

Vaping reforms – overview of regulatory changes

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Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

[tga.gov.au](https://www.tga.gov.au)

Acknowledgement of Country

I would like to acknowledge the Traditional Owners and Custodians of the lands on which we meet today and pay my respects to Elders past present and emerging.

I would like to extend that acknowledgement and respect to Aboriginal and Torres Strait Islander peoples here today.



Welcome

Housekeeping



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What we'll cover today

- Overview and timeline of regulatory reforms
- How the reforms will impact:
 - consumers
 - prescribers
 - pharmacists and other retailers
 - importers, manufacturers and wholesalers
- Approach to compliance and enforcement
- Update on tobacco control and smoking/vaping cessation measures



Reforms to the regulation of vapes

The Australian Government has announced reforms to progressively **ban all vapes** within Australia, unless they are therapeutic vapes that comply with the *Therapeutic Goods Act 1989*.

Therapeutic vapes will only be available from people authorised to supply prescription medicines under state and territory laws, such as in pharmacies, and must meet new product standards, among other requirements.

Once the changes are complete, tobacconists, vape shops and convenience stores will no longer be able to lawfully sell any type of vape.

"These changes will protect Australians, particularly young people, from the harms of vaping and nicotine dependence, while ensuring those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate."

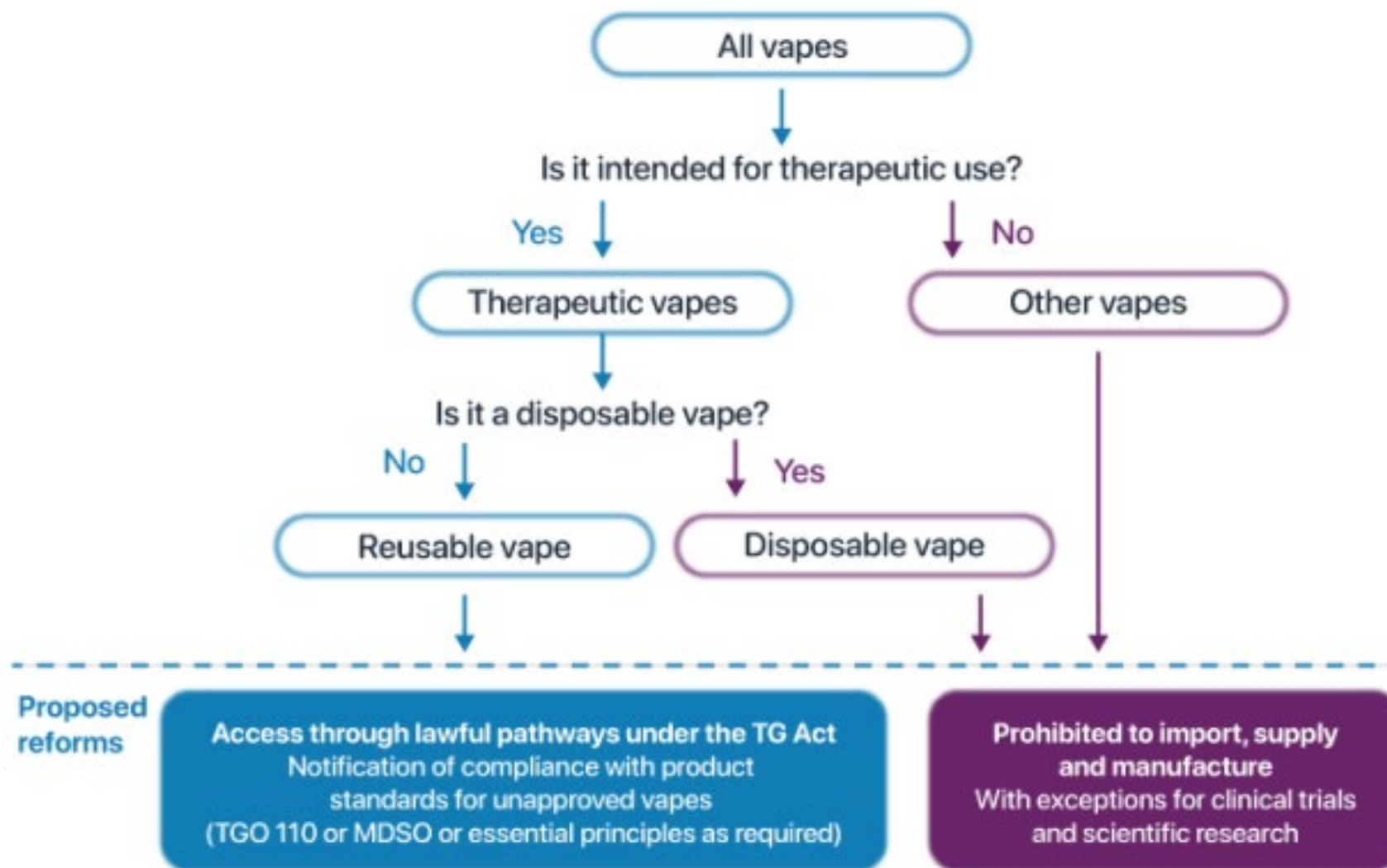
The Hon Mark Butler MP, Minister for Health and Aged Care

Timeline

Date	Milestone
October 2021	Regulatory changes required a prescription to access nicotine vapes
May 2023	Minister for Health and Aged Care announced action on vaping
November 2023	Minister for Health and Aged Care announced enhanced controls on importation, manufacture, advertising, supply and commercial possession of vapes to be implemented throughout 2024
January 2024	Import restrictions commenced for disposable vapes
March 2024	Further import restrictions imposed



Lawful access to vapes under the reforms

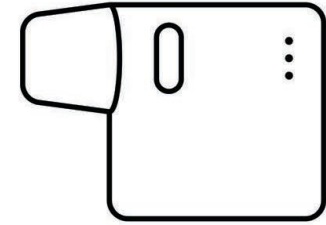


Stage 1: What changed on 1 January 2024?

- The importation of ALL disposable vapes is banned (with limited exceptions)

Note: the sale of previously imported disposable vapes can continue under current laws.

- End of Personal Importation Scheme for disposable vapes.
- New Special Access Scheme (SAS C) pathway to enable medical and nurse practitioners to prescribe therapeutic vapes without requiring pre-authority or approval from the TGA.
- Cessation of advertising permission.



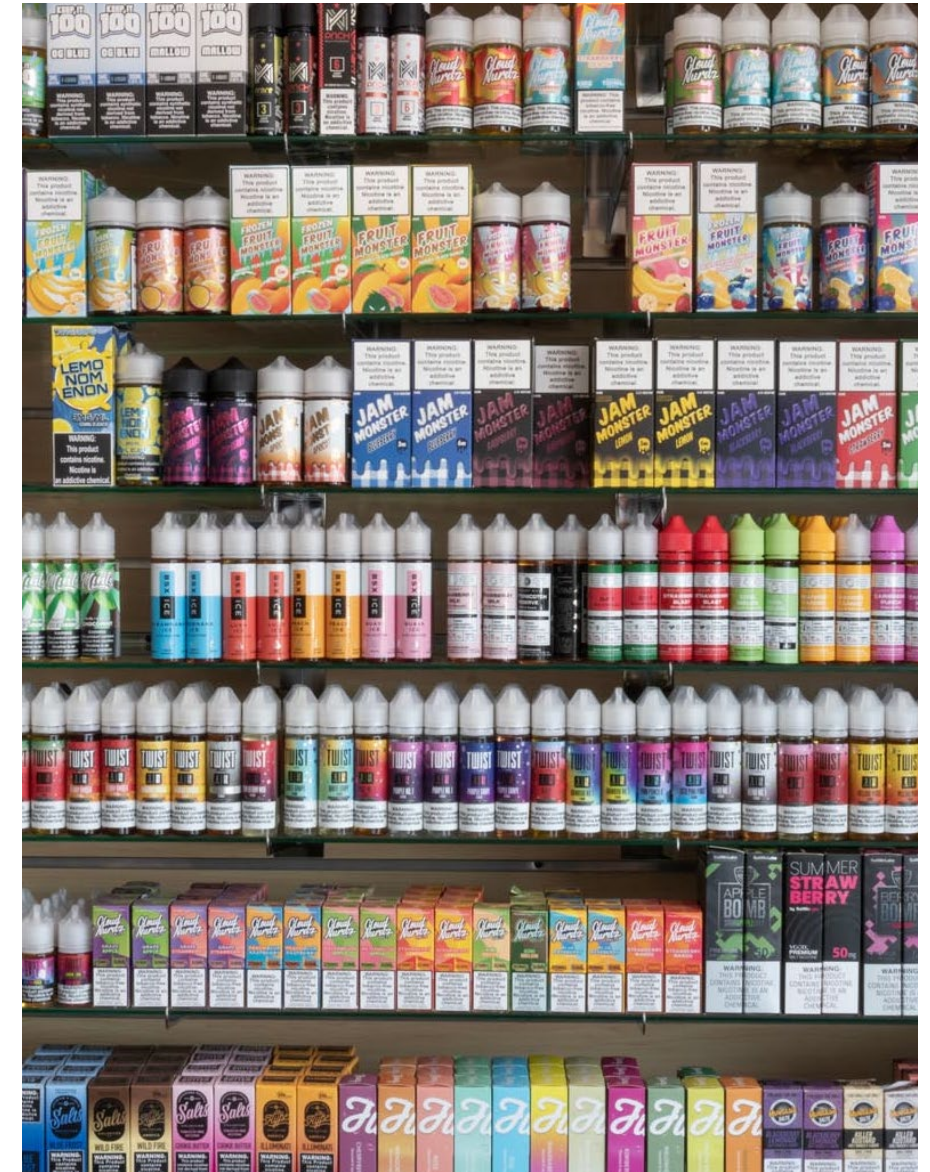
Stage 1: What will change on 1 March 2024?

- The importation of non-therapeutic vapes will be banned.
Note: The supply of previously imported non-therapeutic vapes can continue until domestic controls are implemented in stage 2 of the reforms (est. mid 2024)
- End of Personal Importation Scheme for all therapeutic vapes, including vaping devices and vape accessories (pod etc).
- Manufacturers and sponsors must provide notification that therapeutic vapes comply with relevant product standards (application form available on the TGA website).
- Importers must obtain customs licence and permits from the Office of Drug Control (ODC) to import therapeutic vapes.
- Updates to the Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021 will commence. Updates include limiting flavours to menthol, mint or tobacco for therapeutic vapes.
- Some new requirements for therapeutic vaping devices commence.
- List of vapes that are notified to comply with relevant product standards will be published on TGA website (available from 1 March 2024).

Stage 2: Changes coming mid-2024

(subject to primary legislation being made by the Australian Parliament)

- The domestic manufacture, supply, advertising and commercial possession of non-therapeutic and disposable vapes will be banned (with limited exceptions).
- There will be new criminal offences, with corresponding civil penalty provisions and enhanced enforcement powers.
- It will be illegal to import, manufacture or supply vapes that are not registered on the Australian Register of Therapeutic Goods (ARTG) or do not meet the regulatory requirements for unapproved therapeutic vapes.



Stage 3: Heightened regulatory standards

February–December 2024 (subject to legislative amendments)

- Enhanced requirements for e-liquid components and increased requirements for the device components of therapeutic vapes.
- Minimum quality and safety standard to include new requirements for:
 - plain packaging
 - pharmaceutical labelling
 - permitted ingredients
 - lower maximum nicotine concentrations
- Standards are proposed to commence December 2024 to allow sufficient time for industry to develop compliant products.



Consumers



Impact on consumers

- Consumers will notice that tobacconists, vape shops and convenience stores will no longer stock the disposable vapes that they've previously been able to purchase.
- Doctors or nurse practitioners can prescribe therapeutic vapes through an unapproved product access pathway.
- Where medically appropriate, consumers can purchase therapeutic vapes for smoking cessation or nicotine dependence through an Australian registered pharmacy with a valid prescription.
- Since 1 January, disposable vapes cannot be imported through the Personal Importation Scheme, even with a prescription. From 1 March, the personal importation of all other vapes will be banned.
- Anyone currently using vapes as part of a smoking cessation strategy without a prescription should speak to a health professional as soon as possible.
- Therapeutic vapes are just one option to treat nicotine dependence. Your health professional can help you decide if it is right for you.

Impact on travellers entering Australia

- A new traveller's exemption applies to people bringing vapes into Australia by ship or aircraft with stricter quantity limits.
- The vapes must be for use in the treatment of the traveller or someone the traveller is caring for, who is entering Australia on the same ship or aircraft.
- The maximum allowable quantity is:
 - 2 vapes
 - 20 vape accessories (including cartridges, capsules or pods), and
 - 200mL of vape substance in liquid form.
- The new quantity limits apply to disposable vapes from 1 January 2024 and all other vapes from 1 March 2024.



Prescribers



Impact on prescribers

- There are currently no therapeutic vapes for smoking cessation or the management of nicotine dependence included in the Australian Register of Therapeutic Goods (ARTG).
- Doctors and nurse practitioners can prescribe therapeutic vapes for smoking cessation or the management of nicotine dependence through Special Access Scheme C (SAS C).
- To reduce the administrative burden on prescribers:
 - Doctors and nurse practitioners will be able to prescribe vapes through the SAS C pathway without applying to the TGA for pre-authority or approval.
 - The SAS C notification process has been streamlined to help prescribers manage increased demand for prescriptions.
- Doctors may also prescribe through the Authorise Prescriber (AP) Scheme
- The SAS B may also be used.
- Prescribers should only prescribe vapes that can be lawfully supplied. The vapes that can lawfully be supplied will change over the course of the year and prescribers should keep up to date with information about lawful products on the TGA website.



Impact on prescribers

- The Royal Australian College of General Practitioners (RACGP) and the TGA will be presenting another information session for health practitioners.
- The session will include a demonstration of the SAS and Authorised Prescriber Online System.
- The RACGP is also developing additional guidance material to support prescribers and published provisional guidance on smoking and vaping cessation support late last year.

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Diagram illustrating the TGA network structure, showing interconnected nodes representing various services and systems, including the TGA logo, a first aid kit, surgical instruments, gloves, and a person at a computer.

Pharmacists and other retailers



Impact on pharmacists

- There are currently no therapeutic vapes for smoking cessation or the management of nicotine dependence that have been evaluated by the TGA and included in the ARTG.
- There are established pathways for patients to legally access unapproved vapes, with a valid medical prescription.
- The main pathways for Australian pharmacies to dispense unapproved nicotine vapes are the Authorised Prescriber (AP) scheme and Special Access Scheme Category B (SAS B), and since 1 January 2024, the Special Access Scheme Category C (SAS C).
- Pharmacists may dispense therapeutic vapes with evidence of an AP approval, SAS B approval or in accordance with the SAS C pathway.
- A new validation tool has been developed for pharmacists to confirm the validity of AP and SAS approvals and notifications.
- The validation tool is available to all pharmacists following registration through the **SAS & AP online portal** available at <https://compliance.health.gov.au/sas/>
- The Pharmaceutical Society of Australia (PSA) and TGA will present an information session for pharmacists with further details on the changes.



Impact on pharmacists

- Pharmacists should only dispense therapeutic vapes that conform with TGA requirements, including those in TGO 110.
- As the reforms are rolled out, it will become easier for pharmacists to identify therapeutic vapes that can be lawfully supplied as the TGA will be publishing lists of products that have been notified to the TGA as complying with the relevant standards.
- Pharmacies may take possession of unapproved vapes for the purposes of dispensing before receiving prescriptions. You can hold unapproved vapes in your dispensary until you receive a prescription.

Impact on tobacconists, vape shops and convenience stores

- Once the reforms are fully implemented, tobacconists, vape shops and convenience stores will **no longer be able to lawfully sell** any type of vape in Australia.
- Although the ban for selling vapes will not start until later in 2024, **importation restrictions** will mean that retailers will find it more difficult to get supplies.
- Retailers should act now to minimise financial losses and ensure they comply with the new rules.
- Stage 2 of the reforms (mid-2024, pending legislation) will include bans on the supply of vapes in non-pharmacy settings and on the commercial possession of vapes.
- There will be a transition period until the introduction of the Stage 2 reforms to allow retailers to **run down existing stock**.
- During these periods it will be legal to sell non-therapeutic vapes that adhere to the relevant federal, state and territory laws.
- There will be no compensation available for retailers as part of the changes. Retailers are advised to take advantage of the opportunity to run down their stocks while they legally can.



**Importers,
manufacturers
and wholesalers**



Impact on importers, manufacturers and wholesalers

- As of **1 January 2024**, it is unlawful to import disposable vapes, regardless of nicotine content (with limited exceptions). A transition period will apply to allow businesses to run down stock imported into Australia before this date.
- From **1 March 2024**, new requirements will apply for reusable vapes:
 - Importers and manufacturers of therapeutic vapes must notify the TGA that the vapes comply with relevant product standards.
 - Importers must obtain a customs licence and permit (from ODC).
 - Non-therapeutic vapes will be prohibited imports.
- A transition period will apply to allow businesses to run down existing lawful stock.
- From **mid-2024** it will be illegal to import, manufacture or supply ANY disposable or non-therapeutic vape (pending the passing of legislation). No transition period is proposed for the mid-2024 changes.



Compliance and enforcement



Strong compliance and enforcement focus

- A multi-agency National Vaping Working Group was established in November 2023 following a joint meeting of Health and Police Ministers.
- The NVWG will oversee the development and implementation of a collaborative National Vaping Enforcement Framework to support collaboration among Commonwealth, state and territory health and law enforcement agencies involved in vape enforcement.
- Potential enforcement tools for non-compliance will include:
 - Border seizures
 - Forfeiture of goods
 - Directions and enforceable undertakings
 - Fines
 - Prosecution



Update on tobacco control and smoking/vaping cessation measures

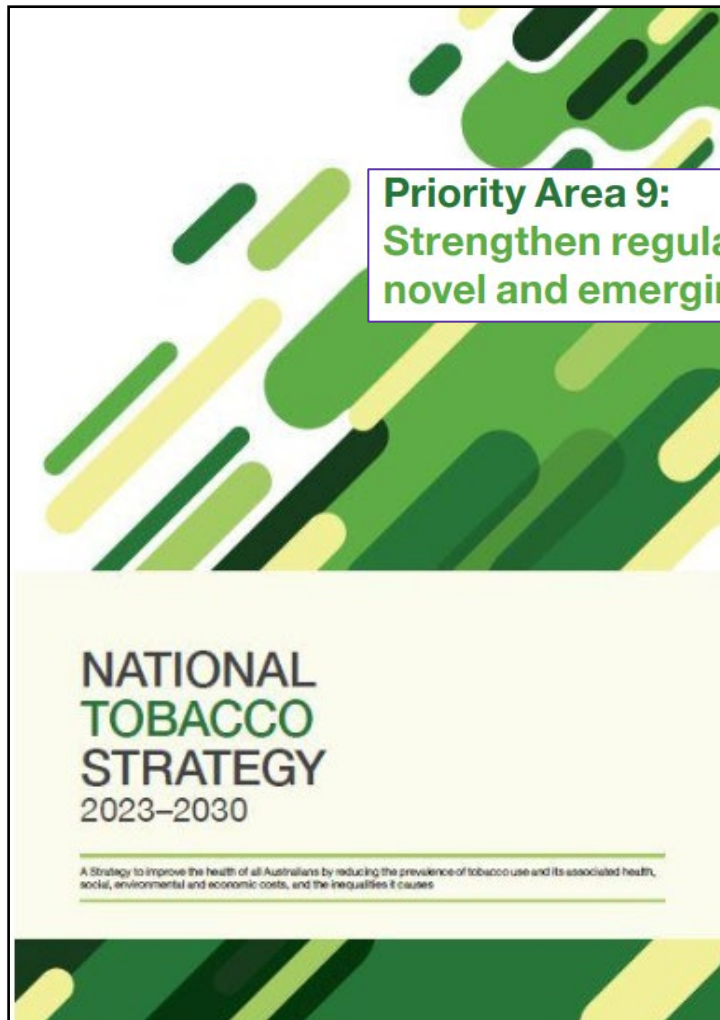
Kate Grlec

Director - Tobacco and E-cigarette Control Branch



Australian Government
Department of Health and Aged Care

National Tobacco Strategy 2023-2030



Priority Area 9:
Strengthen regulations on e-cigarettes and
novel and emerging products

- Published 2 May 2023
- Endorsed by all Australian Governments



Public Health (Tobacco and Other Products) Act 2023

- Passed through parliament on 7 December 2023
- commences on 1 April 2024

- capture e-cigarettes in tobacco advertising regulation;
- update and improve graphic health warnings on packaging, and require health promotion inserts;
- standardise the size of tobacco packets and products;
- prevent use of specified additives; and
- limit appealing names that imply reduced harm

Online quitting support hub

My Quit Buddy app

State and territory Quitline and other quit services

QUIT SUPPORT- cessation measures

2023-24 Budget
(\$29.5 million over 4 years).



QUIT SUPPORT- health professionals

Actions to support health professionals:

- Updating evidence-based clinical guidance
- Development of a targeted workforce education strategy
- Access to training and resources



Supporting smoking cessation:
A guide for health
professionals

Guidance updates on smoking and
vaping cessation support related to
changes to Australia's vaping regulation

Provisional draft for consultation

December 2023

EDUCATION

Public Health Campaigns

- 2023-24 Budget (\$64.3 million over 4 years)
- National Tobacco and E-cigarette Campaign
- National Youth Vaping Education Campaign

Advertisement

STOP SMOKING START REPAIRING

In 1 week
your sense of taste and smell improves

In 5 years
your risk of a stroke has dramatically decreased

In 3 months
your lung function has increased 30%

In 12 weeks
your lungs regain the ability to clean themselves

In 8 hours
excess carbon monoxide is out of your body

In 12 months
your risk of heart disease has halved

In 5 days
most nicotine is out of your body

In 1 year
a pack-a-day smoker will save over \$4,000

**EVERY CIGARETTE YOU DON'T SMOKE
IS DOING YOU GOOD**

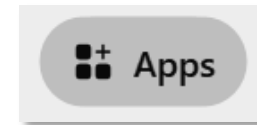
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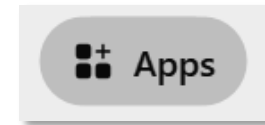
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