From: s.22
To: Helpdesk-OIA@pmc.gov.au
Cc: MCLACHLAN-BENT, Ashley; s.22
Subject: Preliminary Impact Assessment Form - Nicotine Pouches, TGA [SEC=OFFICIAL]
Date: Thursday, 12 February 2026 10:30:55 AM
Attachments: Preliminary Impact Assessment Form - Nicotine Pouches TGA.docx
image001.png

OFFICIAL

Good morning OIA Team,

Please find attached a Preliminary Impact Assessment Form for the TGA's proposal to undertake consultation on reforms to the regulation of nicotine pouches in Australia.

We would be very happy to meet and discuss the approach if you have any questions or concerns.
Please note we will also engage DFAT separately on any impacts on trade.

Thank you,
s.22

s.22
Director
Vaping Engagement and Policy Section

Vaping Implementation and Enforcement Branch | Regulatory Practice and Support Division
Australian Government Department of Health, Disability and Ageing
s.22 @health.gov.au

The Department of Health, Disability and Ageing 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.

OFFICIAL

Australian Government
Department of the Prime Minister and Cabinet
Office of Impact Analysis

OIA
The Office of Impact Analysis

Australian Government Impact Analysis Preliminary Assessment Form

August 2025

Further information can be found in our What to include in the Impact Analysis Preliminary Assessment Form

Overview

Name of department/agency: Department of Health, Disability and Ageing - Therapeutic Goods Administration (TGA)

Name of proposal: Regulation of nicotine pouches in Australia

Type of proposal:
☐ Budget or MYEFO Proposal
☐ Treaties/Conventions
x **Legislation/Regulation Amendment or Proposal**
☐ Sunsetting Instruments
☐ Standards
☐ Industry Codes
☐ Grant Funding
☐ Funding (non-grant)
☐ Other (Specify) _____

Is this an election commitment? ☐ Yes (include link to commitment) x **No**

Key dates and timeline:
March/April 2026: The Therapeutic Goods Administration (TGA) will conduct a targeted consultation with peak health, consumer, government and industry stakeholders on proposed regulatory amendments.
Mid 2026: Following consultation, the TGA will give effect to the proposal through regulatory amendments.

Description of the problem:
The TGA has significant concerns about the increasing prevalence and rapid rise in unlawful importation and supply of nicotine pouches and their impact on nicotine addiction, particularly among young Australians.

Nicotine pouches

Nicotine pouches are small, tobacco-free sachets that are placed between the lip and gum and allow nicotine to be rapidly absorbed into the bloodstream. They are marketed as smoke-free alternatives to smoking or vaping and are increasing targeted to young people as 'performance enhancing'.

Overview

The long-term health effects of nicotine pouches remain unknown and there is little evidence to suggest they support smoking cessation. Early evidence collected by the TGA indicates nicotine pouches can be cheaper, contain higher levels of nicotine than many vaping goods, and are sold in appealing flavours.

Health risks of nicotine pouches

As a novel type of oral nicotine product, there is limited long-term health data available. However, we know that nicotine pouches pose a significant risk of initiating nicotine addiction, particularly among youth and individuals with no prior tobacco use. They deliver nicotine faster and are potentially more potent than cigarettes or vapes - making addiction just as likely. Nicotine exposure during adolescence risks brain development, memory, and learning, and increases vulnerability to addiction and other substance use. Nicotine also has cardiovascular effects with potential for increased risk of heart attack and stroke.

Short-term adverse effects of nicotine pouches include nausea, mouth lesions, sore mouth and throat, and tooth damage. Unregulated packaging and labelling further raises the risk of accidental poisoning, especially in children. They may contain high levels of nicotine and unknown contaminants. Preliminary findings suggest an increase in poisonings associated with nicotine pouches in Australia.

Importantly, there is limited evidence that they are effective in supporting smoking cessation.
This is distinct from approved nicotine replacement therapies (NRT) which have a well-established role in smoking cessation.

Current regulatory controls on nicotine pouches

Nicotine pouches are unapproved goods, have not been evaluated by the TGA for quality, safety or efficacy and are not included on the Australian Register of Therapeutic Goods (ARTG). Nicotine pouches are in Schedule 4 (Prescription Only) of the Poisons Standard and individuals can only lawfully access nicotine pouches via the 5 primary pathways for unapproved goods under the *Therapeutic Goods Act 1989* (Act).

The TGA administers specific regulatory pathways to facilitate access to unapproved therapeutic goods. The relevant pathways for purposes of this proposal are:

1. Personal Importation Scheme (PIS)

The PIS allows individuals to legally import up three-months supply of an unapproved therapeutic good per order for personal use, or for use by an immediate family member, without TGA approval. The goods must **not be sold or supplied to others, and certain conditions apply, such as holding a valid prescription for Schedule 4 medicines.**

2 and 3. Special Access Scheme (SAS) (A and B)

The SAS enables registered health practitioners to prescribe unapproved therapeutic goods for individual patients on a case-by-case basis. TGA approval or notification is required.

4. Authorised Prescriber scheme

The Authorised Prescriber (AP) scheme allows medical practitioners to prescribe specific unapproved therapeutic goods to patients with specified medical conditions, without needing to apply to the TGA for each individual case. Practitioners must obtain approval from a Human Research Ethics Committee or specialist college.

Overview

5. Pharmacist compounding exemption

An exemption under the *Therapeutic Goods Act 1989* allows pharmacists to compound custom formulations for individual patients based on a valid prescription, when proprietary (approved) products are not available or unsuitable.

Prevalence of nicotine pouches

Only the PIS and SAS pathways are currently being used to import nicotine pouches. However, only closing those pathways may result in the exploitation of the remaining pathways. To date, there have only been five applications for nicotine pouches under the SAS pathways. The other relevant TGA pathways exist to meet compelling clinical needs where approved goods are unsuitable or unavailable. There are a range of ARTG-listed pharmacotherapies and nicotine replacement therapies, as well as a regulated pathways for therapeutic goods.

The targeted consultation proposed will seek to understand the behaviours driving prescribing and lawful importation and determine the impact on prescribers and patients who legitimately access nicotine pouches if these pathways were to close.

Since 1 January 2024, the Australian Border Force (ABF), on TGA advice, has seized over 19 million illegal nicotine pouches with an estimated street value of $19 million. Evidence suggests 97% of nicotine pouch imports into Australia are unlawful. Further, the TGA has seized almost half a million nicotine pouches are part of enforcement activities, including from retail outlets.

Referrals from the ABF to the TGA for nicotine pouch imports has increased from approximately 500 in 2023 to more than 9,000 in 2025.

Relevance to vaping reforms.

In May 2023, the Australian Government announced reforms to the regulation of vaping products. These reforms, made under the Act, have been implemented in partnership with states and territories and restrict the ways that vapes can be imported, manufactured, supplied and advertised in Australia. The vaping reforms are designed primarily to protect young people from the harms of nicotine addiction by removing them from general retail and online environments and strengthening penalties for unlawful supply and advertising.

Evidence shows that young people who vape are more likely to transition to smoking. Research has highlighted nicotine pouches as part of increasing poly-product nicotine use behaviour, especially by young people.

Outline of the objectives of government action:

This proposal supports the Government's broader objectives to reduce nicotine addiction and aligns with the objectives, priorities and targets outlined in the National Tobacco Strategy 2023-2030, including to prevent and reduce the marketing and harms associated with nicotine pouches. It would also enable clear community messaging around the legality and health risks of nicotine pouches.

The Government's clear focus on preventing nicotine addiction and regulating all therapeutic and non-therapeutic nicotine products indicates that this measure would fall within the same public health intent that underpins the vaping reforms.

Overview

The specific objectives of government action include to:

- **Reduce community access to nicotine pouches by closing the lawful pathways currently available.**
- **Protect public health, particularly among young people, by preventing the uptake, normalisation and ongoing use of a highly addictive nicotine pouches that have not been assessed for quality, safety or efficacy and have no established role in smoking or vaping cessation.**
- **Strengthen the integrity and credibility of the therapeutic goods regulatory framework by ensuring access pathways for unapproved therapeutic goods are used appropriately and consistently with their intended purpose.**
- **Reduce regulatory, compliance and border enforcement burden on the TGA and ABF, enabling resources to be redirected to higher risk products and priority public health activities.**

Importantly, the proposal does not seek to prevent or restrict access to current or future approved nicotine replacement therapies, which are a mainstay of smoking cessation support and widely available for general sale. Under this measure individuals would continue to have access to a wide range of treatments for smoking cessation and the management of nicotine dependence. Some of these treatments are also subsidised under the Pharmaceutical Benefits Scheme (PBS).

The proposal also does not affect applications to register nicotine pouch products through ARTG registration or for use in clinical trials.

Outline of the options available:

To give effect to this proposal, the TGA proposes to amend the Therapeutic Goods Regulations 1990 (the Regulations) to:

a. prescribe that an approval under SAS B or an authority under the AP scheme must not be given for nicotine pouches (subsection 19(8) of the Act refers)
b. amend sub regulation 12A (1) of the Regulations to exclude nicotine pouches from the exemption under 18(1) of the Act (SAS A pathway), and
c. amend items 1 and 6 in Schedule 5 to the Regulations to prohibit the personal importation and extemporaneous compounding of nicotine pouches.

There is legal authority to amend the Regulations under Section 19 of the Act for this purpose. Consultation with relevant authorities, such as the ABF, and other public health stakeholders would be undertaken to mitigate unintended consequences.

What are the likely impacts of your proposal? (It may be useful to consider impacts on Australian individuals, businesses, and community organisations, and the depth and breadth of those impacts).

The likely impacts of restricting access to addictive unapproved nicotine products have been extensively considered under impact assessment for the Government's vaping reforms.

Overview

Reducing access to nicotine pouches is expected to contribute to a safer, healthier Australia. Benefits included improved protection of public health, through reduced risk of nicotine addiction, accidental poisoning and other health harms associated with unregulated nicotine pouch products.

Preventing youth uptake and normalisation of nicotine use supports the Government's broader efforts to reduce smoking, vaping and nicotine dependence across the Australian community. There would be clearer and more consistent public messaging on the legal status of nicotine pouches, reducing confusion for consumers, health professionals and industry.

This proposal would also reduce administrative and enforcement burden for the TGA and ABF through lower volumes of unlawful imports requiring assessment and intervention. This would ensure greater regulatory certainty and system integrity, ensuring unapproved therapeutic goods pathways remain fit for purpose and focused on legitimate clinical access.

Access to nicotine pouches through potential clinical trials would not be affected. Nor would this measure prevent tobacco and nicotine industry actors seeking inclusion of new nicotine products for smoking cessation support on the ARTG.

Restricting access to nicotine pouches would impact people who may use these products recreationally or as cessation support. It would also impact unlawful suppliers, which may include organised crime.

What is your assessment of the significance of the likely impacts of the proposal? Why?

Individuals who may be using nicotine pouches to quit smoking or manage nicotine dependence would not be adversely impacted because there is already a range of safer and more effective products for this purpose, widely available in Australian supermarkets and/or pharmacies. These include approved nicotine replacement therapies, prescribed pharmacotherapies and therapeutic vapes. Some products are subsidised under the Pharmaceutical Benefits Scheme (PBS).

The importation of nicotine pouches under the PIS is placing excessive administrative burden on the TGA and ABF, exceeding operational capacity and delaying imports of other lawful therapeutic goods, including for essential medicines. These delays risk consumer harm and reputational damage to the TGA. Prohibiting access to nicotine pouches through the unapproved therapeutic goods access pathways would ensure TGA and ABF resources can focus on higher-risk and life-saving products. It would support the processing of medicines and devices imports, and restore confidence and integrity in the PIS, ultimately improving public health outcomes.

How many entities will be affected?

To date, there have been only five applications for nicotine pouches under the SAS pathway. The unapproved therapeutic good access pathways exist to meet compelling clinical needs where approved goods are unsuitable or unavailable. The consultation will include a focus on understanding the premise for these imports and mitigating any unintended impacts. Nicotine pouches should not meet these criteria as there are already ARTG-listed pharmacotherapies to support smoking cessation and the management of nicotine dependence, as well as a regulated pathway for therapeutic vaping goods.

Overview

As an unapproved, Schedule 4 (prescription only) good, there are no businesses lawfully marketing or selling nicotine pouches in Australia.

Have you consulted with stakeholders? If no, what are their likely views and what was the rationale for not having completed this consultation?

Recent roundtables with key health, industry and state and territory stakeholders demonstrated strong support for proactive regulatory action on emerging nicotine products. Participants emphasised the importance of addressing new forms of nicotine delivery early to prevent undermining the Government's broader vaping reform objectives. Stakeholders consistently highlighted the need for strengthened regulation of products such as nicotine pouches to ensure young people are protected and that public health gains from the vaping reforms are maintained.

Measures taken to date include the introduction of a ban on nicotine pouches by the South Australian Government on 30 January 2025. There is also global recognition of the need to regulate emerging nicotine products with a 2024 study finding 34 out of 67 countries surveyed were regulating nicotine pouches in some way including absolute bans.

The TGA intends to undertake targeted consultation on the proposed regulatory changes in early 2026 to ensure the regulation amendments meet the purpose of the reform, all stakeholder feedback is taken into consideration and to support the implementation of the reforms.

s.22

s.22

Contact information (Please enter your contact information below)
Names: s.22
Email and Phone: s.22 @health.gov.au (Ph: s.22) and s.22 @health.gov.au s.22 s.22
Date: 12 February 2026
Please forward the completed form to OIA at Helpdesk-OIA@pmc.gov.au or call (02) 6271 6270 to discuss your proposal with an OIA officer.

From: s.22
To: s.22 ; Helpdesk-OIA
Cc: s.22
Subject: RE: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]
Date: Monday, 16 February 2026 10:05:09 AM
Attachments: image002.jpg
image003.jpg
image006.png
image008.png
image009.jpg
image001.jpg
image004.png

OFFICIAL

OFFICIAL

s.22

To clarify, an additional preliminary assessment (PA) form is required to be submitted to the OIA for an assessment of impact analysis (IA) requirements for the proposal to regulate nicotine pouches. The OIA's expectation is that the additional PA will be informed by the results of the consultation process and enable an assessment of the likely magnitude of the impact of the proposal on Australian businesses and individuals – and thereby a determination of IA requirements.

Happy to discuss,
Regards,
s.22

s.22 | Adviser, Office of Impact Analysis
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s.22
Ngunnawal Country, 1 National Circuit Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600
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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.

OFFICIAL

From: s.22 @Health.gov.au>
Sent: Monday, 16 February 2026 9:44 AM
To: Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>
Cc: s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; s.22 @Health.gov.au>; s.22 @Health.gov.au>
Subject: RE: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]

OFFICIAL

Hi s.22

Thank you so much for your quick response, I called but wasn't able to catch you on Friday – I just wanted to clarify, while the Preliminary Impact Assessment noted we would undertake consultation, it is the intention that if the consultation is supportive that we would proceed with this change.

Can I confirm we are not required to complete an additional preliminary impact assessment?
Thank you,
s.22

s.22
Director
Vaping Engagement and Policy Section
Vaping Implementation and Enforcement Branch | Regulatory Practice and Support Division
Australian Government Department of Health, Disability and Ageing
s.22 @health.gov.au

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From: Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>
Sent: Thursday, 12 February 2026 11:47 AM
To: s.22 @Health.gov.au>
Cc: s.22 @pmc.gov.au>; s.22 s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; MCLACHLAN-BENT, Ashley <Ashley.MCLACHLAN-BENT@health.gov.au>; s.22 s.22 @Health.gov.au>; s.22 s.22 @Health.gov.au>
Subject: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]

OFFICIAL

s.22

Regarding: OIA26-11119 - Regulation of nicotine pouches in Australia

Thank you for submitting your proposal to the Office of Impact Analysis (OIA) for our consideration and advice. Based on the information provided, the OIA has determined that **detailed impact analysis is not required** under the Australian Government's Policy Impact Analysis Framework. This assessment is informed by our understanding that the proposal is to consult on possible amendments to the Therapeutic Goods Regulations 1990 (the Regulations) to:

a. prescribe that an approval under Special Access Scheme (SAS) B or an authority under the Authorised Prescriber (AP) scheme must not be given for nicotine pouches (subsection 19(8) of the Act refers)

b. amend sub regulation 12A (1) of the Regulations to exclude nicotine pouches from the exemption under 18(1) of the Act (SAS A pathway), and

c. amend items 1 and 6 in Schedule 5 to the Regulations to prohibit the personal importation and extemporaneous compounding of nicotine pouches.

If any of the above is inconsistent with your proposal, or should your proposal change significantly from the details provided, please contact us again to ensure our advice remains current. Please quote your reference number (OIA26-11119) to ensure we can assist you promptly.

Regards

s.22

s.22 | Adviser, Office of Impact Analysis
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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: s.22
To: Helpdesk-OIA
Cc: s.22
Bcc: MCLACHLAN-BENT, Ashley
Subject: FW: Follow up Preliminary Impact Assessment form - Regulation of nicotine pouches [SEC=OFFICIAL]
Date: Monday, 20 April 2026 12:53:00 PM
Attachments: image002.jpg
image003.jpg
image006.png
image008.png
image009.jpg
image001.jpg
Preliminary IA - follow up to OIA26-11119 - Nicotine Pouch Regulation.docx
image004.png

Good afternoon s.22

Thanks for your time on the phone just earlier. As discussed, please see the attached Preliminary Assessment Form on the matter of the regulation of nicotine pouches. Following on from **OIA26-11119**, the TGA proceeded with external consultation on the proposed amendments to the regulation of nicotine pouches and received a strong endorsement from a range of stakeholders on the approach.

We note the significant support from external stakeholders and that this proposed amendment does not have an impact on legitimate businesses as there is currently no lawful domestic sale of nicotine pouches in Australia. Furthermore, the proposed approach will strengthen domestic and border enforcement activities and deliver on positive public health outcomes, particularly for young Australians.

Very happy to discuss if you have any questions or concerns. We appreciate your review and advice.
Thank you,
s.22

Director
Vaping Engagement and Policy Section
Vaping Implementation and Enforcement Branch | Regulatory Practice and Support Division
Australian Government Department of Health, Disability and Ageing
s.22 @health.gov.au

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From: s.22 @pmc.gov.au>
Sent: Monday, 16 February 2026 9:35 AM
To: s.22 @Health.gov.au>; Helpdesk-OIA <Helpdesk-OIA@pmc.gov.au>

Cc: s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; s.22 @Health.gov.au>; s.22 @Health.gov.au>

Subject: RE: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]

OFFICIAL

OFFICIAL

s.22

To clarify, an additional preliminary assessment (PA) form is required to be submitted to the OIA for an assessment of impact analysis (IA) requirements for the proposal to regulate nicotine pouches. The OIA's expectation is that the additional PA will be informed by the results of the consultation process and enable an assessment of the likely magnitude of the impact of the proposal on Australian businesses and individuals – and thereby a determination of IA requirements.

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Cc: s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; s.22 @Health.gov.au>; s.22 @Health.gov.au>
Subject: RE: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]

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s.22
Director
Vaping Engagement and Policy Section

Vaping Implementation and Enforcement Branch | Regulatory Practice and Support Division
Australian Government Department of Health, Disability and Ageing
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Sent: Thursday, 12 February 2026 11:47 AM
To: s.22 @Health.gov.au>
Cc: s @pmc.gov.au>; s.22 s.22 @pmc.gov.au>; s.22 @pmc.gov.au>; MCLACHLAN-BENT, Ashley <Ashley.MCLACHLAN-BENT@health.gov.au>; s.22 s.22 @Health.gov.au>; s.22 s.22 @Health.gov.au>
Subject: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]

OFFICIAL

s.22

Regarding: OIA26-11119 - Regulation of nicotine pouches in Australia

Thank you for submitting your proposal to the Office of Impact Analysis (OIA) for our consideration and advice. Based on the information provided, the OIA has determined that **detailed impact analysis is not required** under the Australian Government's Policy Impact

Analysis Framework. This assessment is informed by our understanding that the proposal is to consult on possible amendments to the Therapeutic Goods Regulations 1990 (the Regulations) to:

a. prescribe that an approval under Special Access Scheme (SAS) B or an authority under the Authorised Prescriber (AP) scheme must not be given for nicotine pouches (subsection 19(8) of the Act refers)

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Regards

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Office of Impact Analysis

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The Office of Impact Analysis

sig

Australian Government Impact Analysis Preliminary Assessment Form

August 2025

Further information can be found in our What to include in the Impact Analysis Preliminary Assessment Form

Overview

Name of department/agency: Department of Health, Disability and Ageing - Therapeutic Goods Administration (TGA)

Name of proposal: Regulation of nicotine pouches in Australia

Type of proposal:
☐ Budget or MYEFO Proposal
☐ Treaties/Conventions
x Legislation/Regulation Amendment or Proposal
☐ Sunsetting Instruments
☐ Standards
☐ Industry Codes
☐ Grant Funding
☐ Funding (non-grant)
☐ Other (Specify) _____

Is this an election commitment? ☐ Yes (include link to commitment) **x No**

Key dates and timeline:

- **27 March -15 April 2026**: Targeted consultation key health and peak body representative organisations, government agencies and public health academics.
- **TBC June 2026:** Consideration by the Governor-General at a Federal Executive Council meeting.

As advised by s.22 on 16 February 2026 and following on from our initial preliminary assessment **OIA26-11119**, this additional preliminary assessment is further informed by our targeted stakeholder consultation of 27 March to 15 April 2026.

Description of the problem:
The TGA is concerned about increasing illegal importation, advertising and availability of nicotine pouches in Australia and recently consulted with key stakeholders on proposed regulatory amendments to address this risk.

Overview

Nicotine pouches are Schedule 4 (Prescription Only) therapeutic goods and are not approved for use in Australia, including for smoking cessation or nicotine dependence. There is insufficient evidence to support their use to help quit smoking or vaping.

Since 1 January 2024, the Australian Border Force (ABF) on TGA advice, has seized over 22 million illegal nicotine pouches with an estimated street value of over $22 million. Available evidence suggests that most nicotine pouch imports into Australia may be unlawful. In addition, the TGA has seized almost half a million nicotine pouches as part of enforcement activities, including from retail outlets.

Nicotine pouches are highly addictive products. Their increasing availability and promotion, particularly to young people, raises the risk of nicotine dependence and may undermine broader tobacco and vaping control measures.

Outline of the objectives of government action:

The proposal aims to address the significant community health risk by closing access through established TGA pathways, which are intended to allow access to unapproved therapeutic goods in limited and clinically justified circumstances.

The objectives of government action include to:

- Protect public health, particularly young people, by preventing the uptake and ongoing use of nicotine pouches.
- Support the objectives of the National Tobacco Strategy 2023-2030 and the Government's vaping reforms to prevent the normalisation and use of nicotine products.
- Reduce the risk of consumer displacement from vaping goods to nicotine pouches.
- Strengthen the integrity of the therapeutic goods regulatory framework by ensuring access pathways for unapproved therapeutic goods are used consistently with their intended purpose.
- Reduce regulatory, compliance and border enforcement burden on the TGA and the Australian Border Force (ABF).

Outline of the options available:

The TGA has established pathways to access unapproved therapeutic goods in limited and clinically justified circumstances. These pathways include the Special Access Scheme (SAS), Authorised Prescriber (AP) scheme, Personal Importation Scheme (PIS), and pharmacist compounding. In relation to nicotine pouches, evidence suggests that established pathways are being used in ways that take advantage of the intended purpose, supporting the case for regulatory amendment.

To give effect to this proposal, we propose to amend the Therapeutic Goods Regulations 1990 (the Regulations) to:

a. prescribe that an approval under SAS B or an authority under the AP scheme must not be given for nicotine pouches (subsection 19(8) of the Act)
b. amend sub regulation 12A (1) of the Regulations to exclude nicotine pouches from the exemption under 18(1) of the Act (SAS A pathway), and

Overview

c. amend items 1 and 6 in Schedule 5 to the Regulations to prohibit the personal importation and extemporaneous compounding of nicotine pouches.

Other elements of your proposal (including any consultation undertaken or proposed):
The Minister for Health, Disability and Ageing held a round table in December 2025, with health, industry, and state and territory representatives where there was strong support indicated for proactive regulatory action on nicotine pouches and emerging unapproved nicotine products. Stakeholders emphasised the importance of addressing emerging nicotine products like nicotine pouches early, to support the Government's broader vaping reform objectives.

Regulatory action has already commenced in some jurisdictions. The South Australian Government introduced a ban on nicotine pouches on 30 January 2025. Internationally, there is growing recognition of the need to regulate emerging nicotine products, with a 2024 study finding that 34 of 67 countries surveyed regulate nicotine pouches in some form, including through absolute bans.

Targeted consultation
The TGA undertook a targeted consultation with key health organisations and peak body representatives, government agencies, state and territory stakeholders between **27 March and 15 April 2026** to inform the proposed regulatory amendments. **Over 80 stakeholders were consulted**, including key health and peak bodies, relevant government agencies, states and territories, and tobacco and vaping experts, to ensure a broad range of perspectives were considered and to support effective implementation.

24 written submissions were received by a myriad of key public health stakeholders including Commonwealth, state and territory health and police agencies. There was an overwhelming majority of submissions that were supportive on the basis that nicotine pouches lack evidence of therapeutic benefit, are not TGA evaluated or ARTG listed, and that continued access risks misleading the public and clinicians, and exacerbating youth misperceptions about harm.

Key feedback included that the proposed amendments would further strengthen domestic and border enforcement for these products and strengthen public messaging regarding the public health risks of nicotine products.

One submission supported regulation of the products and stated that while nicotine pouches present a public health risk, their position is to prioritise harm reduction and that nicotine ouches are likely to provide a less harmful alternative method of nicotine consumption than conventional combustible products like cigarettes. This is in contrast to other submissions where responders noted there is no evidence indicating nicotine pouches provide a therapeutic benefit that is not being met by existing cessation pharmacotherapies and the significant risk of nicotine dependence and addiction, particularly for young people.

Overall, respondents considered the impact to be predominantly positive and noted that these products are only lawfully available via a prescription so the impact on genuine business is not tangible and that it would only help to further strengthen enforcement against malicious actors.

Who will the decision maker be?
X Minister/Secretary/CEO

Overview
☐ Cabinet ☐ Ministerial Forum/ Standard Setting Body (If yes, will the changes be implemented by States and Territories) ☐ Other

Summary of impacts on Australians

What are the likely impacts of your proposal? (It may be useful to consider impacts on Australian individuals, businesses, and community organisations, and the depth and breadth of those impacts).

Impacts on individuals who want to quit smoking or vaping
There is no impact on people who want to quit smoking or vaping as approved, evidence-based cessation options are already widely available. These include approved nicotine replacement therapies, other pharmacotherapies, and regulated access to therapeutic vaping goods in pharmacies.

Impacts on people who use nicotine pouches recreationally
The proposal is expected to reduce community access to nicotine pouches. It is important to note, the regulation amendments do not make nicotine pouches prohibited substances, however lawful access would be substantially reduced through the proposed restrictions on existing access pathways. This is consistent with the aims of government and with peak health stakeholder feedback on the health risks associated with pouches.

Impacts on youth
Public health stakeholders express strong support for the proposal, highlighting the importance of preventing youth access to nicotine pouches. Nicotine-related health risks are well established. Evidence indicates that exposure during adolescence, a key period for brain development, can alter reward circuitry in the brain. This increases the risk of long-term nicotine dependence and progression to other substance use, with consequential adverse health, social and economic impacts over the life course.

Impacts on businesses
Legitimate businesses are not impacted as there is currently no lawful domestic sale of nicotine pouches in Australia and no approved products.

Impacts on sponsors or manufacturers of nicotine pouches
The proposal does not affect sponsors or manufacturers who may seek to have a nicotine pouch product approved for use through inclusion in the Australian Register of Therapeutic Goods (ARTG). Product approval pathways are not impact nor is access to clinical trial pathways.

Impacts on health practitioners
Health practitioner stakeholders express strong support for the proposal, noting its alignment with existing clinical guidance on nicotine dependence and lack of an established therapeutic role for nicotine pouches. Clarity about the legal status of nicotine pouches is expected to reduce uncertainty for health practitioners and support consistent, evidence-based advice to patients regarding smoking cessation options.

Impacts on regulatory enforcement agencies such as the Australian Border Force and enforcement agencies.
The proposal is expected to reduce border enforcement pressures associated with unlawful importation of nicotine pouches, enabling regulatory and enforcement resources to be more effectively directed towards higher-priority public health risks.

Impacts on organised crime
Nicotine pouches as part of Australia's illicit nicotine market, alongside illegal cigarettes and vapes, and their trade is linked to organised crime. Better regulatory controls on nicotine pouches complement broader enforcement activities against organised crime.

Summary of impacts on Australians

What is your assessment of the significance of the likely impacts of the proposal? Why?

Overall, the proposal is expected to have nil regulatory and economic impacts, while delivering targeted and positive public health outcomes. There is no material impact on individuals seeking to quit smoking or vaping, as approved and regulated cessation options remain readily available. The primary effect is a reduction in access to nicotine pouches, consistent with the intended policy objective and advice from health stakeholders. Impacts on businesses are nil, as there is no existing lawful domestic market for these products. The proposal is expected to provide public health benefits by reducing youth exposure to nicotine, improve regulatory clarity for health practitioners, and support more efficient use of enforcement resources. The measures also complement broader efforts to disrupt illicit nicotine markets associated with organised crime. Overall, the impacts are narrow in scope and proportionate to the policy intent.

s.22

Contact information (Please enter your contact information below)
Names: s.22
Email and Phone: s.22 @health.gov.au s.22 and s.22 @health.gov.au s.22 s.22
Date: 20 April 2026
Please forward the completed form to OIA at Helpdesk-OIA@pmc.gov.au or call (02) 6271 6270 to discuss your proposal with an OIA officer.

From: Helpdesk-OIA
To: s.22
Cc: OIA - Team 1; s.22 ; s.22
Subject: OIA26-11119 - Regulation of nicotine pouches in Australia [SEC=OFFICIAL]
Date: Monday, 20 April 2026 1:33:34 PM
Attachments: image.jpeg
image.jpeg
image.jpeg

OFFICIAL

s.22

Regarding: OIA26-11119 - Regulation of nicotine pouches in Australia

Thank you for submitting your proposal to the Office of Impact Analysis (OIA) for our consideration and advice. Based on the update information provided (informed by your consultation with stakeholders) and our telephone conversation this afternoon, the OIA has **confirmed** that **detailed analysis is not required** under the Australian Government's Policy Impact Analysis Framework. This assessment is informed by our understanding that the proposal is to amend the Therapeutic Goods Regulations 1990 (the Regulations) to:

1. prescribe that an approval under SAS B or an authority under the AP scheme must not be given for nicotine pouches (subsection 19(8) of the Act)
2. amend sub regulation 12A (1) of the Regulations to exclude nicotine pouches from the exemption under 18(1) of the Act (SAS A pathway), and
3. amend items 1 and 6 in Schedule 5 to the Regulations to prohibit the personal importation and extemporaneous compounding of nicotine pouches.

The OIA notes the proposal does not have an impact on legitimate businesses as there is currently no lawful domestic sale of nicotine pouches in Australia.

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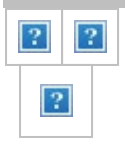
Importantly, seeing as there is no detailed Impact Analysis (IA) requirement, any future explanatory document/s etc. should remain wholly silent to OIA advice and IA requirements - in keeping with paragraph 7.15 in the Legislation Handbook, and/or paragraph 287 in the Instruments Handbook.

If any of the above is inconsistent with your proposal, or should your proposal change significantly from the details provided, please contact us again to ensure our advice remains current. Please quote your reference number (OIA26-11119) to ensure we can assist you promptly.

Regards

s.22

s.22 | Adviser, Office of Impact Analysis
Department of the Prime Minister and Cabinet
s.22
Ngunnawal Country, 1 National Circuit Barton ACT 2600 | PO Box 6500 CANBERRA ACT 2600
s.22 @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.

Australian Government
Department of Health, Disability and Ageing

Ministerial Submission – Standard
MS25-001468
Version (1)
Date sent to MO: 4 February 2026

To: **Minister Butler**

Subject: **Regulation of Nicotine Pouches**

Critical date: **N/A**

Recommendations:

1.	**Agree** the Therapeutic Goods Administration (TGA) proceed with a targeted consultation on proposed amendments to the Therapeutic Goods Regulations 1990 to close the lawful pathways for accessing nicotine pouches as unapproved therapeutic goods.	1. **Agreed/ Not agreed/ Please discuss**
2.	**Note** the TGA will brief you on the outcomes of consultation and next steps regarding any proposed amendments to the Therapeutic Goods Regulations 1990.	2. **Noted/ Please discuss**

Signature.....

Date: 10/ 02/ 26

Comments:

Contact Officer:	*Ashley McLachlan-Bent*	*Assistant Secretary, Vaping Implementation and Enforcement Branch, Regulatory Practice and Support Division*	Ph s.22 [redacted] Mobile s.22 [redacted]
Clearance Officer:	*Prof Anthony Lawler*	*Deputy Secretary Health Products Regulation Group*	Ph s.22 [redacted] Mobile s.22 [redacted]

Submission summary:
This submission seeks your agreement to the Therapeutic Goods Administration (TGA) undertaking a targeted consultation on closing the lawful pathways for accessing nicotine pouches as unapproved therapeutic goods in Australia. The TGA has significant concerns about the increasing prevalence and rapid rise in unlawful importation and supply of nicotine pouches and their impact on nicotine addiction, particularly among young Australians.

Issues:

1. Nicotine pouches are small, tobacco-free sachets that are placed between the lip and gum and allow nicotine to be rapidly absorbed into the bloodstream. They are marketed as smoke-free alternatives to smoking or vaping and are increasingly targeted to young people as 'performance enhancing'. The long-term health effects of nicotine pouches remain unknown and there is little evidence to suggest they support smoking cessation.
2. Early evidence collected by the TGA indicates nicotine pouches can be cheaper, contain higher levels of nicotine than many vaping goods, and are sold in appealing flavours.
3. At your Tobacco Control and Novel Nicotine Products Ministerial Roundtable on 10 December 2025, speakers from s.22 noted that nicotine pouches are contributing to the rise in poly-product nicotine use behaviours, especially by young people. Data was presented that showed 46% of respondents to a survey intended to try nicotine pouches in the next six months.
4. Nicotine pouches are unapproved goods, have not been evaluated by the TGA for quality, safety or efficacy, and are not included in the Australian Register of Therapeutic Goods (ARTG).
5. Nicotine pouches are in Schedule 4 (Prescription Only) of the Poisons Standard and individuals can only lawfully access nicotine pouches via the 5 primary pathways for unapproved goods under the *Therapeutic Goods Act 1989*.
    a. These pathways are the Personal Importation Scheme (PIS), Special Access Scheme A and B (SAS A and SAS B), Authorised Prescriber (AP) Scheme, and pharmacist compounding exemption.
6. Since 1 January 2024, the Australian Border Force (ABF), on TGA advice, has seized at over 19 million illegal nicotine pouches with an estimated street value of $19 million. Evidence suggests 97% of nicotine pouch imports into Australia are unlawful. Further, the TGA has seized almost half a million nicotine pouches as part of its enforcement activities, including from retail outlets.
7. Referrals from the ABF to the TGA for nicotine pouch imports, primarily under the PIS, have increased from approximately 500 in 2023 to more than 9,000 in 2025.
    a. The significant increase in volume of referrals from the ABF to the TGA for nicotine pouches is exceeding the operational capacity of both areas and impacting the timely processing of imports for other therapeutic goods, including lifesaving medicines.
8. This submission recommends undertaking a consultation on contemporaneously closing the five primary pathways for accessing nicotine pouches as an unapproved therapeutic good, as an immediate step to reduce access and prevent the emergence of this new form of nicotine addiction. While this approach will not address emerging nicotine products more broadly, it will provide an immediate step to reduce community access to nicotine pouches and support consistent regulation of importation by deeming all nicotine pouch imports as unlawful.
    a. This would not affect ARTG registration opportunities or clinical trials access.
9. While only the PIS and SAS pathways are currently being used to import nicotine pouches, only closing those pathways may result in the exploitation of the remaining pathways.

10. To date, there have only been five applications for nicotine pouches under the SAS pathways. The other relevant TGA pathways exist to meet compelling clinical needs where approved goods are unsuitable or unavailable. There are a range of ARTG-listed pharmacotherapies and nicotine replacement therapies, as well as a regulated pathway for therapeutic vaping goods.
11. There is no precedent for closing all lawful access pathways for an unapproved product. This approach would effectively mean the TGA does not accept there is a legitimate medical use for these products at this time.
12. There is legal authority to amend the Regulations under Section 19 of the Act for this purpose. Consultation with relevant authorities, such as the ABF, and other public health stakeholders would be undertaken to mitigate any unintended consequences.
13. Subject to your approval in principle, the TGA will undertake a targeted consultation through the TGA's Consultation Hub and prepare a Preliminary Assessment through the Office of Impact Analysis. Following this consultation, you will be briefed further on the recommended approach, including next steps for progressing of any proposed regulatory amendments to Executive Council and related timing.

Background:

Nicotine pouches are small pouches (or bags) containing nicotine and other chemicals such as sweeteners and flavours. Designed to be placed between the lip and gum, nicotine pouches do not contain tobacco leaf, dust, or stem.

Nicotine pouches are different from snus, smokeless oral tobacco products, which have been banned from sale in Australia since 1991.

Regulation of nicotine pouches is evolving both domestically and internationally. Recent developments include the introduction of a ban on nicotine pouches by the South Australian Government on 30 January 2025 and a 2024 study finding 34 out of 67 countries surveyed were regulating nicotine pouches in some way, including absolute bans.

To give effect to this proposal, the TGA would propose to amend the Therapeutic Goods Regulations 1990 (the Regulations) to:

a. prescribe that an approval under SAS (Category B) or an authority under the AP scheme must not be given for nicotine pouches (subsection 19(8) of the Act refers)
b. amend sub regulation 12A(1) of the Regulations to exclude nicotine pouches from the exemption under Section 18(1) of the Act (SAS A pathway), and
c. amend items 1 and 6 in Schedule 5 to the Regulations to prohibit the personal importation and extemporaneous compounding of nicotine pouches.

Noting only 3% of nicotine imports are lawful, the proposed consultation would seek to understand the behaviours driving prescribing and lawful importation and determine the impact on prescribers and patients who legitimately access nicotine pouches if these pathways were to close.

The PIS allows individuals to import up to 3 months' supply of an unapproved therapeutic good for personal use with a valid prescription or written authority from a medical practitioner.

This proposal supports the Government's broader objectives to reduce nicotine addiction and aligns with the objectives, priorities and targets set out in the National Tobacco Strategy 2023-2030, including preventing and reducing the marketing and harms associated with novel and emerging products.

This approach also aligns with the next phase of the National Tobacco and E-cigarette Campaign and Youth Vaping Education Campaign. Launched on 18 January 2026, the campaign includes below-the-line messaging on the risks of nicotine products to help pre-empt a shift towards using emerging nicotine products.

Feedback from public health stakeholders to date, including at your Tobacco Control and Novel Nicotine Products Roundtable on 10 December 2025, has been very supportive of strengthening the regulation of nicotine pouches, to ensure the Government's achievements in vaping regulation are not undermined by new nicotine products aimed at young people.

Under the 2025-26 Budget, $2.9 million was committed to implement a monitoring system and develop early intelligence on the incidence and health impacts of novel nicotine products. The department has commissioned the University of Queensland to undertake a literature review on nicotine pouches, which will be finalised by March 2026. This, and other monitoring and research being undertaken, will be used to inform further options to restrict access to novel nicotine products, where required.

Sensitivities:

Nicotine pouches are marketed by the industry as a 'safe' alternative to smoking and vapes. There is likely to be criticism from some consumers and suppliers that this approach further restricts alternatives to smoking or vaping and impacts on options to support smoking cessation. However, the long-term health impacts of nicotine pouches remain unclear, and there is a clear risk of nicotine addiction.

There are other emerging nicotine products that may present many of the same issues and risks as pouches, such as nicotine pearls, gummies and toothpicks. Due to the surge in nicotine pouch imports and pressure on the ABF and TGA, the proposed approach only includes nicotine pouches in the immediate term.

There may be criticism from health care practitioners and the public about closing the approved access pathways for unapproved goods instead of just the PIS. Targeted consultation will include obtaining an understanding prescribing behaviours and what other lawful alternatives may be accessible. The TGA is concerned that closing only one pathway would just shift the issue to the other pathways and create an additional administrative burden at and post border. Restricting the approved pathways for unapproved goods simultaneously mitigates this risk and sends a strong message to the community about nicotine pouches.

There may be concern from some stakeholders that the approach does not go far enough and there may be calls to regulate nicotine pouches as vaping goods. To do so would require legislative amendment such as declaring nicotine pouches and novel unapproved nicotine products as vaping goods under Section 41P of the Act s.42 s.42 s.42 You will be briefed further on this option if required.

Consultations:

Internal consultation has included the Regulatory Legal Services Division, Regulatory Compliance Branch and Population Health Division. This submission proposes to undertake further consultation both internally and externally before implementation.

Regulatory Burden Implications and/or Deregulation Opportunities:

The Office of Impact Analysis will be consulted for advice on whether an Impact Analysis Assessment is required for any proposed regulatory changes.

Communication/Media Activities:

On 7 August 2025, the TGA published a website community news statement to alert the public, consumers and health professionals to health risks and unlawful advertising and online sales of nicotine pouches. A communications plan would be developed to support any regulatory change.

Australian Government
Department of Health, Disability and Ageing

Ministerial Submission – Standard
MS26-000431
Version (1)
Date sent to MO: 24 April 2026

To: **Minister Butler**

Subject: **Nicotine pouch regulation reform**

Critical date: **30 April 2026** to enable consideration by the Federal Executive Council meeting scheduled on 25 June 2026.

Recommendation:

1. **Approve** the preparation of the proposed amendments to the Therapeutic Goods Regulations 1990 to close the lawful pathways for accessing nicotine pouches as unapproved therapeutic goods in Australia.

1. **Approved/Not approved/ Please discuss**

Signature .....

Date: 01/05/26

Comments:

Please work with my office on a comm's plan

Contact Officer:	Ashley McLachlan-Bent	Assistant Secretary, Vaping Implementation and Enforcement Branch, Regulatory Practice and Support Division	Ph: s.22 Mobile: s.22 s.22
Clearance Officer:	Professor Anthony Lawler	Deputy Secretary, Health Products Regulation Group	Ph: s.22 Mobile: s.22 s.22

Submission summary: This submission seeks your agreement to prepare amendments to the Therapeutic Goods Regulations 1990 (the Regulations) to close the currently lawful pathways for accessing nicotine pouches as unapproved therapeutic goods in Australia. The Therapeutic Goods Administration (TGA) completed a targeted external consultation on the proposed amendments which received overwhelming support from stakeholders. Subject to your approval, the proposed regulations would be progressed for consideration at Federal Executive Council (ExCo) on 25 June 2026.

Issues:

1. On 10 February 2026, you agreed for the TGA undertake targeted consultation on proposed amendments to the Regulations to close the lawful pathways for accessing nicotine pouches (**MS25-001468** refers).
2. Consultation opened on 27 March and closed on 15 April 2026. The TGA received a total of 24 responses. An overwhelming majority of submissions were supportive of the proposed amendments on the basis that nicotine pouches lack evidence of therapeutic benefit and are not TGA evaluated or listed on the Australian Register of Therapeutic Goods (ARTG). Respondents also noted that continued and increasing access risks misleading the public and clinicians, and exacerbating youth misperceptions about harm.
3. One submission, from the s.22 did not support the proposed amendments. While the submission recognised that nicotine pouches present a potential public health risk, it recommended prioritising harm reduction and suggested nicotine pouches are likely to provide a less harmful alternative method of nicotine consumption than conventional combustion products like cigarettes.
4. Submissions from peak health stakeholders, academics, and Commonwealth and state and territory health and policing agencies provided strong support for the proposal, stating there was no evidence to support the use of nicotine pouches as a therapeutic good.
5. Key feedback also included that the proposed regulations would support domestic and border enforcement of these products and strengthen public messaging about the public health risks of nicotine products. There was also strong support for the TGA to ensure the proposed amendments are future-proof to deal with other emerging nicotine products.
    - The proposed approach only includes nicotine pouches in the immediate term due to the surge in imports and pressure on the Australian Border Force (ABF) and TGA. Other products may be considered once the initial regulations are implemented.
6. Based on the outcome of consultation, the TGA recommends progressing amendments to the Regulations to close access to nicotine pouches through the existing TGA special access and personal importation pathways.
7. The proposed amendments would:
    - protect public health, particularly for young people, by preventing the uptake and ongoing use of nicotine pouches
    - support the objectives of the vaping reforms to prevent the normalisation and use of nicotine products, and the risk of consumer displacement from vaping goods to nicotine pouches
    - strengthen the integrity of the therapeutic goods regulatory framework by ensuring access pathways for unapproved therapeutic goods are used consistently with their intended purpose, and
    - reduce regulatory, compliance and border enforcement burden on the TGA and the ABF.
8. The amendments are necessary to address the risks of increasing illegal importation, advertising and availability of nicotine pouches in Australia.
9. The proposed regulation amendments would be prepared for consideration and making by the Governor-General at the ExCo meeting on 25 June 2026. Your final approval of the proposed regulations as part of the ExCo package would be sought prior to this.
10. While timing is compressed, the planned amendments are proposed to go to the 25 June 2026 ExCo to enable the TGA and ABF to limit ongoing public health risks and enable regulatory and enforcement resources to be refocused.

Background:

There are 5 primary pathways to access unapproved therapeutic goods- the Special Access Scheme (SAS A and B), Authorised Prescriber (AP) scheme, Personal Importation Scheme, and pharmacist compounding. They are designed to meet compelling clinical needs and are not intended to provide broad or routine access to products that do not have an established therapeutic role, or present emerging public health risks.

The TGA proposes to contemporaneously close the pathways for nicotine pouches, by amending the Regulations to:

- prescribe that an approval under SAS (category B) or an authority under the AP scheme must not be given for nicotine pouches (subsection 19(8) of the *Therapeutic Goods Act 1989* [the Act])
- amend sub regulation 12A (1) of the Regulations to exclude nicotine pouches from the exemption under 18(1) of the Act (SAS A pathway), and
- amend items 1 and 6 in Schedule 5 to the Regulations to prohibit the personal importation and extemporaneous compounding of nicotine pouches.

This proposal does not affect:

- access to approved nicotine replacement therapies (NRT), such as patches, gum, lozenges or inhalators, which have an established role in smoking and vaping cessation
- sponsors seeking inclusion of nicotine pouch products on the ARTG for a therapeutic indication, or
- access to nicotine pouches for legitimate research purposes through the Clinical Trials Notification or Clinical Trials Approval schemes.

Sensitivities:

As part of the consultation, one stakeholder provided feedback that nicotine pouches should be viewed as a harm-minimisation alternative to smoking and vaping, and that the proposed reforms would limit cessation options. There was significant stakeholder feedback that the long-term health impacts of nicotine pouches are unclear and that there is a clear risk of nicotine addiction. There is a range of ARTG-listed pharmacotherapies and NRTs, as well as a regulated pathway for therapeutic vaping goods for individuals seeking support to manage nicotine dependence or to quit smoking.

Evidence from the ABF and TGA suggests that as many as 3% of nicotine pouch imports into Australia are lawful under the current arrangements. On this basis, there are some people who would be unable to import and use these products following the regulation amendments. Responses provided through the consultation emphasised the lack of evidence supporting the use of nicotine pouches for nicotine dependence or to quit smoking, and that alternative treatments such as approved NRTs or therapeutic vapes are more appropriate. This messaging will be consistent in communication products and responses to enquiries or complaints.

A submission from the ABF sought confirmation from the TGA about whether additional funding would be available to enforcement agencies to implement the proposed changes. The TGA will continue to consult with the ABF about implementation of the amendments and the management of any impact. s.47E(d)

Your Tobacco and E-Cigarette roundtable with health, industry, and state and territory representatives in December 2025 garnered strong support for proactive regulatory action on emerging nicotine products including nicotine pouches. Stakeholders emphasised the importance of addressing these products early to support the Government's broader vaping reform objectives and to protect young people from nicotine addiction.

Consultations:
The TGA undertook a targeted consultation with key health organisations and peak body representatives, government agencies, and state and territory stakeholders from 27 March to 15 April 2026 to inform the proposed regulatory amendments. Over 80 stakeholders were consulted, including key health and peak bodies, relevant government agencies, states and territories, and tobacco and vaping experts, to ensure a broad range of perspectives were considered and to support effective implementation. A list of consulted stakeholders and those who provided a submission is at **Attachment A.**

Regulatory Burden Implications and/or Deregulation Opportunities:
The Office of Impact Analysis has advised that the preparation of an Impact Analysis is not required in relation to the proposed amendments (**OIA26-11119**).

Communication/Media Activities:
Your office will be briefed on a communications plan support the proposed changes and ensure consumers and health practitioners are aware of the changes, what they mean and existing options to support the management of nicotine dependence.

Attachment:
A: List of external stakeholders consulted

From: s.22
To: s.22
Subject: For filing: Update on the inclusion of nicotine pouch-related measures in the TG Fees and Charges regulations package of 25 June [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]
Date: Thursday, 28 May 2026 4:13:05 PM
Attachments: image001.png
image002.png

OFFICIAL:Sensitive//Legal-Privilege

Hi s.22

Can you please file this decision to progress the pouch amendments to ExCo on 25 June noting that the regulations will come into effect on the 29th day after they are made – which is 23 July.

Can you also note this in the project plan.

Thanks,
s.22

OFFICIAL:Sensitive//Legal-Privilege

From: FINTAN, Dave <Dave.FINTAN@Health.gov.au>
Sent: Thursday, 28 May 2026 2:06 PM
To: s @Health.gov.au>; GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; s.22 @health.gov.au>; s.22 @health.gov.au>; MCLACHLAN-BENT, Ashley <Ashley.MCLACHLAN-BENT@health.gov.au>; s.22 s.22 @Health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; s.22 @health.gov.au>; s.22 @Health.gov.au>; s.22 @Health.gov.au>; s.22 @health.gov.au>; SYME, Sarah <Sarah.Syme@health.gov.au>; s.22 @health.gov.au>; s.22 @Health.gov.au>
Subject: RE: Update on the inclusion of nicotine pouch-related measures in the TG Fees and Charges regulations package of 25 June [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

OFFICIAL:Sensitive//Legal-Privilege

Hi s.22 and team

s.42 [redacted]

cheers

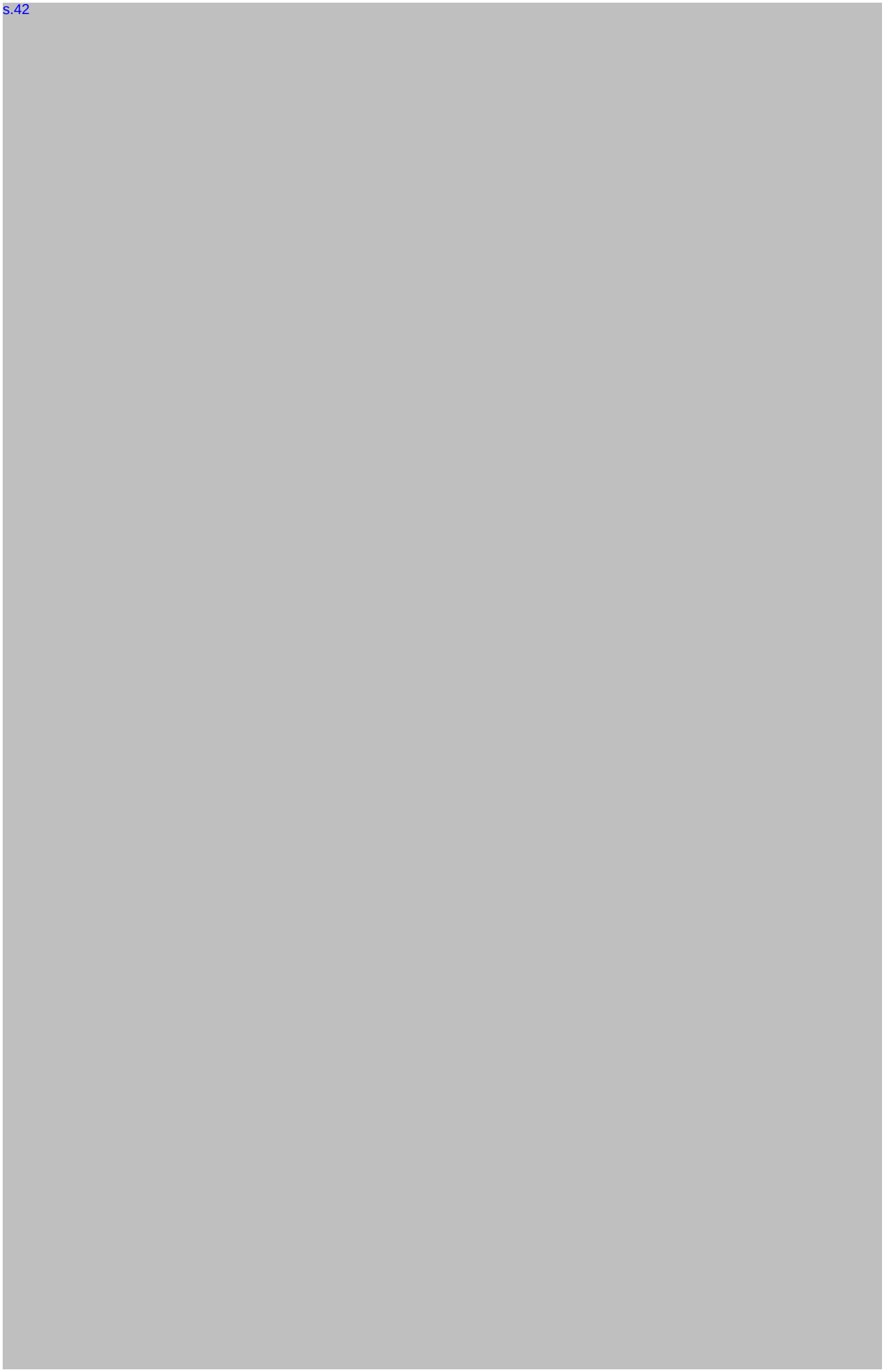
Dave Fintan
s.22 [redacted]

OFFICIAL:Sensitive//Legal-Privilege

From: s.22 [redacted] @Health.gov.au>
Sent: Thursday, 28 May 2026 2:12 PM
To: GILMOUR-WALSH, Bridget <Bridget.GILMOUR-WALSH@Health.gov.au>; FINTAN, Dave <Dave.FINTAN@Health.gov.au>; s.22 [redacted] @health.gov.au>; s.22 [redacted] @health.gov.au>; MCLACHLAN-BENT, Ashley <Ashley.MCLACHLAN-BENT@health.gov.au>; s.22 [redacted] @Health.gov.au>
Cc: BEDFORD, Chris <Chris.Bedford@health.gov.au>; s.22 [redacted] @health.gov.au>; s.22 [redacted] @Health.gov.au>; s.22 [redacted] @Health.gov.au>; s.22 [redacted] @health.gov.au>; SYME, Sarah <Sarah.Syme@health.gov.au>; s.22 [redacted] @health.gov.au>; s.22 [redacted] @Health.gov.au>
Subject: Update on the inclusion of nicotine pouch-related measures in the TG Fees and Charges regulations package of 25 June [SEC=OFFICIAL:Sensitive, ACCESS=Legal-Privilege]

OFFICIAL:Sensitive//Legal-Privilege

s.42 [redacted]


s.42

s.42

Thanks

s.22 he/him)
Lawyer – Legislation
Legislation, Advice and FOI Branch

Regulatory Legal Services Division | Health Products Regulation Group
Australian Government, Department of Health, Disability and Ageing
T: s.22 @health.gov.au

This email comes to you from Wurundjeri Woi-wurrung Country.
Location: Level 15, 595 Collins St, Melbourne VIC 3000

The Department of Health, Disability and Ageing 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.

Australian Government
Department of Health, Disability and Ageing

Ministerial Submission – Standard
MS26-000526
Version (1)
Date sent to MO: 9 June 2026

To: **Minister Butler**

Subject: **Proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 and Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026**

Critical date: **15 June 2026** - to ensure the regulations can progress to the Federal Executive Council meeting on 25 June 2026, and certain measures can commence by 1 July 2026.

If the amendments are not in place by 1 July, the Therapeutic Goods Administration (TGA) risks under-recovering for its cost-recovered activities, affecting the financial sustainability of the TGA's operations.

Recommendations – that you:

1.	**APPROVE** the text of the proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 (**Attachment A**) and the text of the proposed Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026 (**Attachment B**)	1. **Approved / Not approved / Please discuss**
2.	If you approve (1) above, **SIGN (BUT NOT DATE)** the proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 (**Attachment A**) and the proposed Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026 (**Attachment B**)	2. **Signed / Not signed / Please discuss**
3.	**SIGN (BUT NOT DATE)** the Executive Council Minutes for the proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 (**Attachment C**) and the proposed Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026 (**Attachment D**)	3. **Signed / Not signed / Please discuss**

4.	**INITIAL EACH PAGE** of the two Explanatory Memoranda for the proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 (**Attachment E**) and the proposed Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026 (**Attachment F**)	4. **Initialled / Not initialled / Please discuss**
5.	**APPROVE** the two Explanatory Statements for the proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 (**Attachment G**) and the proposed Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026 (**Attachment H**)	5. **Approved / Not approved / Please discuss**

Signature ..... Date: 16 / 06 / 2026

Comments:

Contact Officer:	*Chris Bedford*	*First Assistant Secretary, Regulatory Practice and Support Division*	Ph: s.22 Mobile: s.22
Clearance Officer:	*Professor Anthony Lawler*	*Deputy Secretary, Health Products Regulation Group*	Ph: s.22 Mobile: s.22

Submission summary:

Your approval is sought for amendments to the *Therapeutic Goods Regulation 1990* (the TG Regulations), the *Therapeutic Goods Medical Devices) Regulations 2002* (the MD Regulations), and the *Therapeutic Goods (Charges) Regulations 2018* (the Charges Regulations), for consideration by the Federal Executive Council at its meeting on 25 June 2026.

These amendments would be made by the proposed *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026* and *Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026* (the proposed regulations).

s.22

The *Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026* also seeks to amend the TG and MD Regulations to: s.22

s.22

s.22 (2) close pathways for accessing nicotine pouches as unapproved therapeutic goods in Australia.

Issues:

1. Your approval is sought for the making of the proposed regulations, which would amend the TG Regulations, the MD Regulations and the Charges Regulations.
2. The proposed regulations would:

s.22

   c. close most pathways for accessing nicotine pouches as unapproved therapeutic goods.

3. Subject to your approval, the proposed regulations would be lodged with the Federal Executive Council for its meeting on 25 June 2026.
4. Subject to the Governor-General making the proposed regulations, they would be registered on the Federal Register of Legislation.

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The amendments relating to nicotine pouches would commence on the 28th day after the instrument is registered.

Background:

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8. On 1 May 2026, you approved (MS26-000431) the preparation of amendments to the TG Regulations to close the lawful pathways for accessing nicotine pouches as unapproved therapeutic goods in Australia. The continued supply of unapproved nicotine pouches poses significant health and safety risks to Australians and risks undermining the objectives of the Government's tobacco and vaping control reforms.

9. As such, the proposed regulations also include measures to amend the TG Regulations to exclude nicotine pouches from the Special Access Scheme Category A and B pathways, the Authorised Prescriber pathway, the Personal Importation Scheme, and the extemporaneous compounding exemption.

Sensitivities:

s.22

12. From the targeted external consultation on the nicotine pouch measure, there was overwhelming support for the proposed amendments by health professionals and health peak bodies. There may be some opposition from industry, retailers and consumers who could argue that the amendments remove a lower-risk alternative to cigarettes.

13. There is clear support from the health sector that these products pose a significant public health risk including increasing the risk of nicotine dependence, particularly for young people.

14. Some sensitivities may arise from travellers visiting Australia who will not be permitted to bring nicotine pouches into Australia as there is no "traveller's exemption" proposed. The Australian Border Force (ABF) support the proposed changes, which will provide greater clarity on the regulation of nicotine pouches. The TGA is working with the ABF to finalise border arrangements following the implementation of the changes.

15. The ABF sought advice on potential resourcing implications. The TGA will continue to consult on implementation. s.47E

16. The TGA is producing a communications strategy for the amendments.

17. Existing regulated therapeutic pathways (including ARTG-listed pharmacotherapies, nicotine replacement therapies and therapeutic vaping goods) remain available to support smoking cessation.

Consultations:

s.22

20. As outlined in MS26-000431, the TGA undertook a targeted consultation from 27 March to 15 April 2026 to inform the proposed nicotine pouch regulatory amendments. Over 80 stakeholders were approached as part of the consultation, including key health and peak bodies, relevant government agencies, states and territories, and tobacco and vaping experts. A broad range of perspectives were considered to support effective implementation. The TGA received 24 submissions, 23 of which supported the proposal.

Regulatory Burden Implications and/or Deregulation Opportunities:

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23. In relation to the nicotine pouch amendments, the OIA advised that an impact analysis is not required (OIA reference: OIA26-11119).

Communication/Media Activities:

s.22

25. For the nicotine pouch measures, the TGA is developing a communications strategy to support implementation of the proposed amendments. This will include supporting consumers, healthcare practitioners and other stakeholders to understand the amendments. The TGA will also work closely with the ABF to ensure clarity of arrangements as part of implementation at the border.

Attachments:

s.22 [redacted]

Minister	**Minister Butler**
PDR Number	**MS26-000526**
Subject	**Proposed Therapeutic Goods Legislation Amendment (Fees and Other Measures) Regulations 2026 and Therapeutic Goods (Charges) Amendment (2026 Measures No. 1) Regulations 2026**
Critical Date	**Monday, 15 June 2026**
Contact Officer	Chris Bedford First Assistant Secretary, Regulatory Practice and Support Division s.22 [redacted]
Clearance Officer	Professor Anthony Lawler Deputy Secretary, Health Products Regulation Group s.22 [redacted]
Division/Branch	|Regulatory Practice and Support Division | Regulatory Engagement Branch
Has Budget Branch been consulted if there are financial implications?	Not Applicable
Ensuring connected products across the Portfolio	Have disability/NDIS linkages been considered and outlined as relevant? YES ☐ NO ☒ N/A ☐ Have aged care linkages been considered and outlined as relevant YES ☐ NO ☒ N/A ☐

Adviser/DLO comments:	Returned to Dept for: REDRAFT ☐ NFA ☐

Please complete	
Quality Assurance Check (completed by line area)	s.22

Consultation Analysis

Regulation of Nicotine Pouches

On 10 February 2026, the Minister for Health, Disability and Ageing agreed that the Therapeutic Goods Administration (TGA) undertake targeted consultation on proposed amendments to strengthen the regulation of nicotine pouches.

Consultation was conducted from 27 March to 15 April 2026 with health peak bodies, government agencies, and tobacco control and vaping experts. The TGA identified medical and pharmacy stakeholders who have a primary interest in the proposal – noting nicotine pouches can only be supplied through the existing pathways by prescribers.

The TGA received 24 submissions, the majority of which supported the proposal. This paper summarises the principal issues raised in response to the consultation questions.

Do you support the proposed amendments to prevent access to unapproved nicotine pouches? What impacts do you anticipate if the proposed amendments are implemented or not implemented?

Summary of responses: 24 responses, 23 supportive and 1 not supportive

There was near-unanimous support for strengthening the regulation of nicotine pouches. Stakeholders consider the current evidence base insufficient to demonstrate that nicotine pouches are safe or effective for smoking or vaping cessation. On this basis, there is significant support for the proposal to remove access to nicotine pouches through established TGA pathways for unapproved therapeutic goods. Submissions noted that ongoing access could be interpreted as conferring therapeutic legitimacy.

Protecting young people was a major theme. Nicotine pouches were identified as discreet, flavoured and promoted through social media. Several responses drew parallels with the rapid uptake of vaping among young people. Emerging Australian data was also cited as indicating growing awareness and experimentation among adolescents and young adults, with concerns about nicotine dependence and brain development.

Regulatory clarity and enforcement were also important themes. Current TGA pathways were identified as vulnerable to misuse, creating compliance challenges and potentially weakening state tobacco and nicotine controls. Removing access to nicotine pouches through these pathways is seen as a way to reduce perceived ‘loopholes’ and enable clearer compliance, seizure and enforcement action. s.22 noted this would align with existing state bans. s.22 also supported a clearer prohibition to improve border seizure and disposal. s.22 reiterated that the proposed reforms would increase clarity for s.22 and handling of seized nicotine pouches.

One stakeholder, s.22, raised concerns that removing access could disadvantage highly nicotine-dependent smokers who have not responded to existing therapies and could increase illicit market activity. This highlighted the tension between population-level prevention and targeted harm reduction.

Overall, what do you consider the likely impact to be: predominantly positive or negative?

Summary of responses: 20 positive, 3 mixed and 1 unsure.

Based on your experience or evidence, are there clinical circumstances in which unapproved nicotine pouches provide a therapeutic benefit that is not met by existing smoking and vaping cessation pharmacotherapies?

There was broad agreement that no clinical circumstances were identified in which nicotine pouches provide a therapeutic benefit beyond existing evidence-based cessation therapies.

The 2025 Cochrane Review (Hartmann-Boyce et al., 2025) was frequently cited as indicating that the evidence base for these products remains limited and uncertain. Concerns centred on the small number of trials, high risk of bias, and lack of evidence that nicotine pouches support smoking cessation. Some responses also indicated that nicotine pouches may be less effective than e-cigarettes and do not offer a distinct therapeutic benefit.

Product quality, safety and dosing were also identified as concerns. These included variation in nicotine content, inconsistent labelling and consumer information, and the absence of regulation through inclusion in the Australian Register of Therapeutic Goods (ARTG). Collectively, these issues present avoidable patient safety and poisoning risks, particularly for young children who may be inadvertently exposed.

Allowing unapproved nicotine pouches through therapeutic pathways was generally viewed as likely to weaken public health messaging. This could confuse consumers and clinicians, blur the distinction between approved therapies and quasi-regulated products, and normalise ongoing nicotine use, particularly among young people.

Some stakeholders raised that current clinical guidelines prioritise approved pharmacotherapies supported by behavioural interventions. As such, endorsing nicotine pouches would not align with evidence-based cessation practice.

s.22 raised equity concerns, arguing that reduced access could disproportionately affect disadvantaged groups if access to approved cessation supports is not improved concurrently. However, it also acknowledged that the therapeutic benefit of nicotine pouches has not been established and called for further evidence rather than clinical endorsement.

Overall, the consultation supported a regulatory approach that reinforces clear public health messaging and prioritises ARTG-approved, evidence-based cessation therapies.

Are there any additional issues, risks or considerations relevant to this proposal that the TGA should consider?

The proposed amendments were viewed as an important public health signal that nicotine pouches are unapproved, addictive and not established cessation therapies. Regulation amendments alone however, was generally considered insufficient without strong and sustained enforcement, particularly online.

A consistent concern was that tighter controls could shift supply to illicit markets, including through organised crime. Enforcement resources were described as already stretched by illicit tobacco and vaping activity, with supply likely to move further underground through online platforms, social media and encrypted messaging services.

Misuse of current access pathways was also raised, including online prescribing and commercial practices that may undermine regulatory intent. There was strong support for online compliance measures, platform takedowns and penalties that outweigh commercial incentives.

Several stakeholders mentioned a future-proofed framework. A narrow focus on nicotine pouches was seen as likely to shift demand to other products, including nicotine toothpicks, pearls, nicotine analogues such as 6-methylnicotine, and products marketed as nicotine-free.

Product quality, safety and youth appeal were also identified as key concerns. These included the absence of standards for labelling, ingredients, packaging and child safety, as well as flavours, colours and marketing practices not consistent with therapeutic goods regulation.

Suggested complementary measures included controls on online sales, stronger supply-chain oversight, and coordinated action with states and territories. Public education and affordable, evidence-based cessation support were also identified as important to reduce reliance on unapproved products.

Several responses also emphasised the need to prevent tobacco industry interference and uphold Australia's obligations under the World Health Organization Framework Convention on Tobacco Control.

Overall, the proposal was seen as a necessary first step, to be supported by broader enforcement, supply-side and public health measures.

Should the TGA consider additional regulatory measures to address emerging nicotine products that extend beyond the current scope of this proposal? If so, what should these measures be?

There was strong support for a product-agnostic approach to emerging nicotine products. Regulating products individually was considered a risk to delayed or fragmented controls, allowing market establishment and youth uptake before enforcement could respond effectively. A broad framework was therefore supported to capture all unapproved nicotine products, including other emerging oral formats, as well as nicotine analogues and substitutes such as 6-methylnicotine.

Online and social media marketing was also identified as contributing to youth appeal and misinformation. Active monitoring, stronger enforcement of advertising restrictions and public health communication were advocated for to counter claims that these products are safe, therapeutic or performance-enhancing.

Protecting the integrity of the therapeutic goods framework was also emphasised. Unapproved access pathways were seen as capable of becoming de facto markets and reducing incentives for evidence generation and ARTG registration. If unapproved products remain available, quality standards, child-resistant packaging and warning requirements were identified as important safeguards.

There was also strong support for coordinated national enforcement and close collaboration with states and territories.

Ongoing surveillance was also emphasised to identify emerging products early. Some responses pointed to evidence that young people are already accessing unapproved nicotine gum and other emerging products.

Consultation Submissions

All stakeholder submissions are in Content Manager: E26-248563

Submissions were received from the following groups:

s.22