “subsections 41MN(9), (9A) and (9B)”.

Item 110 - Subsection 41HD(7) (note)

This item omits “subsection 41MN(9)”, substitute “subsections 41MN(9), (9A) and (9B)”.

Item 111 - Subsection 41MN(9)

This item repeals the existing subsection, and substitutes it with offences relating to breaching a condition of an exemption or approval, or a condition applicable under regulations.

The new subsection (9) creates a fault-based offence with an aggravating factor if a person does an act or omits to do an act and the act or omission breaches a condition

of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2) and the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

The maximum penalty is imprisonment for 5 years or 4,000 penalty units or both. The notes for this subsection provide that a jury may acquit a person of an offence against this subsection and may convict the person of an offence against subsection (7) instead: see section 53A and refers to section 54B and 54BA in relation to the liability of an executive officer of a body corporate.

Section 54B is intended to apply to executive officers, such as managing directors or Chief Executive Officers, who are directly involved in or participate in the management of a company, and who should be made accountable for the actions of their company where such officers are in a position to influence the company and are aware of breaches by the company of the TG Act but fail to take reasonable action to prevent the breaches. There is significant public harm from the supply of unapproved therapeutic goods which do not comply with a condition of an unapproved supply pathway under the TG Act in Australia caused by corporate offending. Such unapproved therapeutic goods may include vaping goods. The liability of the corporation is not likely on its own to sufficiently promote compliance and have the desired deterrence effect.

The new subsection (9A) creates a fault-based offence if a person does an act or omits to do an act and the act or omission breaches a condition of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2). The maximum penalty is imprisonment for 12 months or 1,000 penalty units, or both.

The new subsection (9B) creates an offence of strict liability if a person does an act or omits to do an act and the act or omission breaches a condition of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2). The maximum penalty is 100 penalty units.

Item 112 – After subsection 41MNA(2)

This item inserts subsection (2A) after subsection (2) and creates a civil penalty provision if a person does an act or omits to do an act and the act or omission breaches a condition of an exemption applicable under regulations made for the purposes of section 41HA or a condition of an approval under section 41HB or a condition applicable under regulations made for the purposes of subsection 41HB(7) or a condition of an approval under subsection 41HD(1), (1A) or (2).

The maximum civil penalty is 5,000 penalty units for an individual and 50,000 for a body corporate.

Item 113 - Section 53A (after table item 9A)

This item inserts new table item 9B into the table in section 53A of the TG Act. Section 53 provides for alternative verdicts for various offences.

Item 114 - Section 53A (after table item 31)

This item inserts new table item 31 AA into the table in section 53A of the TG Act. Section 53A provides for alternative verdicts for various offences.

Item 115 - Section 54BA (table item 5)

This item inserts “(6)” after “22(2)” in item 5 in the table.

Item 116 - Section 54BA (table item 40)

This item inserts “(9)” after “(5)” in item 40 in the table.

Item 117 - Application of amendments

This item provides that the amendments of the *Therapeutic Goods Act 1989* made by this Part apply in relation to acts or omissions that occur on or after the commencement of this Part.

Part 11—Other amendments

Therapeutic Goods Act 1989

Item 118 - After subsection 58(2)

Section 58 provides for export certifications. Subsection 58(1) provides that the Secretary may issue export certification for goods for therapeutic use in humans. Subsection 58(2) then provides that a state or territory must not issue like export certifications.

This item inserts new subsections 58(2A) and (2B), which are analogous to the existing subsections 58(1) and (2). Subsection 58(2A) will permit the Secretary to issue export certifications for vaping goods for use in humans, except goods for which export certifications may be used under subsection 58(1). Subsection 58(2B) will provide that a state or territory must not issue like export certifications.

Consequently, it is intended for export certifications concerning therapeutic vaping goods to be issued under subsection 58(1), and export certifications concerning non-therapeutic vaping goods to be issued under subsection 58(2A).

Additionally, it is intended that the existing subsection 58(3) will apply to the new subsection 58(2A). Therefore, fees may be prescribed in respect of an application for a certification under subsection 58(2A), or the inspection of a manufacturing site if necessary for the purposes of the issue of a certification under subsection 58(2A).

Items 119 and 120 (Amendments to subsection 61A(4) (after paragraph (g) of the definition of *protected person* and paragraph (h) of the definition of *protected person*)

Item 119 inserts new paragraph (ga) into the definition of ‘protected person’ contained in subsection 61A(4) of the TG Act, to provide that the regulations may prescribe kinds of persons who are ‘*protected persons*’ for the purposes of subsection 61A(1).

Subsection 61A(1) of the TG Act provides the Commonwealth and protected persons with immunity from civil actions or proceedings in certain circumstances. Relevantly, it provides that no civil action lies against a protected person in respect of loss, damage or injury that is suffered by another person, because of an act or omission of the protected person in connection with their performance or exercise, or purported performance or exercise, of a function, duty or power under the TG Act or regulations. An act or omission in connection with the purported performance or exercise of a relevant function, duty or power includes, for example, an act done in accordance with the purported exercise of a power under the TG Act, but where it is later determined that the decision to exercise that power was of no legal effect because it was infected by jurisdictional error.

Importantly, however, the immunity conferred by subsection 61A(1) of the TG Act does not apply in relation to an act or omission of the Commonwealth or a protected person in bad faith (subsection 61A(2)).

Subsection 61A(4) of the TG Act specifies the kinds of persons who are protected persons for the purposes of section 61A. The list includes, for example, the Minister, the Secretary, persons to whom a power of the Minister or Secretary has been delegated under the TG Act, and persons and officers that the Secretary has authorised to perform certain functions and exercise certain powers under the TG Act and its regulations.

However, the list of protected persons does not include all persons who may perform or exercise a function, duty or power under the TG Act or its regulations. For example, it does not expressly include an officer of the Department to whom powers or functions under the MD Regulations are delegated under regulation 10.5 of those regulations.

Consequently, item 119 amends subsection 61A(4) to provide flexibility to, by regulation, broaden the range of persons to whom the immunity in subsection (1) applies.

This will ensure that, for example, any new category of persons empowered to perform functions under the regulations may be subject to the immunity (by disallowable regulation), without the need for a commensurate amendment to the TG Act.

Item 120 makes a minor, consequential amendment to paragraph (h) of the definition of ‘protected person’. Paragraph (h) provides that a ‘protected person’ includes a person assisting any person referred to in another paragraph of the definition of ‘protected person’ (i.e. paragraphs (a) to (g)) in certain circumstances. Item 120 expands paragraph (h) to also include a person assisting a person of a kind prescribed as a protected person under regulation made under paragraph (ga).

Items 121 to 123 (Amendments to subsection 62(1), subsection 62(2) and at the end of section 62)

These items amend section 62 of the TG Act to provide flexibility to, by regulation, broaden the range of persons that are protected from criminal responsibility when carrying out certain investigatory actions under the TG Act or its regulations.

Section 62 enables APS employees in the Department to obtain, possess or convey (or facilitate the conveyance of) goods—in circumstances where such conduct would ordinarily be an offence against a Commonwealth law or a state law (which is defined in section 3 of the TG Act as meaning a law of a state, the Australian Capital Territory, or the Northern Territory)—for the purposes of identifying whether the TG Act or its regulations have been complied with.

Enforcement of the vaping reforms will require the engagement and cooperation of state and territory officials (and Commonwealth officials outside of the Department) in assessing compliance with the TG Act and its regulations.

For example, a state or territory official may seize or purchase vaping goods within their jurisdiction, and then arrange for the same to be conveyed to the TGA for

testing. As section 62 of the TG Act does not currently apply in relation to such cases, the relevant official may be prohibited from doing so (particularly if the goods contain, or are, prescription medicines).

Consequently, it is necessary to extend the protection that is provided by section 62 so that it also applies to persons other than APS employees in the Department. The amendments made by these items give effect to this measure, by providing flexibility to, by disallowable regulation, prescribe kinds of persons as protected persons.

Specifically, item 123 inserts new subsection 62(3) in the TG Act, which provides that for the purposes of section 62, a protected person means:

- an APS employee in the Department; or
- a person of a kind prescribed by the regulations.

Items 121 and 122 make minor, consequential amendments to subsections 62(1) and (2) of the TG Act, by omitting references to “[an] APS employee in the Department” and substituting “[a] protected person”.

SCHEDULE 2 – Amendment of the *Customs Act 1901*

Background

The *Customs Act 1901* (the Customs Act) provides for the forfeiture of a range of goods upon importation into Australia. This includes all smuggled or unlawfully imported goods and all prohibited imports. The *Customs (Prohibited Imports) Regulations 1956* (the CPI Regulations) prescribe goods as prohibited imports for the purposes of the Customs Act. Since 1 January 2024, vaping goods imported without permission are prohibited imports for the purposes of the Customs Act. Prohibited imports fall within the definition of ‘special forfeited goods’, and can be seized with or without a warrant in certain circumstances.

Subdivision G of Division 1 of Part XII of the Customs Act sets out a process for dealing with goods which have been seized as forfeited goods. The Customs Act currently requires seized prohibited imports to be stored in an approved place for a minimum of 30 days before they can be disposed of. The Customs Act also requires that a seizure notice be served on the owner of the goods, or if the owner cannot be identified, on the person in whose possession or under whose control the goods were at the time of seizure. The owner or person in possession may make a claim for the return of seized goods. If no claim is made within 30 days after the day the seizure notice is served, the goods are taken to be condemned as forfeited to the Crown.

Existing section 206 provides that certain goods may be dealt with outside of this process. Relevantly, subsection 206(2A) states that where:

- goods are seized under the relevant provisions of the Customs Act; and
- the Comptroller-General of Customs is satisfied the goods are a prohibited psychoactive substance, tobacco products or a prohibited serious drug alternative;

then the Comptroller-General may cause the goods to be dealt with in such a manner as he or she considers appropriate (including the destruction of the goods). This can include the immediate destruction of the goods which provides streamlined administrative processes and reduced storage time.

Applying this approach to seized vaping goods will significantly enhance the ability of Australian Border Force officials to effectively deal with imported vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.

Effect of the amendments

The Bill has one substantive amendment to the Customs Act that would amend section 206 of the Customs Act to extend the provision’s coverage to ‘vaping goods’ as defined in regulation 5A of the CPI Regulations, and three consequential amendments that would give operational effect to the arrangements for vaping goods.

The substantive amendment will allow the Comptroller-General of Customs to immediately destroy (or otherwise deal with) vaping goods which have been seized as prohibited imports under the Customs Act. The term ‘vaping goods’ is defined in regulation 5A of the CPI Regulations to capture a vape, a vape accessory, or a vape substance.

Owners of vaping goods destroyed under subsection 206(2B) may have the right to recover the market value of the goods, if they can establish that the circumstances required to trigger the destruction did not exist. If the Comptroller-General deals with goods under subsection 206(2B), within seven days of doing so they must give or publish a notice which identifies the goods, provides details of the manner in which the goods have been dealt with and the reasons for doing so, and sets out the owner’s right to seek recovery of the market value.

The amendments to the Customs Act in this Bill would have a positive impact on the Australian Government’s ability to effectively regulate vaping goods by empowering the Comptroller-General of Customs to cause vaping goods seized as prohibited imports to be dealt with in a manner he or she considers appropriate, including the immediate destruction of the goods.

Customs Act 1901

The Customs Act provides for the forfeiture of a range of goods upon importation into Australia. This includes all smuggled or unlawfully imported goods and all prohibited imports. The CPI Regulations prescribe goods as prohibited imports for the purposes of the Customs Act.

Prohibited imports fall within the definition of ‘special forfeited goods’, and can be seized with or without a warrant in certain circumstances.

Schedule 2 to the Bill contains amendments to the Customs Act that will result in a positive impact on the Australian Government’s ability to effectively regulate vaping goods by empowering the Comptroller-General of Customs to cause vaping goods seized as prohibited imports to be dealt with in a manner the Comptroller-General considers appropriate, including the immediate destruction of the goods.

Item 1 - Subsection 183UA(1)

This item inserts a new definition of ‘vaping goods’ into subsection 183UA(1) of Subdivision A of Division 1 of Part XII of the Customs Act, which deals with the powers of officers. Since 1 January 2024, ‘vaping goods’ imported without permission are prohibited imports for the purposes of the Customs Act.

This ‘framework’ definition provides that, in Division 1 of Part XII of the Customs Act, ‘vaping goods’ has the same meaning as in regulation 5A of the CPI Regulations, which currently captures a vape, a vape accessory, or a vape substance.

The reason the definition for this term is in delegated legislation rather than on the face of the Customs Act is that it is vital to have flexibility in the definition, to enable

rapid amendments to cater for novel and unanticipated forms of ‘vaping goods’. Despite the broad range of ‘vaping goods’ that are currently prohibited imports under this definition, an attempted importation of goods in novel and unanticipated forms that would be ‘vaping goods’ but would not readily fit within the current definition is still a possibility and may pose a risk to population health and would also threaten to disrupt the significant achievements that Australia has made in tobacco and vaping goods control to date.

Retaining the definition in delegated legislation is therefore important, as that definition could be readily amended to capture a new range of standards, codes and other international regulatory instruments that may have relevant material applying to emerging developments in the ‘vaping goods’ industry. It is also important to note that any future amendments to the defined term in delegated legislation would be subject to Parliamentary scrutiny and disallowance.

Item 2 - After subsection 206(2A)

Subdivision G of Division 1 of Part XII of the Customs Act sets out a process for dealing with goods which have been seized as forfeited goods. The Customs Act currently requires seized prohibited imports to be stored in an approved place for a minimum of 30 days before they can be disposed of. The Customs Act also requires that a seizure notice be served on the owner of the goods, or if the owner cannot be identified, on the person in whose possession or under whose control the goods were at the time of seizure. The owner or person in possession may make a claim for the return of seized goods. If no claim is made within 30 days after the day the seizure notice is served, the goods are taken to be condemned as forfeited to the Crown.

Section 206 of the Customs Act concerns goods that may be dealt with outside of the afore-mentioned process. By way of an example, subsection 206(2A) of the Customs Act provides that, if

- (a) goods are seized under the relevant provisions of the Customs Act; and
- (b) the Comptroller-General of Customs is satisfied the goods are a prohibited psychoactive substance, tobacco products or a prohibited serious drug alternative;

then the Comptroller-General may cause the goods to be dealt with in such a manner as the Comptroller-General considers appropriate (including the destruction of the goods).

This item amends section 206 of the Customs Act to insert a new subsection (2B), which would extend the provision’s coverage to ‘vaping goods’. Specifically, new subsection 206(2B) provides that, if:

- (a) goods are seized under a seizure warrant or under subsection 203B(2) or (2A), 203CA(3) or 203CB(2); and
- (b) the Comptroller-General of Customs is satisfied that the goods are vaping goods that are prohibited imports;

the Comptroller-General of Customs may cause the goods to be dealt with in such manner as the Comptroller-General considers appropriate (including the destruction of the goods).

The manner in which seized vaping goods that are prohibited imports can be dealt with can include the immediate destruction of the goods, providing streamlined administrative processing and reduced storage time.

The purpose of this amendment is to provide authority for regulating ‘vaping goods’ by empowering the Comptroller-General of Customs to cause ‘vaping goods’ seized as prohibited imports to be dealt with in a manner the Comptroller-General considers appropriate, including the immediate destruction of the goods. This amendment will significantly enhance the ability of Australian Border Force officials to effectively deal with imported vaping goods and would significantly reduce the operational burden of implementing the vaping goods reforms.

Item 3 - Subsection 206(3)

Subsection 206(3) of the Customs Act requires that, as soon as practicable, but not later than 7 days after the goods referred to in subsection (1), (1A), (2) or (2A) have been dealt with, the Comptroller-General of Customs must give or publish a notice in accordance with subsection (5).

This item makes a consequential amendment to subsection 206(3) and has the effect of extending the requirement under subsection 206(3) to goods that have been dealt with under new subsection 206(2B).

Item 4 - Paragraph 206(5)(c)

Subsection 206(5) of the Customs Act provides that the notice must:

- (a) identify the goods; and
- (b) state that the goods have been seized under a seizure warrant or under subsection 203B(2) or (2A), 203CA(3) or 203CB(2) and give the reason for the seizure; and
- (c) state that the goods have been dealt with under subsection (1), (1A), (2) or (2A) and specify the manner in which they have been so dealt with and the reason for doing so; and
- (d) set out the terms of subsection (6).

This item makes a consequential amendment to paragraph 206(5)(c) and has the effect of extending the notice requirements under that provision to goods that have been dealt with under new subsection 206(2B).

Item 5 - Subsections 206(6) and (7)

This item contains an amendment to both subsections 206(6) and (7) of the Customs Act.

Subsection 206(6) of the Customs Act provides that, if goods are dealt with in accordance with subsection (1), (1A), (2) or (2A), the owner of the goods may bring an action against the Commonwealth in a court of competent jurisdiction for the recovery of the market value of the goods at the time they were so dealt with.

This item makes a consequential amendment to subsection 206(6) to extend the right to recover the market value of seized goods that have been dealt with under new subsection 206(2B).

Subsection 206(7) of the Customs Act specifies the circumstances in which a person's right to recover the market value of seized goods that have been dealt with under section 206 is enlivened.

This item makes a consequential amendment to subsections 206(7) to apply the circumstances in which the right to recover the market value of seized goods, to goods that have been dealt with under new subsection 206(2B).

The purpose of this clause is to permit the owners of 'vaping goods' destroyed under subsection 206(2B) the right to recover the market value of the goods, if they can establish that the circumstances required to trigger the destruction did not exist. If the Comptroller-General deals with goods under subsection 206(2B), within seven days of doing so they must give or publish a notice which identifies the goods, provides details of the manner in which the goods have been dealt with and the reasons for doing so, and sets out the owner's right to seek recovery of the market value.

SCHEDULE 3 – AMENDMENTS OF OTHER ACTS

Industrial Chemicals Act 2019

Item 1 - Section 8

This item inserts the term “vaping goods” into the Simplified Outline of the *Industrial Chemicals Act 2019*. This ensures that vaping goods are included in the exception of chemicals that are not industrial chemicals, such as chemicals for therapeutic purposes.

Item 2 – Section 9 (after paragraph (d) of the definition of *industrial use*)

This item inserts new paragraph (da) in section 9 of the *Industrial Chemicals Act 2019* to provide that the definition of *industrial use* means a use other than (or in addition to) use as a vaping good (within the meaning of the TG Act) or in the preparation of such a good.

Public Health (Tobacco and Other Products) Act 2023

Item 3 – Section 64

This item amends section 64 of the *Public Health (Tobacco and Other Products) Act 2023* to add a reference to Part 5-1A of the TG Act. New Part 5-1A regulates the advertising of vaping goods, and associated information about vaping goods.

Section 64 provides for the interaction of Part 2.4, Division 1 of the *Public Health (Tobacco and Other Products) Act 2023* with Part 5-1 of the TG Act.

Item 4 - Section 64

This item adds a reference to “vaping goods” to section 64 of the *Public Health (Tobacco and Other Products) Act 2023*. Section 64 currently provides for therapeutic goods and this amendment ensures that vaping goods are also included for the purposes of this section.

Section 64 provides for the interaction of Part 2.4, Division 1 of the *Public Health (Tobacco and Other Products) Act 2023* with the TG Act.



Australian Government

Department of Health and Aged Care

Ministerial Submission – Standard

MS24-000790

Version (1)

Date sent to MO: 21 June 2024

To: Minister Butler

cc:

Subject: Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 - Replacement Explanatory Memorandum

Critical date: Friday 21 June 2024 at 11:00 AM to enable the replacement explanatory memorandum to be printed and tabled on Monday 24 June 2024.

Recommendation/s:

1. APPROVE the replacement explanatory memorandum for the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (Attachment A)

1. Approved/Not approved/Please discuss

Signature

Date: / /

Comments:

Contact Officer:	<i>Dr Bridget Gilmour-Walsh</i>	<i>Principal Legal and Policy Adviser, Health Products Regulation Group</i>	Ph: (02) 6289 4290 Mobile: s22
Clearance Officer:	<i>Nick Henderson</i>	<i>Acting Deputy Secretary, Health Products Regulation Group</i>	Ph: (02) 6289 4270 Mobile: s22

Issues:

- 1. Ministerial approval is required for the replacement explanatory memorandum (Attachment A) to the Therapeutic Goods Legislation (Vaping Reforms) Bill 2024 (the Bill). The replacement explanatory memorandum is necessary to respond to concerns raised by the Senate Standing Committee for the Scrutiny of Bills, as agreed in recent correspondence (see MC24-005007 and MC24-007728) and otherwise to make corrections to minor typographical errors.**
- 2. Following approval, we will arrange for the replacement explanatory memorandum to be printed for tabling on Monday 24 June 2024 prior to the movement of the proposed Government amendments on the same day.**

Attachments:

A: Replacement explanatory memorandum to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

Sensitivities:

The proposed reforms continue to generate interest in the community and criticism from some importers, manufacturers, retailers and consumers of non-therapeutic vapes. There is, however, clear and public support from health professionals, academia, professional representative organisations, educators and parent representative groups.

Consultations:

Consultations continue with relevant stakeholders, including parliamentarians on proposed Government amendments, separate to the matters addressed in the replacement explanatory statement.

Regulatory Burden Implications and/or Deregulation Opportunities:

An Impact Analysis (IA) was prepared on the proposed vaping reforms to support the policy approval. On 10 October 2023, the Office of Impact Analysis (OIA) considered the IA to demonstrate *good practice*, consistent with Australian Government best practice regulation requirements (OIA23-03933). The IA has been published on the OIA's website.

Minister	Choose an item.
PDR Number	MS24-000790
Subject	Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 Replacement Explanatory Memorandum, Government Amendments and Supplementary Explanatory Memorandum
Critical Date	Friday, 21 June 2024
Contact Officer	Dr Bridget Gilmour-Walsh Principal Legal and Policy Adviser Health Products Regulation Group (02) 6289 4290 s22
Clearance Officer	Nick Henderson Acting Deputy Secretary Health Products Regulation Group (02) 6289 4200 s22
Division/Branch	Health Products Regulation Regulatory Legal Services Unit
Has Budget Branch been consulted if there are financial implications?	Not Applicable

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Please complete	
Quality Assurance Check (completed by line area)	Mandy Edlington, Acting Assistant Secretary, Vaping Legislative Reform Branch, Health Products Regulation Group. s22

From: s22
To: Minister Butler DLO
Cc: EDLINGTON, Mandy; s22; GILMOUR-WALSH, Bridget; HPRG Parliamentary; s22
Subject: RE: Updated TP's and Q&A on vaping [SEC=OFFICIAL]
Date: Monday, 24 June 2024 3:07:26 PM
Attachments: image002.png
 image003.png
 image005.png
 VAPING LEG TPS & CONDENSED Q&A - June 2024 - interim.docx

Hi s22

Attached latest updated vaping legislation TP's and QA's. Some dot points are still being refined, so this is an interim version, however didn't want to delay sending these any longer.

Kind regards

s22

s22 (she/her)

s22
 Regulatory Legal Services Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 Location: Gulgana, Fairbairn ACT, 2.N.454
 PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Monday, June 17, 2024 6:09 PM
To: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; s22
 s22@Health.gov.au>
Cc: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; HPRG Parliamentary
 s22@Health.gov.au>
Subject: FW: Updated TP's and Q&A on vaping [SEC=OFFICIAL]

Hi Mandy and s22

In preparation for debate of the Vaping Reforms Bill in the Senate next week, the MO has asked for updates to the Bill package TP's and Q&A.

Could you please review the attached and send updated versions by 9:00am Monday 24 June 2024?

Thanks

s22

s22 (he/him)
 Departmental Liaison Officer
 Office of the Hon Mark Butler MP
 Minister for Health and Aged Care

T: s22 | M: s22
E: Minister.Butler.DLO@health.gov.au
Suite MG.50 | PO Box 6022
Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 <s22@Health.gov.au>
Sent: Monday, June 17, 2024 3:41 PM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>; s22 <s22@Health.gov.au>
Subject: Updated TP's and Q&A on vaping [SEC=OFFICIAL]

Hi DLOs,

Can I please request for the vaping legislation TP's and QA to be updated, in line with the possible proposed changes?

Can I have these up to the MO by Monday morning next week?

Cheers

s22

s22

Strategic Communications Lead
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
M: s22
E: s22 <s22@health.gov.au>
Suite MG.50 | PO Box 6022
Parliament House, Canberra ACT 2600

The Office and Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

VAPING LEGISLATION INTRODUCED

TALKING POINTS

- When we came to Government it was clear that the rates of vaping in Australia had skyrocketed.
- One in six high school students, and one in five young Australians aged between 18 and 24 are vaping.
- Vapes have become the number one behavioural issue in many schools.
- Nine out of 10 vape shops are within walking distance of schools.
- The truth is Big Tobacco sold smokers – and governments – a furphy.
- Vapes were sold to governments and communities around the world as a therapeutic good: a product that could help hardened smokers – usually people in their 40s or 50s – to quit smoking and kick the habit.
- If vapes are therapeutic goods then it is entirely appropriate that Australia should regulate them as therapeutic goods, instead of allowing them to be sold alongside chocolate and lollies in convenience stores, often down the road from schools.
- Vapes were promised as a healthy alternative to smoking but we now know this is not the case, and they can be just as addictive as cigarettes. Most not only contain nicotine. They can also have more than 200 chemicals in them, including some that are used in nail polish remover, weed killer and even to embalm dead bodies.
- What vapes have become is a product that has hooked a whole new generation onto nicotine.
- Big Tobacco has been cunning; they have purposely targeted our youngest and most vulnerable.
- They have done this with bright colours, bubble gum flavours and disguised them to look like highlighters.
- To ensure this does not occur, strong controls are needed.

- The reason why we're in this position is there has been a huge regulatory loophole left open that has allowed tobacco retailers to lawfully sell "non-nicotine vapes". And we all know these "non-nicotine vapes" have nicotine in them.
- We are working hard to end recreational vaping. But we need also to ensure that those people who really need a therapeutic vape to help them quit can get one.
- If a person who is smoking or vaping finds the resolve to walk into their local pharmacy and say, "I want to quit", then we want that pharmacist to have a conversation with them, then and there.
- We want the pharmacist to be able to offer the gum, patches, or therapeutic vape that might help that smoker give up for good.
- We don't want the pharmacist to have to tell people to make a GP appointment that might be several days or weeks later, when their resolve might have waned, without being able to offer them appropriate nicotine replacement in the meantime.
- Importantly, pharmacies will not be selling nicotine vapes with candy flavours or brightly coloured packaging – or sky-high nicotine concentrations.
- We think that 1 October is an appropriate date for this streamlined access through pharmacies to take effect.
- It allows time for protections and oversight to be established, while also ensuring that access is improved before March next year, when the price of tobacco products will rise, and a whole range of new smoking protections will see new graphic warnings and changes to the look of tobacco products and packs to make them more dissuasive and less appealing.
- This policy is not prohibition. Any adult who is in genuine need will be able to purchase a therapeutic vape from a pharmacist.
- Nicotine vapes will continue to be available on prescription from a doctor or nurse practitioner from 1 July.
- But from 1 October, access will be expanded to allow people aged 18 years or over to purchase vapes with appropriately limited nicotine concentrations directly from a pharmacy, without the need for a prescription.

- It is important that vapes be provided alongside health advice about the harms of vaping – and the best way to vape less and, ultimately, give up.
- The right person to provide that health advice is a doctor, nurse practitioner or pharmacist – not a convenience store worker across the road from a school.
- Smoking has taught us – the hard way – just how harmful nicotine addiction can be, and just how difficult it is to unravel, once it becomes entrenched.
- That is why it is imperative we move quickly, now, through this Bill, to immediately ban the supply of vapes through tobacco retailers and convenience stores.
- The best time to have done this would have been five years ago, but the second-best time is now.
- As parliamentarians, we have a once-in-a-generation opportunity and responsibility to act now, to safeguard the health of young Australians for generations to come.
- How will history judge us if – instead of acting – we just put up the white flag and let another generation get addicted to another dangerous nicotine product?
- How will our children and grandchildren judge us, then?
- To that end, I hope that our world leading vaping reforms are met with support from across the parliament.

QUESTIONS AND ANSWERS

Why the new pharmacy model?

- We are working hard to end recreational vaping. But we need to ensure that those hardened smokers who really need a therapeutic vape to help them quit can get one.
- Most smokers quit without any nicotine replacement tools.
- But if a hardened smoker finds the resolve to walk into their local pharmacy and say "I want to quit", then we want that pharmacist to have a conversation with them, then and there.
- We want the pharmacist to be able to offer the gum, patches, or therapeutic vape that might help that smoker give up for good.
- We don't want the pharmacist to tell people to make a GP appointment that might be several days or weeks later, when their resolve might have waned, without being able to offer them appropriate nicotine replacement therapies in the meantime.
- Pharmacies will still only stock therapeutic vapes, without the candy flavours or brightly coloured packaging or sky-high nicotine concentrations.
- We think that 1 October is an appropriate date for this streamlined access through pharmacies to take effect.
- It allows time for protections and oversight to be established, while also ensuring that access is improved before March next year, when the price of tobacco products will rise, and a whole range of new smoking protections will see new graphic warnings and changes to the look of cigarettes and tobacco products and packs to make them more dissuasive and less appealing.

Why not put the pharmacy model in place from 1 July, or delay the introduction of the laws in the first place?

- From 1 July, we want every Australian that has been lured into vaping by Big Tobacco to start having a conversation with their GP or nurse practitioner, to get the information and supports they need to quit.

- They can be supported by other government-funded resources like the Quitline, quit.org.au and the My QuitBuddy app, as well as the 'Give Up For Good' vaping and smoking public health campaigns.
- Over the next three months, that support and those conversations with their GP will help Australians plot out a pathway to quit.
- From 1 October, some Australians will keep seeing their GP for help along the pathway to quit.
- Others will then be able to access the products they need through a pharmacy – but importantly, with ongoing health advice from their pharmacist.

Do these amendments prove that the Government legislation got it wrong and you have needed to water down your laws to get it through the Senate?

- These are Government amendments that have come out of good faith consultation with the crossbench.
- These amendments strengthen the laws and clarify the intent that has always been in the laws: to return vaping to its original stated purpose of helping hardened smokers to quit, by cracking down on the commercial sale and supply of recreational vapes, while ensuring that those people who really need a therapeutic vape to help them quit can get one.
- We've listened to feedback about how important it is for people to have quick access to a consultation with a healthcare professional, when they seek it.
- We know that a pharmacy is often the most accessible place that people turn to when they need health advice.
- And so, after a three-month period of having those conversations with their GP, we believe it is sensible to also allow pharmacists to have those conversations and recommend whether a therapeutic vape is needed.

When do you hope legislation will take effect?

- The ban on recreational vapes would commence on 1 July 2024 or the day after the Act receives Royal Assent.
- From 1 October 2024, therapeutic vaping products containing nicotine would be down-scheduled from Schedule 4 (prescription medicines) to Schedule 3 (pharmacist-only medicines).
- The Bill would amend the Poisons Standard directly to introduce a new entry in Schedule 3 for nicotine in therapeutic vaping goods in final dosage form for smoking cessation or the management of nicotine dependence, as a pharmacist-only medicine, for adults.
- The effect of the new entry would be to enable pharmacists to supply therapeutic vaping goods containing nicotine to adults without a prescription, with the goods to be kept behind the counter, and not accessible to the public on pharmacy shelves for self-selection.
- At the end of this year, it is anticipated that standards for vapes will be further strengthened, to reduce nicotine concentrations and require plain pharmaceutical packaging.

How will young people be protected and what safeguards are proposed?

- The Government's vaping reforms are focused on protecting our young people from the physical and mental health harms of vaping and nicotine dependence.
- This is why this Bill limits the sale of nicotine vapes to pharmacies – and not tobacco retailers and convenience stores.
- This will ensure that consumers are accessing vapes where they can get professional advice from a health practitioner on the risks associated with their use, as well as information on cessation supports and therapies to support them to quit.
- There will be additional safeguards introduced with these reforms to provide further protections for our young people.
 - Therapeutic vapes under Schedule 3 will only be available to people aged 18 or over, unless they have a prescription. This

is to ensure people under 18 are only accessing vapes under medical supervision.

- There will be limits applied to the amount of vapes that can be purchased through a pharmacy and ID will be required for purchase.
- We are also moving on tackling the attractive flavours, bright colours and packaging that industry has used to target and encourage use among our youngest and most vulnerable.
- At the end of this year, it is anticipated that standards for vaping products will be further strengthened to require plain pharmaceutical packaging.

Can therapeutic vapes be prescribed to under-18s?

- Each state and territory has different tobacco control legislation, which includes a range of restrictions on the supply of e-cigarettes, particularly to minors.
- The prescribing of therapeutic vapes, to people under 18 years of age would continue to be available under Schedule 4 for smoking cessation and the management of nicotine dependence where clinically appropriate and where state and territory legislation allows it.
- The Government is committed to providing further guidance to medical and nurse practitioners, and pharmacists, on state and territory legal settings regarding prescribing and dispensing of therapeutic vapes to children under the age of 18.

Isn't this just a consumer model that allows pharmacies to profit?

- No. These reforms focus on cracking down on commercial sale and supply of recreational vapes at the same time as boosting our investment in support services and education to help people to quit.
- Our approach aims to balance the need for adult smokers and people who are nicotine dependent to have reasonable access to therapeutic vapes where it helps them to quit smoking and vaping, with safeguards built in to ensure clinical advice is provided,

product standards are improved, and there are limitations to access to improve the safe and appropriate use of vapes.

- This will be a pharmacist-only medication, kept behind the counter, and not accessible to the public on pharmacy shelves for self-selection.
- Vapes will only be available without a prescription to people aged 18 years or over. This is to ensure people aged under 18 are only accessing vapes under medical supervision.
- Pharmacists will provide advice about the appropriate dosage, as well as available supports, to help patients quit smoking or manage their nicotine dependence.
- When vapes are supplied without a prescription, nicotine concentrations cannot exceed 20mg/mL and a maximum of the equivalent of one month's supply can only be purchased at any one time, once per month.
- Consumers should still speak to a health professional such as a doctor, nurse practitioner or pharmacist about their options to quit smoking or manage their nicotine dependence and what is most appropriate for them.

Will individuals be penalised if they possess vapes for personal use?

- The Bill targets commercial and criminal actors involved in the illicit supply of vapes, not users.
- The Bill will not punish young people who are being deliberately targeted by an industry determined to make money.
- Possession for personal use, whether by adults or children, will not be penalised.
- To ensure that the offences are clear and enforceable, limits will apply to possession for personal use.
- Limits on possession for personal address the legitimate need to stockpile vaping goods in rural and remote areas.

What will be deemed commercial possession? What are the new penalties under the Bill?

- The number of vapes that would amount to a commercial quantity will be set in the regulations. The quantities are still being settled.

However, the quantities will be an appropriate regulatory deterrent and allow possession for personal and other authorised use.

- Different penalties will apply depending on the quantity of vapes possessed.
- An individual who possesses at least the commercial quantity of vapes could face a maximum criminal penalty of up to two years imprisonment or a fine of \$313,000, or both.
- Higher penalties will apply for possession of at least 100 times the commercial quantity. The penalties will be higher again for possession of at least 1000 times the commercial quantity.

From July 1 how will enforcement occur? How quickly will it take for the vape stores to close?

- From 1 July, the TGA and states and territories will use new powers to enforce vape laws and be able to more readily seize and dispose of illicit vapes. Illicit vapes will be easier to detect and the opportunities for unlawful trade in these products will be significantly reduced.
- As a result, the TGA and states and territories will be able to more efficiently disrupt illegal domestic supply.
- As the retail supply of any vapes outside a pharmacy setting will be prohibited, vape stores are anticipated to disappear quickly.
- States and territories will be able to take fast enforcement action on vape stores without the need to determine whether vapes with labelling that conceals the presence of nicotine actually contain nicotine or not.
- Enforcement will continue to be cooperative between the Commonwealth and states and territories.
- The ABF will lead enforcement at the border, in partnership with the TGA which will lead on compliance in relation to advertising, and work with states and territories on wholesale and retail supply, and commercial possession.

Will the reforms increase the black market?

- Strengthening the regulation of all vapes, by enhancing border controls, banning all disposable single-use vapes and ending the

supply of vapes outside of pharmacy settings, will make it easier to identify and disrupt the illicit supply of vapes and take effective enforcement action.

- The benefit of the new approach is that it will enable compliance and enforcement action to be taken immediately on illicit vapes without requiring laboratory testing.
- Strengthened enforcement activities across all levels of the supply chain will also combat the black market.
- To support the implementation and enforcement of these reforms, the Government is providing an additional \$25 million to the Australian Border Force and \$56.9 million to the TGA over two years.
- All states and territories are also committed to sharing and increasing compliance action and supporting a national enforcement approach. The benefit of the new approach is that it will enable compliance and enforcement action to be taken immediately on illicit vapes without requiring laboratory testing.
- Importers and suppliers of illicit vapes are now on final notice that changes proposed to the Therapeutic Goods Act will enhance compliance and enforcement efforts.

How do we know the enforcement of the Bill will work?

- While we are not going to be able to flick the switch and stop access to unlawful vapes entirely, the Government is determined to do everything it can to limit access to non-therapeutic vapes and protect young Australians.
- The TGA, along with the ABF and states and territories, is actively taking enforcement action and monitoring any changes and trends in relation to the importation, supply and advertisement of other illegal nicotine products.
- The Bill will support this work and provide a strong deterrent to those seeking to do the wrong thing.

What is the Government doing to address illicit tobacco? When does the Illicit Tobacco and E-cigarette Commissioner start?

- The main driver that reduces illicit tobacco demand is the same one that reduces consumption of legally sold tobacco. That is, declining consumption. The Government's measures to support people to quit smoking and to prevent uptake will also reduce the use of illicit tobacco.
- Illicit tobacco enforcement, and the elements of organised crime associated with its trade, are the shared responsibility of relevant law enforcement agencies within the Commonwealth and states and territories.
- On [14 January 2024](#), the Government committed \$188 million over four years to the ABF to deliver a new coordinated compliance model, in partnership with the states and territories, to tackle all aspects of illicit tobacco.
- In March 2024, the Australia and New Zealand Police Commissioners Forum included discussion on the shared jurisdictional focus on targeting the involvement of organised crime in illicit tobacco and vaping.
- The *Public Health (Tobacco and Other Products) Act 2023* establishes the role of the Illicit Tobacco and E-cigarette Commissioner within the Australian Border Force.
- The Illicit Tobacco and E-cigarette Commissioner will support a nationally consistent approach to enforcing the Government's tough new measures and look at further strategies to reduce the quantities of illicit products entering the community.
- On XX June, Minister Butler announced the appointment of XX to this role.

What are the import requirements and standards for vapes?

- Under customs regulations, vaping goods can only be imported into Australia if the goods are therapeutic vaping goods and the importer has a licence and permission to import the vaping goods.
- There are a small number of exceptions, including for travellers who can import a small quantity of vaping goods for their own treatment or the treatment of a person under their care.

- Licences and permissions are processed and issued by the Office of Drug Control (ODC) within the Department of Health and Aged Care.
- To obtain a permission to import a vaping good, an importer must have notified the TGA that the vaping goods comply with TGA standards. These are:
 - the TGA standard Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 (TGO 110); or
 - the applicable essential principles (these are standards for medical devices), set out in the Therapeutic Goods (Medical Devices) Regulations 2002 (MD Regulations).
- A notification to the TGA is also required for a person to lawfully manufacture or supply vaping goods in Australia, under the applicable exemptions for unapproved therapeutic vaping goods.
- Between 1 January 2024 and 19 June 2024, the TGA received 795 valid notifications for nicotine vapes (including vaping substances, vaping accessories and vaping devices) that may be supplied in pharmacies for smoking cessation or the management of nicotine dependence.
- In the same period, ODC granted 45 import licences and 329 import permissions for vapes that can be supplied in Australia, under the new border controls.
- TGO 110 includes requirements designed to ensure the safety of therapeutic vaping goods, by prohibiting the use of known dangerous ingredients, requiring the amount of nicotine in the vaping good to be within specified limits, specifying child-resistant packaging requirements and limiting flavours to mint or menthol, or tobacco.
- The essential principles set out benchmarks for the safety and performance of medical devices, including that a medical device must not compromise the clinical condition or safety of a patient and must perform in the way intended by the manufacturer.
- Sponsors of vaping devices that were excluded from the therapeutic goods regulatory framework prior to 1 January 2024 may demonstrate compliance with the essential principles by

complying with a new medical device standard for vaping devices. The medical device standard can be complied with by meeting certain international standards. Sponsors and manufacturers are familiar with these standards as key international benchmarks for quality management of product design and manufacture.

- The TGA is continuing to consult industry, health representative bodies and other stakeholders to further strengthen both TGO 110 and the standard for vaping devices. Further amendments are expected to be made in the near future to strengthen the regulatory requirements.

Will these reforms mean that a large quantity of vapes are going to be dumped?

- No. Sufficient time has been provided to retailers to sell any lawful stock since the reforms were announced in May 2023, noting that it has been unlawful to import disposable single-use vapes since 1 January 2024 and all non-therapeutic vapes since 1 March 2024.
- Unlawful stocks of vapes may be seized by the Australian Border Force, the Therapeutic Goods Administration, state and territory health authorities and police, and will be disposed of by these authorities.
- Health and environment officials in the Commonwealth and states and territories are cooperatively considering disposal issues with a view to reducing the environmental impacts of vape waste.
- The TGA is commencing a process to secure long-term storage and disposal solutions for unlawful vape products.
- Waste management is a matter for states and territories, including their environment departments.

What is the Government doing to reduce the environmental impacts of vapes?

- The Government's reforms will contribute to a reduction in vaping rates and therefore reduce the availability of vapes except those for therapeutic purposes.
- Reducing the number of vapes available will, in effect, also reduce their overall impacts on the environment.

- The removal of all disposable single-use vapes from the Australian market will be particularly important in achieving these outcomes.
- Health and environment officials in the Commonwealth and states and territories are working together to consider disposal issues with a view to reducing the environmental impacts of waste vapes.

How will the Government monitor and evaluate the effectiveness of the reforms?

- The legislation commits us to undertake an independent review of the Bill and associated instruments within three years.
- In addition, the Government is using a range of resources and data to monitor the impacts of the vaping reforms over the short and longer term.
- It is important to note these reforms include a series of different regulatory activities, many of which are yet to be implemented.
- These reforms are part of a broader suite of regulatory and non-regulatory measures being implemented by all Australian governments to reduce rates of vaping and smoking.
- We have commenced work with states and territories and other key partners to develop an evaluation program, including outcome indicators to monitor progress.
- The work of states and territories is critical to the success of these reforms and the development of nationally agreed monitoring and evaluation activities, including agreed measures of success.

What cessation supports will be available?

- To support people to quit vaping, the Australian Government committed \$29.5 million over four years in the 2023–24 Budget for specialised programs and health service expansions to meet increased demand arising from the new vaping reforms.
- The suite of measures included:
 - The creation of an online cessation hub that contains information, tools, resources and a system to direct consumers to the best support mechanisms to help them quit vaping.
 - The hub went live at quit.org.au in early June, and will be progressively updated to reflect the implementation of the

reforms, best practice evidence-based cessation approaches, and to introduce linkages with state and territory quit services.

- The redevelopment of the My Quit Buddy app to provide both smoking and vaping cessation support to adults.
 - The revised My Quit Buddy app went live in early June, and provides new content and support to manage cravings.
- Expansion of state and territory Quitlines and other quit services to ensure national equity of access to support services as a result of anticipated increased demand. Funding is being sent to each state and territory so they can bolster their surge capacity and develop and deliver targeted supports to priority populations, including young people.
- New clinical guidance is under development, including for general practitioners and pharmacists, on vaping cessation.
- Provisional guidance was published on the RACGP website in December 2023. It will be progressively updated over the course of this year to reflect the regulatory reforms.
- New vaping campaigns have been launched.
 - The first phase of the Youth Vaping Education campaign launched on 28 February 2024 – and the second phase launched 10 June 2024, alongside the adult National Tobacco and E-Cigarette campaign.
 - Additional communication materials, including fact sheets and conversation guides for parents and carers, are available along with campaign materials.
- Finally, \$141 million was allocated to extend and widen the Tackling Indigenous Smoking program to reduce both vaping and smoking among First Nations people.

What cessation support is available for youth?

- There are a number of initiatives that include targeted support for young people wanting to quit vaping.
 - Young people can call the Quitline (13 QUIT) to talk to a counsellor for advice or to help design a quitting plan. States and territories are using Commonwealth funding to develop targeted youth support, such as webchat and sms functions.

- They can also talk to their GP or trusted health professional for advice on options available on their quit journey. The RACGP has published strategies and interventions for young people and will be developing further guidance this year for health professionals to guide these conversations.
- Digital supports such as quit.org.au and the My Quit Buddy app provide 24/7 access to information, including tips/tricks and distractions to help manage cravings.
- Mental health support services are also able to help manage addiction, including those dedicated to young people such as headspace, Beyond Blue, Kids Helpline and ReachOut.

What cessation medicines are on the PBS?

- PBS-listed smoking cessation medicines include NRTs in patch form, bupropion (Zyban) and varenicline (Champix, Varenapix).
- PBS-listed smoking cessation medicines can be prescribed by medical practitioners and nurse practitioners.
- In December 2023, the Department of Health and Aged Care published advice to clarify that the PBS restriction for NRT aims to provide an affordable intervention to help people quit smoking.
 - This means that where clinically appropriate, medical and nurse practitioners are able to prescribe NRTs, subsidised under the PBS, to help people quit smoking and/or vaping.
 - Other NRT products (such as sprays, lozenges and gums) are widely available in commercial settings (such as supermarkets and pharmacies). These products have been evaluated and approved by the TGA.

How much will vapes cost in pharmacies?

- The pricing of vapes is a business decision for pharmacies. At this stage, there is no intention to set, restrict or otherwise influence the cost of vapes obtained through a pharmacy. The level of competition between pharmacies should ensure that prices for vapes are not artificially increased.
- The TGA is monitoring the supply chain to ensure a reliable and sustainable supply of vapes to pharmacies.
- At present, there are no therapeutic vapes subsidised under the PBS.

Why do we need to regulate advertising of vaping through these reforms? Haven't we already done that?

- Vaping and the use of e-cigarettes are a major public health concern. The Government's Bill seeks to introduce a new, tailored framework designed to protect consumers from the advertising of vaping goods.
- The Government's tobacco reforms already extended the existing ban on tobacco advertising to vaping goods. However, that ban does not regulate vapes that fall under the therapeutic goods framework.
- It is appropriate that the vaping reforms, squarely directed to the health risks of vaping, also include a ban on the advertising of vapes.
- The interactions between the existing laws and this Bill have been carefully considered.
- The vaping reforms provide higher penalties, including terms of imprisonment, and are tailored to the needs of the therapeutic setting with appropriate authorisations.
- The Bill allows the Department of Health and Aged Care Secretary to take additional measures if he or she is satisfied that there has been a contravention of the advertising ban, including by issuing a public warning notice or directing the non-compliant party to take action such as issuing a correction.
- Comprehensive advertising bans are critical to eliminate the public health risks posed by vaping.

Do the reforms apply to nicotine pouches?

- Nicotine pouches are not covered by the reforms. The importation, manufacture, commercial supply and advertisement of nicotine pouches is already strictly regulated in Australia.
- Consumers can continue to import nicotine pouches under the Personal Importation Scheme with a valid prescription from an Australian-registered medical practitioner, subject to state and territory requirements. However, these arrangements will continue

to be closely monitored. Advertisement of nicotine pouches to the public in Australia is not permitted.

- No nicotine pouches have been evaluated by the TGA for quality, safety or efficacy in Australia.

What action is the Government taking on snus and snuff?

- The commercial importation and supply of smokeless tobacco products, including chewing tobacco and snuffs intended for oral use, has been prohibited in Australia since June 1991.
- The *Public Health (Tobacco and Other Products) Act 2023* replaces the permanent ban that existed under the *Trade Practices Act 1974*.

How many Australians are currently vaping or have tried vaping?

- Australia has witnessed a dramatic increase in vaping rates in recent years, particularly among young people.
- The latest national survey data shows that around 1.5 million people in Australia aged 14 years or over currently vape, and of these, around 700,000 people are vaping on a daily basis.
- Additionally, around 4.3 million Australians tried vaping in 2022–2023, which is a significant increase from the 1.7 million who had tried vaping in 2016.
- However, it is the rapid rise in vape use by young people that has prompted the Government to take strong action on vaping.
- Young people aged 18 to 24 have the highest use of vapes of all age groups, with almost half (49%) having used them at least once in their lifetime – with 21% currently using vaping products.
- Among secondary school students (12-17 years), almost one-third (30%) have vaped in their lifetime and 16% of students have vaped in the past month.

What should parents do to help their kids get off the vapes?

- Parents and carers have an important role in supporting children to quit vaping. We know that parents' attitudes influence young people's decisions to vape or smoke.
- Quitting any kind of nicotine dependence can be very difficult, especially in the early days.
- We encourage parents to have an open conversation with their children about the risks and impacts of vaping. It's important to try to understand what is motivating them to vape and avoid judgements or assumptions.
- A range of information resources, such as conversation guides, factsheets and FAQs for parents and carers, have been launched as part of the \$63 million 'Give Up For Good' campaign that was funded in the last Budget.
- Confidential support and advice, including free counselling services, are available through the Quitline on 13 78 48.
- Nicotine patches, gum, inhalators, spray and lozenges are sold in a range of retail outlets, including supermarkets and pharmacies, for people aged 12 years and over.

What resources are available for schools and parents/carers?

- The Department of Health and Aged Care has been engaging with the Department of Education to ensure schools are informed about:
 - the vaping reforms that are being implemented throughout 2024
 - what resources are available to support student education about e-cigarettes in their jurisdiction, and
 - guidance on cessation support available for any students who are using vapes and having trouble quitting.
- Joint letters from the Commonwealth, state and territory governments have been distributed to school principals informing them of the above, as well as the Commonwealth's ongoing commitment to protect youth from this public health threat.
- To date, letters to all jurisdictions have been distributed, with the exception of Tasmania, which was in caretaker mode at the time.

- All letters reiterate the national curriculum and Student Wellbeing Hub already equip schools to educate students on the dangers of vaping.
- The Commonwealth has also invested in Collaborating with Life Education, Our Futures-Matilda Centre, Seeing through the Haze and Youth Encounter. This collaboration with these public health entities has supported the development of resources to assist school teachers in Years 5-10, as well as parents, on vaping.
- Nationally, jurisdictions are implementing ongoing prevention measures in collaboration with the Department of Education and public health organisations, including targeted materials, classroom resources, lesson plans and seminars for students and teachers.
- The Commonwealth has developed resources for parents and carers, including a parent guide and accompanying factsheets. These were made available upon the launch of the second phase of the Youth Vaping Education Campaign on Monday 10 June 2024.

Won't this just make people who vape switch to smoking?

- This is a major public health issue. I'm not willing to raise the white flag and let a whole new generation get addicted to nicotine.
- A range of supports are available nationally to help people quit smoking and the use of e-cigarettes.
- These regulatory reforms complement a wider set of actions being taken by the Government in line with the National Tobacco Strategy 2023–2030 to reduce rates of tobacco and e-cigarette use, including investment in education and support to encourage people to permanently give up smoking and vaping.
- A range of supports are available nationally to help people quit smoking and the use of e-cigarettes.

From: s22
To: s22
Cc: GILMOUR-WALSH, Bridget; EDLINGTON, Mandy; BEDFORD, Chris; s22; MCLAY, Nicole
Subject: TRIM: Re: Response to issues raised on the phone earlier - vaping bill [SEC=OFFICIAL]
Date: Thursday, 20 June 2024 6:17:00 PM
Attachments: image003.png
image003.png

Thanks s22 and all for input. Helpful advice - really appreciate the quick turn around

s22

s22 (He/Him)

Office of the Hon Mark Butler MP
Minister for Health and Aged Care

E: s22 @health.gov.au

P: s22

M: s22

Parliament House, Canberra ACT 2600, Australia

We acknowledge the Traditional Owners of the lands on which we live and work.

On 20 June 2024 at 6:14:33 PM AEST, s22
s22 @health.gov.au> wrote:

Hi s22

As discussed on the phone, responses to issues raised below.

Issue for response - Concern about 6 month gap in commencement of pharmacy model.

- Can we have a 3 month transition to introduce s3?
- If it is not 3 months, what is it?
- Can we get PSA guidance up, and IT systems going in this time?

Response:

s47C



s47C

**Issue for response – Concern with the period of retention of identity data –
Can this be retained for 12 months?**

Response:

s47C

Please let me know if you require anything further.

Kind regards

s22 (she/her)

Executive Officer to Dr Bridget Gilmour-Walsh – Principal Legal and Policy Adviser

Regulatory Legal Services Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22@health.gov.au

Location: Gulgana, Fairbairn ACT, 2.N.454

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

[SEC=OFFICIAL]

From: [MCLAY, Nicole](#)
To: [REDACTED]; RCB Reporting: [FIRTH, Clare](#); [s22](#); [Minister Butler DLO](#); [News](#), [REDACTED]
Cc: [LAWLER, Tony](#); [BEDFORD, Chris](#); [REDACTED]
Subject: RE: Vapes - Regulatory Compliance and Enforcement Update - 12 June 2024 [SEC=OFFICIAL:Sensitive]
Date: Friday, 14 June 2024 12:58:00 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.gif](#)
[image004.png](#)

Hi [REDACTED]

The TGA enforcement team is in the early stages of planning our next operations which may lead to seizures however these aren't expected until July and, in the meantime, we're expecting that ABF border seizures will take us up to the 3 million mark.

My ABF contacts aren't aware of any big seizures that aren't yet in the data, and the weekly amount detected fluctuates. In the last week it was 65k.

We estimate that we'll achieve 3 million in 3-6 weeks.

We'll discuss with ABF for a media release, and possible event.

Thanks

Nicole

Nicole McLay

Assistant Secretary, Vaping Implementation and Enforcement

Regulatory Practice and Support Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: 02 6289 3637, [REDACTED] | E: nicole.mclay@health.gov.au

Location: 27 Scherger Drive, Fairbairn, ACT

PO Box 100, Woden ACT 2606, Australia



The Department of Health and Aged Care acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.

From: [s22](#) <[REDACTED]@Health.gov.au>

Sent: Friday, June 14, 2024 6:36 AM

To: RCB Reporting <RCBReporting@Health.gov.au>; [FIRTH, Clare](#) <Clare.FIRTH@Health.gov.au>;

[s22](#) <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>; [s22](#) <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>;

[s22](#) <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>; Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>;

[News](#) <news@health.gov.au>

Cc: [LAWLER, Tony](#) <Anthony.LAWLER@Health.gov.au>; [MCLAY, Nicole](#)

<Nicole.McLay@health.gov.au>; [BEDFORD, Chris](#) <Chris.Bedford@health.gov.au>

Subject: Re: Vapes - Regulatory Compliance and Enforcement Update - 12 June 2024

[SEC=OFFICIAL:Sensitive]

Hey,

When do we expect to hit 3 million seizures?

We'll want a release and possibly an event to announce?

Thanks

Sent from [Workspace ONE Boxer](#)

On 13 June 2024 at 4:13:31 PM ACST, RCB Reporting <RCBReporting@Health.gov.au> wrote:

| Good afternoon all

Please find attached this week's report.

Kind regards

RCB Reporting

Data Analytics, Intelligence and Reporting
Compliance Assessment and Monitoring Section
Regulatory Compliance Branch | Health Products Regulation Group
Australian Government, Department of Health and Aged Care

E: RCBReporting@health.gov.au

PO Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

[SEC=OFFICIAL:Sensitive]

From: s22
To: BEDFORD, Chris; MCLAY, Nicole
Cc: s22; Minister Butler DLO
Subject: RE: Enforcement Q&A [SEC=OFFICIAL]
Date: Monday, 24 June 2024 8:58:24 AM
Attachments: image001.png

We've got briefing with repping senator at 9.30 can it be before

From: BEDFORD, Chris <Chris.Bedford@health.gov.au>
Sent: Monday, June 24, 2024 8:23 AM
To: s22; s22@Health.gov.au; MCLAY, Nicole <Nicole.McLay@health.gov.au>
Cc: s22; s22@Health.gov.au; Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Subject: Re: Enforcement Q&A [SEC=OFFICIAL]

Hi all.

Nicole will have a go. It is more difficult as the strength of the govt response is mostly done for enforcement (we have removed the real time monitoring).

Nicole can we emphasise the ID check, the ability to look at pharmacist dispensing total volumes through sas.

Note the approach to packaging and flavours and strength that help with identification.

The reiterate the already good measures in place.

It may be a little after 930 as dropping kids etc.

Cheers, Chris

Sent from [Workspace ONE Boxer](#)

On 24 June 2024 at 8:11:35 AM GMT+10, s22; s22@Health.gov.au> wrote:

Hi in the Q&A this is all we have on the below questions – it is pretty weak; can this please be strengthened within the next hour.

How do we know the enforcement of the Bill will work?

- While we are not going to be able to flick the switch and stop access to unlawful vapes entirely, the Government is determined to do everything it can to limit access to non-therapeutic vapes and protect young Australians.
- The TGA, along with the ABF and states and territories, is actively taking enforcement action and monitoring any changes and trends in relation to the importation, supply and advertisement of other illegal nicotine products.
- The Bill will support this work and provide a strong deterrent to those seeking to do the wrong thing.
- We have observed that, since 1 January 2024, some unlawful advertisers and suppliers of vapes have been closing their businesses or expressing their intention to do so.

Thanks,

s22

s22

Office of the Hon Mark Butler
Minister for Health and Aged Care

M: s22

E: s22 [@health.gov.au](mailto:s22@health.gov.au)

PO Box 6022, Parliament House, Canberra ACT 2600, Australia

I acknowledge the Traditional Custodians of the land on which I work and their continued connection to land, sea and community. I pay my respects to all Elders past and present.

[SEC=OFFICIAL]

From: [Minister Butler DLO](#)
To: s22
Cc: [BEDFORD, Chris](#); [MCLAY, Nicole](#); [REDACTED]
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
Date: Friday, 14 June 2024 2:21:01 PM
Attachments: [image004.png](#)
[image005.png](#)

Hi all

Confirming Erin Dale and Chris have both been added to the Outlook invite.
 Chris, if you're planning to come into the MO just note that you won't be able to have any personal mobile devices or a laptop connected to wifi.

Let me know if you need anything else before the meeting on Monday.

Thanks

From: s22 [REDACTED]@health.gov.au>
Sent: Friday, June 14, 2024 11:00 AM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole <Nicole.McLay@health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Thanks so much [REDACTED] Appreciate it (understand it's a busy day).

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Friday, June 14, 2024 10:59 AM
To: s22 [REDACTED]@health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole <Nicole.McLay@health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Hi [REDACTED]
 I'm still waiting to confirm with the Minister's diary manager but I have asked for Erin Dale and Chris to be added (following a quick chat with Nicole this morning).
 I'll let you know the outcome a bit later today.

Thanks

[REDACTED]
 Departmental Liaison Officer

Office of the Hon Mark Butler MP
 Minister for Health and Aged Care
 T: [REDACTED] | M: s22 [REDACTED]
 E: Minister.Butler.DLO@health.gov.au
 Suite MG.50 | PO Box 6022
 Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [REDACTED]@health.gov.au>
Sent: Thursday, June 13, 2024 12:19 PM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole

<Nicole.McLay@health.gov.au>

Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]

Dear s22 and team

Re: Minister's Meeting with National Vaping Working Group Co-Chairs (MB24-001463 – on way to MO - refers).

The ABF Commissioner's Office has requested that ABF Acting Deputy Commissioner National Operations, Tony Smith, be added to the invitation for the meeting on Monday. Please see below.

I didn't want to go to Rob direct – are you able to please confirm whether DC Smith is able to attend and whether the MO is happy for him to attend in person or online?

Thank you as always.

s22

s22

Director | Engagement and Policy Section
Vaping Implementation and Enforcement Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22@health.gov.au

Location: PO Box 9848, Canberra ACT 2601, Australia

From: s22@abf.gov.au>

Sent: Thursday, June 13, 2024 11:58 AM

To: s22@health.gov.au>

Subject: RE: National Vaping Enforcement Framework briefing Invitation | Monday 17 June [SEC=OFFICIAL]

OFFICIAL

Good morning s22

Hope that you are well on this overcast Thursday morning and I'm hoping you are able to help me with the below query.

I have been asked if we are able to have Acting Deputy Commissioner National Operations, Tony Smith, added to the invitation for Monday's briefing with the Minister's? Acting Deputy Commissioner Smith would be attending in support of the Commissioner and we are happy for him to attend virtually if this is the preference.

I wanted to touch base with you to confirm the preference for additional officers attending this briefing and then if appropriate have Acting Deputy Commissioner Smith added to the invitation – should you require it the email address is: TONY.SMITH@ABF.GOV.AU.

Please let me know if I can provide any further information in relation to this request.

With thanks,

s22

Executive Assistant to Michael Outram APM
Commissioner

Australian Border Force

P: s22 M: s22

E: s22@abf.gov.au

OFFICIAL

From: s22

Sent: Thursday, 6 June 2024 4:30 PM

To: s22 [REDACTED] <[REDACTED]@health.gov.au>
Subject: RE: National Vaping Enforcement Framework briefing Invitation | Monday 17 June
 [SEC=OFFICIAL]

OFFICIAL

Many thanks s22 [REDACTED] and all good – just didn't want to forward the Minister's invitation.
 No fault at all, just want to make sure the correct details are in the Commissioner's calendar.
 Have a lovely afternoon.

Cheers,

s22 [REDACTED]

Executive Assistant to Michael Outram APM
Commissioner

Australian Border Force

P: s22 [REDACTED] **M:** s22 [REDACTED] **E:** s22 [REDACTED] <[REDACTED]@abf.gov.au>

OFFICIAL

From: s22 [REDACTED] <[REDACTED]@health.gov.au>
Sent: Thursday, 6 June 2024 4:28 PM
To: s22 [REDACTED] <[REDACTED]@abf.gov.au>
Subject: RE: National Vaping Enforcement Framework briefing Invitation | Monday 17 June
 [SEC=OFFICIAL]

Dear s22 [REDACTED]

Thank you for this and apologies for the invite going to the group mailbox – that was my fault!
 I have provided the Commissioner's email address as advised by you to the Minister's EA.

Thank you

s22 [REDACTED]

s22 [REDACTED]

Director | Engagement and Policy Section
Vaping Implementation and Enforcement Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 [REDACTED] | E: s22 [REDACTED] <[REDACTED]@health.gov.au>

Location: PO Box 9848, Canberra ACT 2601, Australia

From: s22 [REDACTED] <[REDACTED]@abf.gov.au>
Sent: Thursday, June 6, 2024 4:00 PM
To: s22 [REDACTED] <[REDACTED]@health.gov.au>
Subject: National Vaping Enforcement Framework briefing Invitation | Monday 17 June
 [SEC=OFFICIAL]

OFFICIAL

Good afternoon s22 [REDACTED]

Can you please send the invitation for the above meeting to Michael.Outram@abf.gov.au?

I do not want to forward the Minister's invitation from our group mail box.

With thanks,

s22 [REDACTED]

s22

Executive Assistant to Michael Outram APM
Commissioner

Australian Border Force

P: s22 M: s22 E: s22 @abf.gov.au

OFFICIAL

Important Notice: The content of this email is intended only for use by the individual or entity to whom it is addressed. If you have received this email by mistake, please advise the sender and delete the message and attachments immediately. This email, including attachments, may contain confidential, sensitive, legally privileged and/or copyright information.

Any review, retransmission, dissemination or other use of this information by persons or entities other than the intended recipient is prohibited. The Department of Home Affairs, the ABF and the National Emergency Management Agency respect your privacy and have obligations under the Privacy Act 1988.

Unsolicited commercial emails MUST NOT be sent to the originator of this email.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: Minister Butler DLO
To: s22; Minister Butler DLO
Cc: EDLINGTON, Mandy; GILMOUR-WALSH, Bridget; s22; MCLAY, Nicole; MPS; HPRG Parliamentary
Subject: RE: Waiver request Ministerial Submission - proposed letter to the Prime Minister seeking policy approval for Government amendments to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]
Date: Wednesday, 5 June 2024 12:19:53 PM
Attachments: image003.png
image001.png

Thanks, s22

This is approved, noting our discussion with Tony, Bridget and Mandy yesterday.

Thanks
s22
s22 (he/him)
Departmental Liaison Officer
Office of the Hon Mark Butler MP
Minister for Health and Aged Care
T: s22 | M: s22
E: MinisterButler.DLO@health.gov.au
Suite MG.50 | PO Box 6022
Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 @Health.gov.au
Sent: Wednesday, June 5, 2024 12:16 PM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s22 @health.gov.au; s22 @health.gov.au; s22 @health.gov.au; s22 @Health.gov.au; s22 @health.gov.au; s22 @health.gov.au; MCLAY, Nicole <Nicole.McLay@health.gov.au>; s22 @Health.gov.au; MPS <MPS@health.gov.au>; HPRG Parliamentary s22 @Health.gov.au
Subject: Waiver request Ministerial Submission - proposed letter to the Prime Minister seeking policy approval for Government amendments to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 [SEC=OFFICIAL]
Dear DLOs,
Please find below waiver request.
Please let us know if you require anything further,
Thank you.

Critical Date – Waiver Request	
MS number	MS24-XXXXXX
Subject	Proposed letter to the Prime Minister seeking policy approval for Government amendments to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024.
Critical date	By Thursday 6 June 2024
Brief summary of submission	As noted by the Minister in MS24-000575, the department has prepared a proposed letter seeking policy approval from the Prime Minister for the proposed Government amendments to the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill).

Why is a waiver to the 5-day critical date rule required? Note – this must include why the critical date cannot be extended to allow the Minister’s Office more than 5 days to consider the submission.	A waiver is required to enable policy approval to be sought from the Prime Minister for the proposed Government amendments to ensure the measures can be progressed, if required, to facilitate passage of the Bill through the Parliament prior to the proposed commencement date of 1 July 2024.
What is the risk to the Minister/Department or Agency if the critical date is not met?	If the critical date of Thursday 6 June 2024 is not met there is a risk that the Government Amendments to the Bill may not be expeditiously progressed for introduction in the Senate to support passage of the Bill prior to the proposed commencement date of 1 July 2024.
What is preventing/has prevented the Department/Agency providing this Ministerial Submission at an earlier date?	On 31 May 2024 the department sought agreement from the Minister to prepare proposed Government amendments to the Bill to address the concerns of the Senate Standing Committee Scrutiny of Bills and otherwise facilitate passage of the reforms through the Senate. Agreement was provided by the Minister on 4 June 2024.
When will the Ministerial Submission be provided to the Minister’s Office? Note – if this date is not met, a new waiver must be requested	Before midday Thursday 6 June 2024.
Waiver approved by	DLOs to complete

Kind regards,

S22 (she/her)

Lawyer – Vaping Legislative Reform Branch

Health Products Regulation Group

Australian Government, Department of Health and Aged Care

T: S22 | E: S22@Health.gov.au

P.O. Box 100, Woden ACT 2606, Australia

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to elders both past and present.

Please note that this email and attachments may contain confidential or legally privileged information. Please consult with Regulatory Legal Services Branch before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

From: [EDLINGTON, Mandy](#)
To: s22
Cc: [LAWLER, Tony](#); [GILMOUR-WALSH, Bridget](#); [GOODCHILD, Tiali](#); s22; [BEDFORD, Chris](#); [MCLAY, Nicole](#)
Subject: State and territory mechanism for modifying or disapplying amendments to the Poisons Standard [SEC=OFFICIAL]
Date: Wednesday, 5 June 2024 10:00:17 AM
Attachments: [State and territory mechanism for modifying or disapplying amendments to the Poisons Standard.docx](#)
[image001.png](#)
Importance: High

Dear s22

Please find **attached** our preliminary analysis (in the time available) on the state and territory mechanisms for modifying or disapplying the Commonwealth Poisons Standard in preparation for your meeting this morning. Happy to discuss any aspect further.

Kind regards

Mandy Edlington

General Counsel (Acting)

Vaping Legislative Reform Branch
Regulatory Legal Services Division | Health Products Regulation Group
Australian Government Department of Health and Aged Care
T: 02 6289 2910 | E: mandy.edlington@health.gov.au
PO Box 100 Woden ACT 2606 Australia | Location: Fairbairn

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past, present and emerging.

This email and attachments may contain confidential or legally privileged information. Please consult the Regulatory Legal Services Division before disclosing any part of this email, or attachment, outside the Department. If you receive this email in error, please delete it and contact the sender immediately.

State and territory mechanism for modifying or disapplying amendments to the Commonwealth Poisons Standard

Jurisdiction	Mechanism for <i>adopting</i> amendments to the Cth Poisons Standard	Mechanism for <i>modifying or disapplying</i> amendments to the Commonwealth Poisons Standard
ACT	Cth Poisons Standard as amended from time to time is incorporated by reference in the ACT subject to any modifications prescribed by the regulations: s 15 of the <i>Medicines, Poisons and Therapeutic Goods Act 2008</i> (ACT)	Regulations may be made by the Executive to modify the references to the Cth Poisons Standard: ss 15 and 184 of the <i>Medicines, Poisons and Therapeutic Goods Act 2008</i> (ACT). The Regulations are subject to disallowance.
NSW	Cth Poisons Standard as amended from time to time is automatically adopted by proclamation as the NSW Poisons List: s 3(2) of the <i>Poisons and Therapeutic Goods (Poisons List) Proclamation 2016</i> (NSW)	A proclamation may be made by the Governor on recommendation of the Minister to amend or replace the NSW Poisons List: s 8(6) of the <i>Poisons and Therapeutic Goods Act 1966</i> (NSW). The proclamation is subject to disallowance.
NT	Cth Poisons Standard as amended from time to time is automatically adopted as the NT Poisons Standard: s 14(5) of the <i>Medicines, Poisons and Therapeutic Goods Act 2012</i> (NT)	Regulations may be made to modify the NT Poisons Standard: r 6 of the <i>Medicines, Poisons and Therapeutic Goods Regulations 2014</i> (NT). The regulations are subject to disallowance.
QLD	Cth Poisons Standard as amended from time to time is automatically applies in QLD: s 9 and Schedule 1 to the <i>Medicines and Poisons Act 2019</i> (QLD)	Regulations may be made by the Governor in relation to the possession and purchase of S2 and S3 medicines. Otherwise, an Act of Parliament may be needed to amend the application of the Cth Poisons Standard in QLD. Further analysis required.
SA	Cth Poisons Standard as amended from time to time is automatically applied in SA with modification: s 11A of the	Regulations may be made by the Governor on recommendation of the Minister to modify the Cth Poisons Standard as it applies in SA:

	<i>Controlled Substances Act 1984</i> (SA) and s 3 of the <i>Controlled Substances (Poisons) Regulations 2011</i> (SA)	s 11A of the <i>Controlled Substances Act 1984</i> (SA). The regulations are subject to disallowance.
TAS	Cth Poisons Standard as amended from time to time is automatically adopted as the TAS Poisons List with modification: s 14(1) of the <i>Poisons Act 1971</i> (TAS) and s 4 of the <i>Poisons (Adoption of Uniform Standard) Order 2012</i>	An order may be made by the Minister to amend the TAS Poisons List: s 14(2) of the <i>Poisons Act 1971</i> (TAS). Power to make the order may be delegated to the Secretary or, on the recommendation of the Secretary, to a State Service officer or State Service employee: s 24 of the <i>Poisons Act 1971</i> (TAS). The order is subject to disallowance.
VIC	Cth Poisons Standard as in force from time to time or as in force at a particular time is incorporated by reference in the VIC Poisons Code: s 12D of the <i>Drugs, Poisons and Controlled Substances Act 1981</i> (VIC).	A subordinate instrument may be made by the Minister to amend the VIC Poisons Code: s 12E of the <i>Drugs, Poisons and Controlled Substances Act 1981</i> (VIC). No apparent power to delegate the instrument making power identified at this stage. The instrument is subject to disallowance.
WA	Cth Poisons Standard as amended from time to time is incorporated by reference in WA: <i>Medicines and Poisons Regulations 2016</i> (WA)	Regulations may be made by the Governor on recommendation of the Minister to modify any reference to the Cth Poisons Standard in the <i>Medicines and Poisons Regulations 2016</i> (WA): s 131 of the <i>Medicines and Poisons Act 2014</i> (WA). The regulations are subject to disallowance.

From: [BEDFORD, Chris](#)
To: [s22](#); [FIRTH, Clare](#); [s22](#); [News](#)
Cc: [LAWLER, Tony](#); [MCLAY, Nicole](#); [RCB Reporting](#)
Subject: Vapes - Regulatory Compliance and Enforcement update - 5 June 2024 [SEC=OFFICIAL:Sensitive]
Date: Friday, 7 June 2024 5:08:00 PM
Attachments: [Vapes - Regulatory Compliance and Enforcement Update - 5 June 2024.pdf](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)

Good afternoon

Please find attached the weekly vaping report – not much new this week. New ABF numbers next week.

We have a briefing with the Minister et al on the Enforcement Framework in for 17 June. We will do a prebrief for advisors prior and will have a meeting brief before too.

Have a good weekend all.

Cheers, Chris

Chris Bedford

Acting First Assistant Secretary

Regulatory Practice and Support Division

Australian Government Department of Health and Aged Care

T: 02 6289 5327 | M: [s22](#) | E: chris.bedford@health.gov.au

Location: Gulgana Building, Fairbairn, Canberra

GPO Box 9848, Canberra ACT 2601, Australia

Executive Officer | [s22](#)

T: [s22](#) | E: [s22](#)@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.





Vapes - Regulatory Compliance and Enforcement Update

Enforcing compliance of the vape laws for importation, manufacture, advertising, supply and commercial possession through an intelligence-led multi-agency effort as part of a comprehensive approach to e-cigarette control.

Enforcement Highlights

- Combined ABF and TGA seizures from 1 January 2024 are now over 2.2 million (estimated \$66 million in street value).
- The National Vaping Enforcement Framework has been agreed. Co-chairs of the National Vaping Working Group will brief Minister Butler on 17 June 2024 including on the future of the working group.
- Planning for joint operations in July including with NSW Health and Police, and with Qld Health and Police.
- Frequently advising NSW Police highway patrol in their recent targeting of interstate transport of unlawful vapes, and assisting with laboratory testing.
- Visiting ABF cargo facilities in Melbourne, Brisbane and Sydney to expedite sampling and investigations of unlawful pouch importations. It is expected that as vapes become less available the market will shift to pouches and illicit tobacco. ABF nicotine pouch seizures are increasing.
- Alleged unlawful nicotine pouch advertising reported by ██████████ has been removed following TGA action.
- Enforcement planning has identified enabling training, qualifications, tools and equipment, and enhanced investigative procedures required to enforce the reforms for the TGA.

Other Updates

- Transport, storage and disposal (TSD)**
- Following the Minister’s decision on MS24-000674, we are progressing work on agreed proposals including consumer level collection and disposal scheme, and potential business level surrender scheme.
- Vapes – market value**
- A review of the current market value of vaping goods and nicotine pouches has been undertaken and is being consulted on with ABF/S/T to replace the current prices being used to calculate street value. TGA will maintain the prices for national use.
- Regulatory communications**
- A boosted social media campaign on the reforms targeted at industry and health professionals will run in June 2024.
- Therapeutic vape compliance**
- Letters have been sent to 12 sponsors of notified vapes requesting samples of 117 products, in total, for the TGA to conduct laboratory testing for compliance with the TGO110 product standard for therapeutic vapes.

Meetings and Events

- 11 June, Vaping Regulation Reform and Smoking Cessation Program Board Meeting
- 13 June, meeting with NZ Health on Australia's vape reforms
- 14 June, Health Ministers Meeting
- 17 June, Vaping Compliance and Enforcement Forum (health officials)
- 20 June, National E-cigarette Working Group

Enforcement Data from 1 January 2024 to 5 June 2024

Vaping goods	Nicotine pouches	Vapes seized and surrendered	Infringement notices	Civil / Criminal court actions	TGA & State / Territory joint operations
1,532,959 units seized by the ABF	1,351,766 units seized by ABF on TGA advice	688,313 units seized	18 notices issued	0 / 0 Completed	8
\$46Mil street value	\$1.3Mil street value	\$20.6Mil street value	\$157,752 in fines	2 / 0 Ongoing	State / Territory seizures
7,985 consignments detected by ABF	907 referrals received by TGA	Active cases 36 import / supply 28 Adv	Website takedowns 6 Vapes 11 Pouch	Websites Blocked (s313) 23	TBA units seized
ABF + Border		TGA		S / T	

Enforcement Data from 1 October 2021 to 31 December 2023

Vaping goods	Nicotine pouches	Vapes seized and surrendered	Infringement notices	Civil / Criminal court actions	TGA & State / Territory joint operations
1,341,944 units seized by ABF on TGA advice	136,694 units seized by ABF on TGA advice	141,413 units seized	172 notices issued	1 / 0 Completed	6
\$40Mil street value	\$0.13Mil street value	\$2.8Mil street value	\$1,552,248 in fines	2 / 0 Ongoing	
2,214 referrals received by TGA	662 referrals received by TGA		Website takedowns 1,025 Vapes 0 Pouch		
ABF + Border		TGA		S / T	

Regulatory Reforms Timeline

JANUARY	FEBRUARY	MARCH	APRIL	MAY	JUNE	JULY	December
1	30	1				1	1
Passage of Bill through both Houses							
Ban on importation of disposable vapes including personal importation.		Import ban on all non-therapeutic vaping goods Import license and permits required, personal importation closed. Requirement to notify the TGA of compliance with product standards commences.		Parliamentary progress Bill passes HoR and introduced to Senate. 15,16 May Therapeutic Goods Law Application Bill 2023 passes WA parliament – national coverage for TG Act.		Bill commences Domestic ban on the manufacture, supply and commercial possession of non-therapeutic vaping goods. Ban on advertising of vaping goods	
		New vaping exemptions and standards (including restrictions on flavours) All therapeutic vapes, imported or manufactured from 1 March 2024 must comply with applicable standards.				Heighten vaping standards All therapeutic vaping goods, imported or manufactured from 1 December, will need to comply with updated applicable standards.	
		Transitional arrangements commence Transitional arrangements for goods imported or manufactured prior to 1 March commence		Transitional arrangements end		New compliance & enforcement powers in force	
NWVG established				Agreement of National Vaping Enforcement Framework			

Therapeutic Vape Regulation

From 1 January 2024

- 799 / 294 notifications of product compliance received (nicotine / cannabis)
- 458 / 237 notifications of product compliance valid (nicotine / cannabis)
- 55 / 43 import licenses (applications / granted)
- 288 import permits granted
- 2,750 Authorised Prescriber approvals (current)
- 841 Special Access Scheme C notifications of product supply

Laboratory Results

From 1 October 2021

- 1,641 samples tested
- 1,433 (87%) tested samples contained undeclared nicotine
- 137 samples labelled as having nicotine

<u>Regulatory Compliance and Advertising Compliance CRMs</u> Enforcement Data - ABF + Border - Vaping goods - Referrals received by the TGA - Units seized by ABF on TGA advice - ABF + Border - Nicotine pouches - Referrals received by the TGA - units seized by ABF on TGA advice - TGA - Vapes seized and surrendered 1 Oct 2021 to 31 Dec 2023 only	<u>From Section / Branch</u> Product and Import Compliance Section(PICS) Therapeutic Vape Regulation - Notifications of product compliance received (nicotine / cannabis) - Notifications of product compliance accepted (nicotine / cannabis) Office of Drug Control (ODC) Therapeutic Vape Regulation - import licenses (applications / granted) - import permits granted Vaping Implementation and Enforcement Branch (VIEB) Enforcement Data - TGA - Completed civil / criminal court actions - Ongoing civil / criminal court actions - Active cases Laboratories Branch Laboratory Results - samples tested - tested samples contained undeclared nicotine - samples labelled as having nicotine
<u>SharePoint lists and spreadsheets</u> Enforcement Data - TGA - Infringement notices - State / territory - TGA and state / territory joint operations Therapeutic Vape Regulation - Authorised Prescriber approvals (current) - Special Access Scheme C notifications of product supply Vaping Regulation Reform Program News Stakeholder Engagement Hub	
<u>External to health</u> Australian Border Force Enforcement Data - ABF + Border - Vaping goods - consignments detected by ABF - units seized by the ABF 1 January 2024 to (report date) To Be Advised Enforcement Data - State / Territory - Units seized	

From: [BEDFORD, Chris](#)
To: [Minister Butler DLO](#)
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
Date: Friday, 14 June 2024 4:15:00 PM
Attachments: [image001.png](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)
[image005.png](#)

Thanks s22 Have a good weekend.

Chris Bedford

Acting First Assistant Secretary
 Regulatory Practice and Support Division
 Australian Government Department of Health and Aged Care
 T: 02 6289 5327 | M: s22 | E: chris.bedford@health.gov.au
 Location: Gulgana Building, Fairbairn, Canberra
 GPO Box 9848, Canberra ACT 2601, Australia

Executive Officer | s22
 T: s22 | E: s22@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Friday, June 14, 2024 4:13 PM
To: BEDFORD, Chris <Chris.Bedford@health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Hi Chris

No real preference, it is probably easier if you join via Webex.

Thanks

s22

From: BEDFORD, Chris <Chris.Bedford@health.gov.au>
Sent: Friday, June 14, 2024 3:28 PM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Hi s22 – do you know if there is a preference? Happy either way.

Chris Bedford

Acting First Assistant Secretary
 Regulatory Practice and Support Division
 Australian Government Department of Health and Aged Care
 T: 02 6289 5327 | M: s22 | E: chris.bedford@health.gov.au
 Location: Gulgana Building, Fairbairn, Canberra
 GPO Box 9848, Canberra ACT 2601, Australia

Executive Officer | s22
 T: s22 | E: s22@health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their

continued connection to land, sea and community. We pay our respects to all Elders past and present.



From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Friday, June 14, 2024 2:21 PM
To: s22 [REDACTED] <[REDACTED]@health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole <Nicole.McLay@health.gov.au>; s22 [REDACTED] <[REDACTED]@health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Hi all

Confirming [REDACTED] and Chris have both been added to the Outlook invite.
 Chris, if you're planning to come into the MO just note that you won't be able to have any personal mobile devices or a laptop connected to wifi.
 Let me know if you need anything else before the meeting on Monday.

Thanks

s22 [REDACTED]

From: s22 [REDACTED] <[REDACTED]@health.gov.au>
Sent: Friday, June 14, 2024 11:00 AM
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole <Nicole.McLay@health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Thanks so much [REDACTED] Appreciate it (understand it's a busy day).

From: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>
Sent: Friday, June 14, 2024 10:59 AM
To: s22 [REDACTED] <[REDACTED]@health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole <Nicole.McLay@health.gov.au>
Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]
 Hi [REDACTED]

I'm still waiting to confirm with the Minister's diary manager but I have asked for [REDACTED] and Chris to be added (following a quick chat with Nicole this morning).
 I'll let you know the outcome a bit later today.

Thanks

s22 [REDACTED]

s22 [REDACTED] (he/him)
 Departmental Liaison Officer

Office of the Hon Mark Butler MP
 Minister for Health and Aged Care
 T: [REDACTED] | M: s22 [REDACTED]
 E: Minister.Butler.DLO@health.gov.au
 Suite MG.50 | PO Box 6022
 Parliament House, Canberra ACT 2600

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of

Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22 [REDACTED] <[REDACTED]@health.gov.au>

Sent: Thursday, June 13, 2024 12:19 PM

To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>

Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; MCLAY, Nicole <Nicole.Mclay@health.gov.au>

Subject: RE: Minister Meeting with National Vaping Co-Chairs | Monday 17 June [SEC=OFFICIAL]

Dear s22 [REDACTED] and team

Re: Minister's Meeting with National Vaping Working Group Co-Chairs (MB24-001463 – on way to MO - refers).

The ABF Commissioner's Office has requested that ABF Acting Deputy Commissioner National Operations, Tony Smith, be added to the invitation for the meeting on Monday. Please see below.

I didn't want to go to s22 [REDACTED] direct – are you able to please confirm whether DC Smith is able to attend and whether the MO is happy for him to attend in person or online?

Thank you as always.

s22 [REDACTED]

s22 [REDACTED]

Director | Engagement and Policy Section
Vaping Implementation and Enforcement Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 [REDACTED] | E: s22 [REDACTED] <[REDACTED]@health.gov.au>

Location: PO Box 9848, Canberra ACT 2601, Australia

From: s22 [REDACTED] <[REDACTED]@abf.gov.au>

Sent: Thursday, June 13, 2024 11:58 AM

To: s22 [REDACTED] <[REDACTED]@health.gov.au>

Subject: RE: National Vaping Enforcement Framework briefing Invitation | Monday 17 June [SEC=OFFICIAL]

OFFICIAL

Good morning s22 [REDACTED]

Hope that you are well on this overcast Thursday morning and I'm hoping you are able to help me with the below query.

I have been asked if we are able to have Acting Deputy Commissioner National Operations, Tony Smith, added to the invitation for Monday's briefing with the Minister's? Acting Deputy Commissioner Smith would be attending in support of the Commissioner and we are happy for him to attend virtually if this is the preference.

I wanted to touch base with you to confirm the preference for additional officers attending this briefing and then if appropriate have Acting Deputy Commissioner Smith added to the invitation – should you require it the email address is: TONY.SMITH@ABF.GOV.AU.

Please let me know if I can provide any further information in relation to this request.

With thanks,

s22 [REDACTED]

Executive Assistant to Michael Outram APM
Commissioner

Australian Border Force

P: s22 [REDACTED] M: s22 [REDACTED]

E: s22 [REDACTED] <[REDACTED]@abf.gov.au>

OFFICIAL

From: s22
Sent: Thursday, 6 June 2024 4:30 PM
To: s22 @health.gov.au>
Subject: RE: National Vaping Enforcement Framework briefing Invitation | Monday 17 June
 [SEC=OFFICIAL]

OFFICIAL

Many thanks s22 and all good – just didn't want to forward the Minister's invitation.
 No fault at all, just want to make sure the correct details are in the Commissioner's calendar.
 Have a lovely afternoon.

Cheers,

s22

Executive Assistant to Michael Outram APM
Commissioner

Australian Border Force

P: s22 **M:** s22 **E:** s22 @abf.gov.au

OFFICIAL

From: s22 @health.gov.au>
Sent: Thursday, 6 June 2024 4:28 PM
To: s22 @abf.gov.au>
Subject: RE: National Vaping Enforcement Framework briefing Invitation | Monday 17 June
 [SEC=OFFICIAL]

Dear s22

Thank you for this and apologies for the invite going to the group mailbox – that was my fault!
 I have provided the Commissioner's email address as advised by you to the Minister's EA.

Thank you

s22

s22

Director | Engagement and Policy Section
Vaping Implementation and Enforcement Branch

Regulatory Practice and Support Division | Health Products Regulation Group

Australian Government Department of Health and Aged Care

T: s22 | E: s22 @health.gov.au

Location: PO Box 9848, Canberra ACT 2601, Australia

From: s22 @abf.gov.au>
Sent: Thursday, June 6, 2024 4:00 PM
To: s22 @health.gov.au>
Subject: National Vaping Enforcement Framework briefing Invitation | Monday 17 June
 [SEC=OFFICIAL]

OFFICIAL

Good afternoon s22

Can you please send the invitation for the above meeting to Michael.Outram@abf.gov.au?

I do not want to forward the Minister's invitation from our group mail box.

With thanks,

s22

s22

Executive Assistant to Michael Outram APM

Commissioner

Australian Border Force

P: s22 M: s22 E: s22 [@abf.gov.au](mailto:s22@abf.gov.au)

OFFICIAL

Important Notice: The content of this email is intended only for use by the individual or entity to whom it is addressed. If you have received this email by mistake, please advise the sender and delete the message and attachments immediately. This email, including attachments, may contain confidential, sensitive, legally privileged and/or copyright information.

Any review, retransmission, dissemination or other use of this information by persons or entities other than the intended recipient is prohibited. The Department of Home Affairs, the ABF and the National Emergency Management Agency respect your privacy and have obligations under the Privacy Act 1988.

Unsolicited commercial emails MUST NOT be sent to the originator of this email.

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

From: [Minister Butler DLO](#)
To: s22
Cc: [EDLINGTON, Mandy](#); [GILMOUR-WALSH, Bridget](#); s22
s22; [HPRG Parliamentary](#); [MPS](#); s22; [HENDERSON, Nick](#); s22
s22; [GOODCHILD, Iain](#); s22; [DEVELIN, Liz](#); s22; [BEDFORD, Chris](#); s22
[LAWLER, Tony](#); s22
Subject: Re: MS24-000724 - ****REDRAFT**** Vaping Scheduling Information - Comparison of regulatory models
[SEC=OFFICIAL]
Date: Friday, 21 June 2024 8:08:34 PM
Attachments: [image001.png](#)
[image001.png](#)

Thanks [REDACTED] and everyone involved for getting this to us today. This is now with the MO.

On 21 June 2024 at 19:55:58 AEST, s22
<[REDACTED]@health.gov.au> wrote:

Dear DLOs,

Please find attached the document package for the Ministerial Submission MS24-000724 - ****REDRAFT**** Vaping Scheduling Information - Comparison of regulatory models as cleared by A/g Deputy Secretary Nick Henderson. This has also been assigned to MPS in PDMS.

Kind regards,

s22
s22

A/g Executive Officer to A/g Deputy Secretary Nick Henderson

Health Products Regulation Group
Australian Government, Department of Health and Aged Care

☎: [REDACTED] | ✉: s22@health.gov.au

Location: 27 Scherger Drive Fairbairn, Level 2

I may send emails out of hours at a time that suits me. I look forward to receiving your response during your normal working hours.

The Department of Health and Aged Care acknowledges the traditional owners of country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

[SEC=OFFICIAL]

From: [BEDFORD, Chris](#)
To: [s22](#) [FIRTH, Clare](#)
Cc: [GILMOUR-WALSH, Bridget](#); [MCLAY, Nicole](#); [DEVELIN, Liz](#); [GOODCHILD, Tiali](#); [EDLINGTON, Mandy](#); [s22](#)
Subject: FW: MS24-000724 - **REDRAFT** Vaping Scheduling Information - Comparison of regulatory models [SEC=OFFICIAL:Sensitive]
Date: Friday, 21 June 2024 8:02:00 PM
Attachments: [MS24-000724.docx](#)
[Att A_Regulatory models - Comparison snapshot.docx](#)
[Att A2_Regulatory models - at 21 June 2024 - Comparison snapshot.docx](#)
[Att B_Down Sched implications.docx](#)
[s42](#)
[MS24-000724 - Advice provided at 7 June 2024.pdf](#)
[MS24-000724 - MO approved waiver.pdf](#)
[APPROVAL OF CRITICAL DATE FROM MO.pdf](#)
[MO request - Supplementary advice - s42](#)
[image002.png](#)
[image003.png](#)
[image004.png](#)

Hi [s22](#) – the docs are on their way in PDMS too.

We are all happy to discuss any of the content at any time.

Hope you have a good Friday and weekend.

Chris Bedford

Acting First Assistant Secretary

Regulatory Practice and Support Division

Australian Government Department of Health and Aged Care

T: 02 6289 5327 | M: [s22](#) E: chris.bedford@health.gov.au

Location: Gulgana Building, Fairbairn, Canberra

GPO Box 9848, Canberra ACT 2601, Australia

Executive Assistant | [s22](#)

T: [s22](#) | E: [s22](#) nobbs@health.gov.au

Executive Officer | [s22](#)

T: [s22](#) | E: [s22](#) @health.gov.au

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.



From: [GILMOUR-WALSH, Bridget](#)
To: S22; [BROWN, Karlie](#); [EDLINGTON, Mandy](#)
Cc: S22; [BEDFORD, Chris](#); [HENDERSON, Nick](#)
Subject: RE: Defensive responses re Guild [SEC=OFFICIAL]
Date: Monday, 24 June 2024 11:22:46 PM
Attachments: [image001.png](#)

Hi S22

Joint suggestions below

Happy to discuss.

Bridget

Supply of unregistered therapeutic vaping goods

- The Government is working hard to end recreational vaping while at the same time ensuring legitimate patient access to therapeutic vaping goods for smoking cessation or the management of nicotine dependence where appropriate.
- Until 1 October, Australians will need to go and talk to their GP about the best approach to support them to stop smoking or vaping. This will help patients understand what approach is right for them and any considerations for them with that approach.
- Pharmacists will not be required to supply therapeutic vaping goods. It remains a matter of professional judgement as to whether pharmacists supply therapeutic vaping goods not included in the Australian Register of Therapeutic Goods.
- The TGA is enhancing quality and safety standards to mitigate concerns relating to the use of unapproved therapeutic vaping goods. Where therapeutic vaping goods are not included in the Australian Register of Therapeutic Goods, sponsors of those goods must notify the TGA about the compliance of their goods with enhanced quality and safety standards, including restrictions on ingredients and flavours, to lawfully supply in Australia. The TGA is undertaking post-notification surveillance of notified therapeutic vaping goods. The TGA has requested sponsors of notified therapeutic vaping goods to provide samples for testing.
- The RACGP guidelines advise that it may be reasonable to recommend vapes, in conjunction with behavioural support, for people who want to quit but have failed to do so with first line therapy. First line therapies include behavioural support combined with TGA approved pharmacotherapy. This is why the proposed down scheduling requires the pharmacist to provide contact details for cessation support services.
- Pharmacists already provide advice to patients about quitting smoking. The Pharmaceutical Society of Australia guidelines on smoking cessation recommend everyone who smokes should be given brief advice. The proposed down scheduling makes another treatment option available to pharmacists if appropriate for a particular patient.

Professional indemnity insurance matters

- Pharmacists already dispense unapproved therapeutic vaping goods under the current framework. Presumably, insurance policies already offer some cover in this area.
- Pharmacist indemnity insurance is a commercial matter between pharmacists and insurers.

- I am advised that there is no legal reason why an insurance policy could not provide cover for pharmacists to dispense unapproved vaping goods that have not been prescribed. I understand there is insurance available that already covers this.
- There are also steps that pharmacists can take to mitigate the risk of liability arising. Pharmacists can manage their liability by providing appropriate advice to patients and ensuring that they only supply therapeutic vaping goods from the TGA notified list.

Down scheduling

- We are dealing with an unprecedented problem of increasing magnitude.
- Down scheduling in these circumstances ensures passage of the legislation so we can get vapes out of convenience stores, petrol stations and tobacconists across the road from schools, while maintaining appropriate supports for people to quit. My top priority is to stop children from getting access to vapes and this is what we need to do to make this happen.
- Access issues have been raised as a concern and we want people with nicotine dependence to be provided with ready and sufficient supports to help them quit.
- These reforms complement the range of supports already available nationally to help people quit smoking and the use of vapes. The Government is investing in additional supports to encourage and support people to quit smoking and vaping, including:
 - New public health information campaigns to prevent and reduce the use of tobacco and vapes, and to encourage people to give up for good.
 - Expansion of specialised programs and services to support Australians to quit smoking and vaping, including the development of an online cessation hub now live at quit.org.au, expansion of state and territory Quitline services, workforce support including updated clinical guidance, and the redevelopment and enhancement of the My QuitBuddy mobile app.
 - Extending the Tackling Indigenous Smoking program to reduce both vaping and smoking among First Nations people.

From: S22 [REDACTED]@Health.gov.au>

Sent: Monday, June 24, 2024 4:19 PM

To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; BROWN, Karlie <Karlie.Brown@health.gov.au>; EDLINGTON, Mandy <Mandy.Edlington@health.gov.au>

Cc: S22 [REDACTED]@health.gov.au>

Subject: Defensive responses re Guild [SEC=OFFICIAL]

Hi there,

Can we please have a counter to the below Guild lines for tomorrow's media.

Given no vaping product has been approved by the Therapeutic Goods Administration based on its safety, efficacy or performance. No vaping product is listed on the Australian Register of Therapeutic Goods and there is limited evidence to support the use of vaping products for smoking cessation and nicotine dependence, we do not support the uptake of S3.

- There are unknown long-term patient harms and high-level of involvement from Big Tobacco companies, meaning pharmacists find the provision of a vaping product without prescription unethical and do not want to be involved.
- It is uncertain whether pharmacists' professional indemnity insurance covers the

supply of a vaping product without prescription.

- The Guild supports decisions on poison scheduling being made by the Advisory Committee on Medicines Scheduling, not Parliament.

Best,

s22

Office of the Hon Mark Butler
Minister for Health and Aged Care

M: s22

E: s22@health.gov.au

PO Box 6022, Parliament House, Canberra ACT 2600, Australia

I acknowledge the Traditional Custodians of the land on which I work and their continued connection to land, sea and community. I pay my respects to all Elders past and present.

From: s22
To: s22; Minister Butler DLO
Cc: MCLAY, Nicole; BEDFORD, Chris; GILMOUR-WALSH, Bridget; EDLINGTON, Mandy; s22
Subject: FW: RE: Enforcement Q&A [SEC=OFFICIAL]
Date: Monday, 24 June 2024 9:31:34 AM
Attachments: image001.png
 image002.png
 Additional C&E TPs for MO.docx

s22

Please see attached additional TPs on compliance and enforcement as requested.

s22

s22

Director | Engagement and Policy Section
Vaping Implementation and Enforcement Branch

Regulatory Practice and Support Division | Health Products Regulation Group
 Australian Government Department of Health and Aged Care
 T: s22 | E: s22@health.gov.au
 Location: PO Box 9848, Canberra ACT 2601, Australia

From: MCLAY, Nicole <Nicole.McLay@health.gov.au>

Sent: Monday, June 24, 2024 9:11 AM

To: s22@health.gov.au

Subject: Fwd: RE: Enforcement Q&A [SEC=OFFICIAL]

Nicole McLay

Assistant Secretary Vaping Implementation and Enforcement

Department of Health and Aged Care

Ph s22

----- Forwarded message -----

From: s22@Health.gov.au>

Date: 24 June 2024 at 8:58:24 AM GMT+10

Subject: RE: Enforcement Q&A [SEC=OFFICIAL]

To: BEDFORD, Chris <Chris.Bedford@health.gov.au>, MCLAY, Nicole
 <Nicole.McLay@health.gov.au>

Cc: s22@Health.gov.au>, Minister Butler DLO
 <Minister.Butler.DLO@Health.gov.au>

We've got briefing with repping senator at 9.30 can it be before

From: BEDFORD, Chris <Chris.Bedford@health.gov.au>

Sent: Monday, June 24, 2024 8:23 AM

To: s22@Health.gov.au>; MCLAY, Nicole
 <Nicole.McLay@health.gov.au>

Cc: s22@Health.gov.au>; Minister Butler DLO
 <Minister.Butler.DLO@Health.gov.au>

Subject: Re: Enforcement Q&A [SEC=OFFICIAL]

Hi all.

Nicole will have a go. It is more difficult as the strength of the govt response is mostly done for enforcement (we have removed the real time monitoring).

Nicole can we emphasise the ID check, the ability to look at pharmacist dispensing total volumes through sas.

Note the approach to packaging and flavours and strength that help with identification.

The reiterate the already good measures in place.
It may be a little after 930 as dropping kids etc.
Cheers, Chris

Sent from [Workspace ONE Boxer](#)

On 24 June 2024 at 8:11:35 AM GMT+10, s22

s22 @Health.gov.au> wrote:

Hi in the Q&A this is all we have on the below questions – it is pretty weak;
can this please be strengthened within the next hour.

How do we know the enforcement of the Bill will work?

- While we are not going to be able to flick the switch and stop access to unlawful vapes entirely, the Government is determined to do everything it can to limit access to non-therapeutic vapes and protect young Australians.
- The TGA, along with the ABF and states and territories, is actively taking enforcement action and monitoring any changes and trends in relation to the importation, supply and advertisement of other illegal nicotine products.
- The Bill will support this work and provide a strong deterrent to those seeking to do the wrong thing.
- We have observed that, since 1 January 2024, some unlawful advertisers and suppliers of vapes have been closing their businesses or expressing their intention to do so.

Thanks,

s22

s22

Office of the Hon Mark Butler
Minister for Health and Aged Care

M s22

E s22 @health.gov.au

PO Box 6022, Parliament House, Canberra ACT 2600, Australia

I acknowledge the Traditional Custodians of the land on which I work and their continued connection to land, sea and community. I pay my respects to all Elders past and present.

[SEC=OFFICIAL]

[SEC=OFFICIAL]

How do we know the enforcement of the Bill will work?

- While we are not going to be able to flick the switch and stop access to unlawful vapes entirely, the Government is determined to do everything it can to limit access to non-therapeutic vapes and protect young Australians.
- The TGA, along with the ABF and states and territories, is actively taking enforcement action and monitoring any changes and trends in relation to the importation, supply and advertisement of other illegal nicotine products.
- The Bill will support this work and provide a strong deterrent to those seeking to do the wrong thing.

From July 1 how will enforcement occur? How quickly will it take for the vape stores to close?

- From 1 July, the TGA and states and territories will use new powers to enforce vape laws and be able to more readily seize and dispose of illicit vapes.
- Illicit vapes will be easier to detect and the opportunities for unlawful trade in these products will be significantly reduced.
- As a result, the TGA and states and territories will be able to more efficiently disrupt illegal domestic supply.
- As the retail supply of any vapes outside a pharmacy setting will be prohibited, vape stores are anticipated to disappear quickly.
- States and territories will be able to take fast enforcement action on vape stores without the need to determine whether vapes with labelling that conceals the presence of nicotine actually contain nicotine or not.
- Enforcement will continue to be cooperative between the Commonwealth and states and territories.
- The ABF will lead enforcement at the border, in partnership with the TGA which will lead on compliance in relation to advertising, and work with states and territories on wholesale and retail supply, and commercial possession.

Will the reforms increase the black market?

- Strengthening the regulation of all vapes, by enhancing border controls, banning all disposable single-use vapes and ending the supply of vapes outside of pharmacy settings, will make it easier to identify and disrupt the illicit supply of vapes and take effective enforcement action.
- The benefit of the new approach is that it will enable compliance and enforcement action to be taken immediately on illicit vapes without requiring laboratory testing.
- Strengthened enforcement activities across all levels of the supply chain will also combat the black market.
- To support the implementation and enforcement of these reforms, the Government is providing an additional \$25 million to the Australian Border Force and \$56.9 million to the TGA over two years.
- All states and territories are also committed to sharing and increasing compliance action and supporting a national enforcement approach. The benefit of the new approach is that it will enable compliance and enforcement action to be taken immediately on illicit vapes without requiring laboratory testing.
- Importers and suppliers of illicit vapes are now on final notice that changes proposed to the Therapeutic Goods Act will enhance compliance and enforcement efforts.
- Pharmacists will check ID of people seeking vaping goods for the purposes of smoking cessation and the management of nicotine dependence – ensuring that young people cannot access vapes unless prescribed by a medical practitioner.

- The Department will also be able to monitor in a limited way pharmacist dispensing volumes through the Special Access Scheme administered by the Therapeutic Goods Administration.
- Vaping goods, under the new standards, are available only in limited flavours and strengths.
- This will assist with identifying unlawful vaping goods and taking necessary compliance and enforcement action.

Will the reforms increase the black market?

- Strengthening the regulation of all vapes, by enhancing border controls, banning all disposable single-use vapes and ending the supply of vapes outside of pharmacy settings, will make it easier to identify and disrupt the illicit supply of vapes and take effective enforcement action.
- The benefit of the new approach is that it will enable compliance and enforcement action to be taken immediately on illicit vapes without requiring laboratory testing.
- Strengthened enforcement activities across all levels of the supply chain will also combat the black market.
- To support the implementation and enforcement of these reforms, the Government is providing an additional \$25 million to the Australian Border Force and \$56.9 million to the TGA over two years.
- All states and territories are also committed to sharing and increasing compliance action and supporting a national enforcement approach. The benefit of the new approach is that it will enable compliance and enforcement action to be taken immediately on illicit vapes without requiring laboratory testing.
- Importers and suppliers of illicit vapes are now on final notice that changes proposed to the Therapeutic Goods Act will enhance compliance and enforcement efforts.