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

Submission of the Department of Health and Aged Care to the  
Senate Standing Committee on Community Affairs Legislation  
Inquiry into the Therapeutic Goods and Other Legislation Amendment  
(Vaping Reforms) Bill 2024

**12 April 2024**



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## Introduction

The Department of Health and Aged Care (the department) welcomes the opportunity to make a submission to the Senate Standing Committee on Community Affairs Legislation *Inquiry into the Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024*.

The marketing and use of vapes (also known as e-cigarettes-) has rapidly increased in Australia and internationally over the past few years, particularly among young people. There is strong evidence that non-smokers who vape are more likely to take up smoking, compared to those who do not vape.<sup>1</sup> Normalisation of vaping has the potential to disrupt Australia's significant achievements in tobacco control. Evidence of widespread non-compliance with existing Commonwealth, state and territory laws also underscores the need for action.<sup>2</sup>

The Australian Government has committed to strengthening the regulation of vapes as part of a comprehensive approach to reduce tobacco and e-cigarette use. The Government's approach acknowledges the current evidence regarding the direct health risks that vapes may pose to human health, and the impact that vaping may have on population-wide tobacco use.

The Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (the Bill) would amend the *Therapeutic Goods Act 1989* (the TG Act) to restrict the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable single use vapes while at the same time preserving legitimate patient access to therapeutic vapes for smoking cessation and the management of nicotine dependence. The Bill builds on the Government's reforms to the regulation of vaping goods, which commenced from 1 January 2024.

Strengthening the regulation of all vapes across all stages of the supply chain, banning all disposable single use vapes and ending sales outside of pharmacy settings will make it easier to identify and disrupt the illicit supply of vapes and take enforcement action against commercial operators.

The vaping reforms complement and support the broader actions being taken by the Government to meet the objectives of the National Tobacco Strategy 2023-2030<sup>3</sup>, and are in line with Australia's obligations as a Party to the World Health Organization Framework Convention on Tobacco Control (WHO FCTC).<sup>4</sup> The reforms build on the comprehensive range of tobacco control measures implemented by all Australian governments to reduce smoking rates. New public health information campaigns and a range of measures to support Australians to quit smoking and vaping will be implemented nationally to ensure Australians have access to education and support to prevent and reduce the use of tobacco and e-cigarettes.

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<sup>1</sup> Baenziger ON et al. (2021) 'E-cigarette use and combustible tobacco cigarette smoking uptake among non-smokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis,' *BMJ Open* 11(3). Available at: <https://pubmed.ncbi.nlm.nih.gov/33785493/>

<sup>2</sup> Throughout this submission, the term vape is used synonymously with e-cigarette unless expressly indicated otherwise. E-cigarette is the expression used in the National Tobacco Strategy 2023-2030. For convenience, vape is a shorthand expression for vaping goods, which is defined in the Bill to mean one or more, vaping substances, vaping accessories and vaping devices.

<sup>3</sup> Department of Health and Aged Care, 'National Tobacco Strategy 2023-2030' (2023). Available at: National Tobacco Strategy 2023-2030 | Australian Government Department of Health and Aged Care.

<sup>4</sup> United Nations, 'Chapter IX, Health, WHO Framework Convention on Tobacco Control' (Web Page, United Nations Treaty Collection, 21 May 2003) UNTC.



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Further detail on the contents of the Bill and the consultation undertaken in its development is available in the [Explanatory Memorandum](#). The Committee may also wish to consider the [Impact Analysis](#) which is available online. The Impact Analysis includes detailed discussion of the policy objectives, the rationale for reform, the outcomes of consultations with stakeholders and the evidence base for the measures contained in the Bill.

Finally, the department draws the Committee's attention to a recent response from the Minister to the Senate Standing Committee for the Scrutiny of Bills relating to several matters contained in the Bill. The response is expected to be published shortly.

## Tobacco and e-cigarette control in Australia

### National Tobacco Strategy 2023-2030

Australia's National Tobacco Strategy 2023-2030 (the Strategy) sets out a policy framework for the Commonwealth, state and territory governments to work together and in collaboration with non-government organisations to improve the health of all Australians by reducing the prevalence of tobacco use, associated health, social, environmental and economic costs, and the inequalities caused by its use.<sup>5</sup> The Strategy includes targets to reduce daily smoking prevalence in Australia to below 10% by 2025 and to 5% or less by 2030, and to reduce smoking rates among First Nations people to 27% or less by 2030.

The Strategy complements and strengthens the implementation of Australia's obligations as a Party to the WHO FCTC.<sup>6</sup> Australia has committed to implement a range of tobacco control measures to reduce supply and demand and to protect these measures from commercial and other vested interests of the tobacco industry, in accordance with national law. Article 5.2(b) of the WHO FCTC obliges Parties to adopt and implement effective measures to prevent and reduce nicotine addiction. Australia continues to be guided by its obligations under the Convention and decisions of the Conference of the Parties (COP), the governing body to the WHO FCTC.<sup>7,8</sup>

The objectives, priorities and actions of the Strategy also provide a national policy framework for reducing the widespread marketing and use of e-cigarettes. The Strategy recognises the importance of ensuring that sufficient controls are in place to protect the Australian community from the range of tobacco, nicotine and other drug delivery systems that may be marketed by the tobacco industry, the e-cigarette industry and their associated interests. Accordingly, Priority Area 9 of the Strategy is to '*Strengthen regulations on e-cigarettes and novel and emerging products*'.<sup>9</sup>

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<sup>5</sup> [National Tobacco Strategy 2023–2030 | Australian Government Department of Health and Aged Care](#).

<sup>6</sup> WHO Framework Convention on Tobacco Control. Available at WHO Framework Convention on Tobacco Control.

<sup>7</sup> The COP has previously invited Parties to take measures in relation to Electronic Nicotine Delivery Systems (ENDS)/Electronic Non-nicotine Delivery Systems (ENNDS) and to consider prohibiting or otherwise regulating them, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health. The COP has also invited Parties to apply regulatory measures to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS.

<sup>8</sup> See: <https://extranet.who.int/fctcapps/fctcapps/fctc/kh/legalchallenges/challenges-measures-which-regulate-novel-and-emerging-tobacco-and>.

<sup>9</sup> Ibid.



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## International experiences

Globally, the regulatory arrangements applicable to vapes vary considerably within and across countries. These range from prohibition to minimal or no regulation, with a range of models to regulate vapes as tobacco products, consumer products, medicines or standalone frameworks specific to vapes. Different approaches have been adopted according to national contexts.

As vapes have been marketed and used in Australia for the therapeutic purpose of smoking cessation, it is appropriate that they are subject to the same regulatory controls as any other therapeutic goods. This is proposed to be delivered through a pharmacy-only model for the supply of vapes. The proposed approach builds on the experiences of other countries responding to the public health challenges posed by vapes, tobacco and other drug delivery systems. The policy intent is to prohibit the widespread importation, marketing and supply of vapes in Australia except for smoking cessation or the management of nicotine dependence. Vapes must comply with enhanced quality and safety standards and be supplied only in pharmacy settings, with a prescription being required to access a vape containing nicotine.

Numerous other countries are increasingly announcing and implementing strict controls to prohibit or restrict the supply, availability and promotion of e-cigarettes in view of their public health harms. For instance, New Zealand, the United Kingdom, France, Belgium and Scotland have recently announced plans to prohibit the supply of disposable single use vapes.<sup>10</sup>

## National Response to Vaping

All Australian governments are working together to support a coordinated and comprehensive national response to the regulation of vapes through stronger legislation, enforcement, education and support.

Cooperation between the Commonwealth and states and territories is led by a National E-cigarette Working Group established by the Health Ministers' Meeting in February 2023. The National E-cigarette Working Group, comprising senior health officials from all jurisdictions, has overseen the development of an implementation plan to support the National Response to Vaping, and continues to meet regularly to guide the reforms.

In May 2023, the Government announced a range of new measures to reduce smoking and vaping rates, including new measures to strengthen the regulation of all vapes under the customs and therapeutic goods frameworks.<sup>11,12</sup> This remains a key priority for all Australian Health Ministers.

In September 2023, Health Ministers agreed to the proposal to extend the operation of the TG Act to restrict the importation, domestic manufacture, and supply of all vapes. Health Ministers further agreed that the Commonwealth would lead the enforcement of new importation and manufacturing

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<sup>10</sup> See: <https://www.smoke-free.ca/SUAP/2020/vaping-regs-timeline.pdf>.

<sup>11</sup> See: <https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/taking-action-on-smoking-and-vaping>

<sup>12</sup> See: <https://www.health.gov.au/sites/default/files/2023-05/tackling-smoking-and-vaping-and-improving-cancer-outcomes-budget-2023-24.pdf>.



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controls, advertising controls, and controls on therapeutic vapes, and that states and territories would lead the enforcement efforts at the point of wholesale and retail supply.

Health Ministers have engaged across portfolios to ensure the reforms are well supported. In November 2023, Health Ministers held a joint meeting with Police Ministers on the proposed development of a national enforcement framework for vaping products. At that meeting, a National Vaping Working Group comprising senior health and law enforcement officers was established to oversee the development and implementation of a National Vaping Enforcement Framework.

### Regulatory settings governing vapes in Australia

Responsibility for the regulatory settings for vapes, including compliance and enforcement, is shared between Commonwealth and state and territory governments and draws on legislation and regulations that apply to therapeutic goods and/or tobacco products.

At the Commonwealth level, the *Public Health (Tobacco and Other Products) Act 2023* (Tobacco Act) and associated regulations prohibit the advertising and promotion of e-cigarettes. Among other measures, the Tobacco Act establishes an Illicit Tobacco and E-cigarette Commissioner (ITEC) within the Australian Border Force (ABF). The ITEC will support the development and implementation of strategies for the enforcement of illicit tobacco and e-cigarette laws, advise on the development of new laws relating to the illicit trade, and publish relevant reports on the illicit tobacco and e-cigarette trade in Australia.

State and territory tobacco control legislation includes a range of other restrictions on the advertising, promotion and supply of e-cigarettes, including sales to minors, and to prohibit the use of e-cigarettes in legislated smoke-free areas.

The TG Act and associated regulations provide for the establishment and maintenance of a national system of controls to ensure the quality, safety, efficacy and timely availability of therapeutic goods. Further information regarding the regulation of vaping goods under the TG Act and the corresponding laws of the states and territories, known as the federal cooperative scheme for therapeutic goods, is outlined at **Attachment A**. The TG Act is complemented by state and territory medicines and poisons legislation, which regulates retail and wholesale supply of medicines, including nicotine vapes.

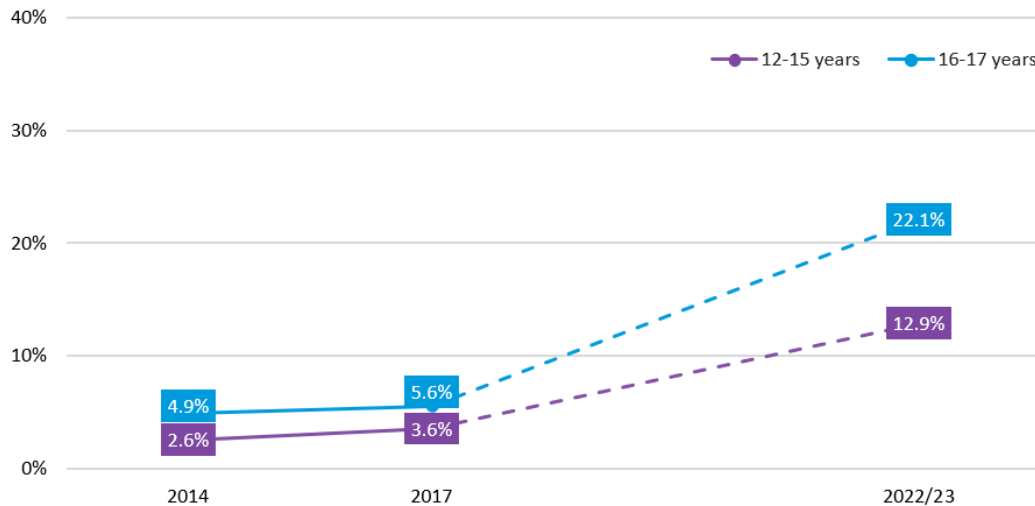
### E-cigarette use and marketing and impacts on public health

Recent data shows that among people aged 14 years and over, current use of vaping goods nearly tripled between 2019 (2.5%) and 2022–2023 (7.0%). The increase was even more marked among young people, with current use of vaping goods increasing from 5.3% to 21% among people aged 18 - 24, and from 1.8% to 9.7% among people aged 14 -17 during the same period.<sup>13</sup> Separate findings collected from secondary school students show that from 2017 to 2022-23, past month vaping increased rapidly among school students, as shown in Figure 1.

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<sup>13</sup> Ibid.

**Figure 1:** Past month vaping over time among Australian secondary school students by age group, 2014-2022/23<sup>14</sup>



Evidence demonstrating the impacts of vaping on many important health outcomes is still emerging and requires more long-term research. However, a systematic review of global evidence found that vaping increases the risk of a range of adverse outcomes including poisoning, seizures, toxicity from inhalation, addiction to nicotine and lung injury.<sup>15</sup> The review also highlighted early signs of adverse effects of vapes on cardiovascular health markers, including blood pressure and heart rates. More recent evidence suggests that vape use may increase the risk of heart failure.<sup>16</sup>

Vaping may also increase the risk of adverse oral health outcomes. Evidence suggests that vaping promotes inflammation of the gums, changes the profile of mouth bacteria toward more harmful bacteria, and reduces the gums' healing capacity.<sup>17</sup>

The wide and unpredictable variation in vapes, including unknown manufacturing quality, and the ability of users to customise device settings and vary the quantity and concentration of vaping substances, make it difficult to provide a consistent assessment about the safety and effects of vapes as a group. This submission does not provide a complete assessment of the public health risks posed by vapes. However, all users of vapes are exposed to chemicals that have the potential to cause adverse effects on physical and mental health.<sup>18, 19, 20</sup> There is also evidence of devices exploding due to overheating, causing trauma and burns.<sup>21</sup>

<sup>14</sup> ASSAD 2022/2023: Australian secondary school students' use of tobacco and e-cigarettes, Figure 11, Available at [www.cancer.org.au](http://www.cancer.org.au).

<sup>15</sup> Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

<sup>16</sup> See: <https://www.eurekalert.org/news-releases/1039622>

<sup>17</sup> Charde, P, Kamran, A and Hamden N. 2024. Effects of e-cigarette smoking on periodontal health: A scoping review. PLoS Global Public Health. Available at: <https://journals.plos.org/globalpublichealth/article?id=10.1371/journal.pgph.0002311>

<sup>18</sup> National Health and Medical Research Council. CEO Statement: Electronic Cigarettes. Canberra: National Health and Medical Research Council; June 2022.

<sup>19</sup> England LJ, Bunnell RE, Pechacek TF, Tong VT, McAfee TA. Nicotine and the developing human: a neglected element in the electronic cigarette debate. *Am J Prev Med* 2015; 49(2): 286-93.

<sup>20</sup> Australian Institute of Family Studies. The Impact of vaping on adolescent mental health: Policy and practice paper. October 2023. Available at: <https://aifs.gov.au/sites/default/files/2023-10/2309-CFCA-Vaping-and-mental-health.pdf>

<sup>21</sup> Kaltenborn A, Dastagir K, Bingol AS, Vogt PM, Krezdorn N. E-cigarette explosions: patient profiles, injury patterns, clinical management, and outcome. *JPRAS Open*. 2023 May 18;37:34-41. doi: 10.1016/j.jpra.2023.05.001. PMID: 37693690; PMCID: PMC10491958.



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Australian evidence indicates that most vapes are being used with nicotine, including by young people.<sup>22</sup> For example, a recent study conducted in NSW found that 98% of vapes confiscated from school students contained nicotine.<sup>23</sup> Research shows that adolescents who are exposed to nicotine may become addicted rapidly, and that exposure to nicotine during adolescence may have long-term adverse impacts on health and higher-level cognitive functioning.<sup>24</sup>

The impacts vaping may have on population wide tobacco use is also a relevant consideration. While current evidence regarding the effectiveness of e--cigarettes as a smoking cessation aid is limited, there is strong evidence that non-smokers who vape are more likely to take up smoking, compared to those who do not.<sup>25</sup> There is also evidence that concurrent (dual) use of e-cigarettes and conventional tobacco products is common. Data from the first quarter of 2023 showed that 1 in 5 people who smoke and/or vape in Australia are dual users.<sup>26</sup>

The widespread marketing of vapes contributes to their social acceptability, appeal and use, particularly among young people. Evidence suggests that young people exposed to e-cigarette advertising and promotion are more likely to try e-cigarettes compared to young people who are not exposed.<sup>27</sup> E-cigarette marketing communication messages contribute to decreased risk perceptions and influence attitudes about e-cigarette use.<sup>28</sup> Colours and flavours of vapes further contribute to their appeal and uptake among youth and young adults.<sup>29,30</sup>

## Proposed reforms

The Bill is the centrepiece of regulatory measures being implemented in stages over 2024. The measures support legitimate patient access to therapeutic vapes, while restricting the importation, domestic manufacture, supply, commercial possession and advertisement of disposable single use and non-therapeutic vapes. Together with other supports, the reforms are intended to reduce rates of vaping and smoking, and prevent long term adverse effects on population health, particularly among youth and young adults.

<sup>22</sup> See: <https://www.tga.gov.au/resources/publication/tga-laboratory-testing-reports/testing-vapes>.

<sup>23</sup> NSW E-Cigarette Analysis Project Summary Report. 2023. Available at: <https://www.health.nsw.gov.au/tobacco/Publications/e-cigarette-analysis-project-summary-report.pdf>

<sup>24</sup> US Department of Health and Human Services. E-cigarette use among youth and young adults. A report of the Surgeon General. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health: Atlanta, GA: U.S., 2016. Available from: [https://ecigarettes.surgeongeneral.gov/documents/2016\\_SGR\\_Full\\_Report\\_non-508.pdf](https://ecigarettes.surgeongeneral.gov/documents/2016_SGR_Full_Report_non-508.pdf).

<sup>25</sup> Ibid.

<sup>26</sup> See: Cancer Council Victoria. 2023. Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023. Available at: <https://www.health.gov.au/sites/default/files/2023-06/current-vaping-and-smoking-in-the-australian-population-aged-14-years-or-older-february-2018-to-march-2023.pdf>.

<sup>27</sup> Moola S, Tyagi J, Miller M, et al. The effects of e-cigarette advertising, promotion, and sponsorship on people's attitudes, beliefs and perceptions, intentions, and behaviours: a mixed methods systematic review. Sydney: The George Institute for Global Health, 2021.

<sup>28</sup> Office of Impact Analysis (2023). Proposed reforms to the regulation of vapes: Impact Analysis. Therapeutic Goods Administration. Australian Department of Health and Aged Care.

<sup>29</sup> Scientific Committee on Health Environmental and Emerging Risks (SCHEER). SCHEER (Scientific Committee on Health Environmental and Emerging Risks) scientific opinion on electronic cigarettes. European Commission, 2021. [https://ec.europa.eu/health/system/files/2021-04/scheer\\_o\\_017\\_0.pdf](https://ec.europa.eu/health/system/files/2021-04/scheer_o_017_0.pdf) (accessed 31 July 2021).

<sup>30</sup> Cancer Council NSW. Generation Vape study Factsheet. Available at: <https://www.cancercouncil.com.au/wp-content/uploads/2023/03/Generation-Vape-infographic.pdf>





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### Stage 1: New restrictions on importation and enhanced controls for therapeutic vapes

The first stage of the Government's vaping reforms was implemented through amendments to customs and therapeutic goods regulations. These amendments:

- ban the importation of disposable single use vapes from 1 January 2024, subject to very limited exceptions
- ban the importation of all other vaping goods from 1 March 2024, except where for smoking cessation or the management of nicotine dependence
- facilitate and enhance clinically appropriate access to therapeutic vapes in pharmacy settings.

The changes apply to all vapes irrespective of nicotine content or therapeutic claims. Sponsors must have import licences and permits. After 1 March 2024, vapes imported or manufactured must have been notified to the Therapeutic Goods Administration (TGA) as compliant with relevant quality and safety standards. Notification is a pre-condition for lawful importation and supply of vapes in Australia. The TGA has published a list of notified vapes, which is updated regularly and available [here](#). The TGA will undertake post-notification monitoring and surveillance of notified vapes against relevant safety and quality standards, including laboratory testing where relevant.

### Stage 2: Nationally consistent approach to the regulation of all vapes

The second stage of the Government's vaping reforms involves proposed amendments to primary legislation, which is the subject of this inquiry. The Bill proposes to extend the national system of controls for therapeutic goods under the TG Act to the regulation of all vapes, irrespective of nicotine content or therapeutic claims. The Bill would provide a single consistent framework to regulate the importation, domestic manufacture, supply, commercial possession, and advertisement of all vapes, not simply therapeutic vapes. Consistent with the federal cooperative scheme for therapeutic goods (outlined at **Attachment A**), the new framework for the regulation of vapes would automatically apply in all states and territories.

The Bill would introduce new offences and civil penalty provisions relating to the importation, domestic manufacture, supply, commercial possession, and advertisement of vaping goods. New offences and civil penalty provisions for commercial possession would address a critical difficulty in enforcing the current controls, where supply must generally be proven before action may be taken.

Further, the Bill would make unlawful vapes easier to detect and reduce opportunities for illicit trade. This is because nicotine content would not need to be demonstrated through laboratory testing before action could be taken under the TG Act. This would address the common practice observed throughout the industry of concealing and otherwise misrepresenting nicotine content, which has hampered enforcement efforts both domestically and at the border.

The intention of the new offences and civil penalty provisions is to deter unlawful conduct, among commercial and criminal groups seeking to profit from vapes. Numerous exceptions to the offences



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and civil penalty provisions outline the circumstances for lawful importation, domestic manufacture, supply, and commercial possession.

Importantly, the controls in the Bill would not prohibit possession of vapes for personal use. The Bill would not penalise personal possession. Individuals will not be penalised for vaping. The Bill only seeks to prevent possession for the purposes of commercial supply.

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

- enabling state and territory officers to exercise powers and functions of the Secretary, particularly compliance and enforcement powers relating to wholesale supply, retail supply and commercial possession
- extending the authority of persons able to issue warrants to court registrars and other court officers to expedite court processes while maintaining appropriate safeguards for entry, search and seizure
- facilitating information sharing with the states and territories and other compliance and enforcement bodies
- enabling the publication of information to the public about vaping goods
- creating new powers for the automatic forfeiture and destruction of unlawful vaping goods to allow the TGA to deal more effectively with seized vaping goods
- introducing a power to allow enforceable directions to be made in relation to suspected unlawful vapes to protect the health and safety of humans.

The provisions in the Bill build on global evidence on tobacco control, which demonstrates that reducing the social acceptability of e-cigarettes, ensuring effective and comprehensive governance arrangements and regulatory settings across the supply chain, and addressing the availability of informal distribution networks are critical to reducing the illicit supply of vapes.<sup>31</sup>

## Implementation

### Education and communication of regulatory reforms to stakeholders

Following the Government's announcement to strengthen the regulation of all vapes, the department is undertaking a range of education and communication initiatives, including:

- health practitioner education and communications on the regulatory reforms, codesigned with medical and pharmacy professionals and delivered by TGA, the Royal Australian College of General Practitioners and the Pharmaceutical Society of Australia
- industry education and communications on the regulatory reforms developed using ongoing feedback received from industry in response to the reform

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<sup>31</sup> World Bank Group, 2019. Controlling Illicit tobacco trade: a global review of country experiences. Available at: <https://documents1.worldbank.org/curated/en/677451548260528135/pdf/133959-REPL-PUBLIC-6-2-2019-19-59-24-WBGToBaccollicitTradeFINALvweb.pdf>.



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- webinars for national health investigators, policing authorities and prosecutors to be developed using a co-design approach with health investigators and law enforcement and delivery by TGA staff.

In 2024, the Minister for Health and Aged Care has partnered with Australian and state and territory Health and Education Ministers to write to school Principals to raise awareness of the reforms and resources available to support schools, students and their families to address vaping.

Communication channels continue to be explored to ensure community and industry awareness of the regulatory reform. Implementation of the reforms will also be supported by broader public health education and awareness raising and support initiatives as discussed below.

### Compliance and enforcement activities

Compliance and enforcement activities form an essential component of the approach to the reforms. Through MYEFO 23-24, the Government committed \$25 million over 2 years to the Australian Border Force (ABF) and \$56.9 million to the TGA to introduce and enforce these reforms.

Enforcement is a shared responsibility between Commonwealth, state and territory governments in accordance with the federal cooperative scheme for therapeutic goods (detailed at Attachment A). Compliance monitoring and enforcement of obligations under the TG Act are generally undertaken by the TGA with assistance from the police and the ABF.

To coordinate and implement this national approach, a National Vaping Working Group (NVWG) was established following a joint meeting of Health and Police Ministers on 23 November 2023. The NVWG is overseeing the development and implementation of a National Vaping Enforcement Framework. The NVWG includes senior health and law enforcement representatives from the Commonwealth, including the TGA and ABF, and all states and territories. The NVWG is jointly chaired by the Commissioner of the Australian Border Force and the Secretary of the New South Wales Ministry of Health.

The TGA has increased enforcement activity including working in conjunction with the ABF, state and territory health departments, and law enforcement agencies. Ongoing collaboration on enforcement will be supported through the National Vaping Enforcement Framework.

Under the reforms, the Commonwealth would continue to enforce the controls on importation, manufacture, sponsor supply and advertising for vapes, while the states and territories would enforce wholesale supply, retail supply and commercial possession controls. This is consistent with the existing arrangements for the enforcement of therapeutic goods laws.



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### Access and support for smoking and vaping prevention and cessation

The Government's regulatory reforms align with the latest advice from the Royal Australian College of General Practitioners, which indicates that vapes are not first line treatment options for smoking cessation or the management of nicotine dependence.<sup>32</sup> Ensuring that vapes are only accessed with medical supervision via pharmacies provides an opportunity for users to receive appropriate advice from a health professional on the risks associated with their use and other tailored health advice.

A range of support is available to help people quit smoking and vaping. This includes the provision of quit advice and support through health professionals, such as GPs, pharmacists, nurses and specialists. Confidential support advice is also available through the Quitline. A broad range of first line smoking cessation products continues to be available. These have been approved by the TGA following a rigorous assessment for safety, quality and efficacy. These products include nicotine replacement therapies (NRTs), such as nicotine gums and patches, which are widely available in supermarkets and other retail outlets, and certain other prescription only medicines.

The Government also continues to subsidise certain NRTs and prescription only medicines for smoking cessation under the Pharmaceutical Benefits Scheme.

To support health professionals, the Government also provides funding to the National Best Practice Support for Nicotine and Smoking Cessation (Quit) Centre to ensure health professionals have access to current clinical information, resources and training on smoking and vaping cessation.

The 2023-24 Budget committed \$29.5 million to expand and enhance smoking and vaping cessation support and \$63.4 million for public health campaigns aimed at addressing tobacco and vaping. This includes funding for:

- a national campaign to target young people, their parents, carers and communities, as well as a stream of activities dedicated to reaching teachers and the education sector
- a national campaign to target adults, with a focus on priority and at-risk population groups
- a national online cessation hub that contains information, tools, resources and a system to direct consumers to the best support mechanisms to assist them quit smoking and vaping
- redevelopment of the My QuitBuddy app to support smoking and vaping cessation
- clinical guidance updates to support the health workforce, developed and delivered by relevant health professional bodies such as the Royal Australian College of General Practitioners and the Pharmaceutical Society of Australia
- improved access to Quitline services across the country.

Additionally, the Government has committed \$141.2 million to expand and enhance the Tackling Indigenous Smoking Program, to reduce smoking and vaping among First Nations people.

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<sup>32</sup> See: [RACGP - Supporting smoking cessation: A guide for health professionals](#)



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Since 2015, the Medical Research Futures Fund (MRFF) has invested \$5.3 million in 4 grants with a focus on researching effective strategies to prevent the uptake of smoking and vaping amongst young people, including evidence-based resources for prevention, a process to identify effective interventions across multiple clinical trials and a generative AI project to create personalised social media campaigns that will be tested for effectiveness.

MRFF funding has supported a research trial of *The OurFutures Vaping Program* implemented as part of the health education curriculum for year 7 and 8 students, aiming to reduce the number of students vaping and smoking. The research trial was developed and delivered by the University of Sydney's Matilda Centre. The program has seen early success with more than 8 in 10 students and teachers rating the program highly, and more than 8 in 10 students saying it would help them in the future. Interest in the program is growing, with a 2024 early access scheme for 250 schools already fully subscribed.

### Monitoring impacts

The department is using a range of data sources to monitor the impacts of the regulatory reforms to vaping goods, and other complementary measures aimed at reducing vaping and tobacco use. This includes monitoring:

- vaping and tobacco prevalence and trends across the population and in key target groups, such as young people
- knowledge, attitudes and/or behaviours among key target groups, such as young people, teachers, parents and the health workforce
- industry marketing activities and behaviours
- results from compliance, enforcement and testing
- existing and emerging domestic and international research relevant to tobacco and e--cigarette control.

Strengthening monitoring and evaluation activities remains a key priority to support and guide the ongoing implementation of the vaping reforms. As part of this work, the department is consulting with states and territories on development of outcome indicators to monitor the impacts of the vaping reforms over the short, medium and longer term. These activities will also inform the development of a monitoring and evaluation framework and other implementation activities which continue to be oversee by the National E-cigarette Working Group.



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## Attachment A

### The federal cooperative scheme for therapeutic goods

The TG Act sets out the legal requirements for the importation, exportation, manufacture, supply and advertising of all therapeutic goods in Australia. Therapeutic goods include medicines, medical devices, vaccines, and biologicals. Vapes that are represented or likely to be taken to be for therapeutic use are regulated as therapeutic goods. The TG Act is supported in its operation by various forms of delegated legislation, including regulations, orders, principles and determinations.

The federal cooperative scheme for therapeutic goods is achieved by each participating jurisdiction enacting a corresponding law that adopts the Commonwealth TG Act as a law of the relevant jurisdiction. The corresponding laws in each jurisdiction fill a gap in the Commonwealth's constitutional power to regulate the activities of non-corporate entities and activities done during, or in preparation for, intrastate trade and commerce. The TG Act, and corresponding state and territory laws adopting the TG Act, are currently enforced by the TGA.

Any amendments to the TG Act to implement bans on the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable single use vapes would be automatically adopted in participating jurisdictions.

The therapeutic goods cooperative scheme operates in all jurisdictions except Western Australia ("WA"). However, the Therapeutic Goods Law Application Bill 2023 (WA) was introduced into the WA Parliament on 29 November 2023. It remains under consideration.

The TG Act does not generally regulate the wholesale supply and retail supply of therapeutic goods. It is complemented by state and territory medicines and poisons laws which regulate these matters and are enforced by the states and territories.

Separately, the [\*Therapeutic Goods \(Poisons Standard-February 2024\) Instrument 2024\*](#) (the Poisons Standard) is an instrument made under the Commonwealth TG Act for the scheduling of substances. It supports uniform controls on medicines and poisons within Australia. It is a legislative instrument that is applied by each state and territory, subject to any limitation specified by the relevant jurisdiction.