



Public Health Association
AUSTRALIA

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

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The **Public Health Association of Australia** (PHAA) is Australia's peak body on public health. We advocate for the health and well-being of all individuals in Australia.

We believe that health is a human right, a vital resource for everyday life, and a key factor in sustainability. The health status of all people is impacted by the social, commercial, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the root causes of poor health and disease. These determinants underpin the strategic direction of PHAA. Our focus is not just on Australian residents and citizens, but extends to our regional neighbours. We see our well-being as connected to the global community, including those people fleeing violence and poverty, and seeking refuge and asylum in Australia.

Our mission is to promote better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Our vision is for a healthy population, a healthy nation and a healthy world, with all people living in an equitable society, underpinned by a well-functioning ecosystem and a healthy environment.

Traditional custodians - we acknowledge the traditional custodians of the lands on which we live and work. We pay respect to Aboriginal and Torres Strait Islander elders past, present and emerging and extend that respect to all other Aboriginal and Torres Strait Islander people.

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Introduction

Background to the legal status of vaping products

The present bill deals with several matters concerning the ‘supply’ side of the vaping epidemic – importation, manufacture, commercial possession, advertising and promotion, distribution, and retailing.

It is important to recall the legal status of vaping products. Emerging after their invention in around 2005, and expressly described by suppliers at that period as being an aide to smoking cessation, nicotine-based vaping products were identified under Australian law as ‘therapeutic goods’, and were therefore regulated under the *Therapeutic Goods Act* and by the Therapeutic Goods Administration (TGA).

The processes set out in that Act provide for products to achieve the status of an ‘*approved* therapeutic good’ on the Australian Register of Therapeutic Goods after appropriate testing and certification of the good’s actual properties and effects on human health. There exists, necessarily, a defined category of ‘*unapproved* therapeutic goods’ for products which are inherently such goods, but which have yet to complete their approvals.

Under their present legal status, vaping products have continually been subject to the control of the therapeutic goods legislation as “unapproved therapeutic goods”. The policy response has included a range of restrictions and prohibitions, largely imposed on importation, manufacture, advertising and supply.

Vaping products have remained in that status for almost two decades, because no manufacturer has ever submitted any vaping product to the TGA for formal assessment according to the Act’s procedures. The present Bill proposes significant amendments to the Act designed to better manage the anomalous position of vaping products.

The Bill does not *initiate* a discussion of whether to ‘ban vapes’. Under the existing regulations vaping products containing nicotine cannot legally be sold in Australia.

But the current regulatory scheme does not achieve all our policy aims, and is difficult to enforce due to the technical challenge of determining the presence or absence of nicotine at locations of seizure by the responsible national, state and territory agencies.

This Bill is designed to modernise and clarify the present legal situation related to supply controls to achieve agreed national health policy goals.

National policy consensus of all governments

A consensus exists among all nine Commonwealth, state and territory governments for a uniform national approach to vaping. The consensus has been developed over many years through dialogue at the regular forum of health ministers (currently titled the National Health Ministers Meeting), together with the Ministerial Drug and Alcohol Forum (which also includes law enforcement ministers).

In 2019 all jurisdictions, acting through the Ministerial Drug and Alcohol Forum, agreed to a national statement in which the risk of harm from vaping was fully recognised, and ***the protection of young people from addiction to nicotine through vaping products*** was identified as the pre-eminent national concern.¹

A second policy goal relating to vaping products has also been agreed by all governments. It is accepted that (despite no nicotine vaping products being approved and registered under the Act, as discussed above) some people who smoke seek to use vaping products as an aid to quitting smoking. This has been specifically allowed for in national resulting policy response. This regime has come to be referred to as the 'prescription model'.

It is essential to understand this national response to vaping as a subordinate component in Australia's overall nicotine addiction response. The resulting arrangements aim to ensure clear and unambiguous advice to quit smoking from health service providers and the provision of best-practice evidence-based support, including referral to behavioural counselling and prescription of approved medications such as varenicline or combination (slow+rapid acting) nicotine therapy.

Cessation support will also include advice on the risks of vaping products as unapproved medicines. Where a prescription for vaping products is made, it will include advice on how to use such products most effectively (and to prevent relapse to tobacco smoking) and in the least risky manner, monitoring for adverse events and longer-term health effects, support to manage ongoing nicotine dependence, and eventually support for individuals to also quit vaping.²

After detailed consultations through 2022 and 2023 the inter-government consensus position was re-expressed in the Communique issued 1 September 2023.³ The position reflects the detailed directions of the *National Tobacco Strategy 2023-30*, which itself was developed in consultation with governments, stakeholders and the public.⁴

On 19 April 2024 this consensus was restated with great clarity through the joint communique of all nine health ministers calling for the passage of the present Bill.⁵ The communique states that:

"Vapes were sold to governments and communities around the world as a therapeutic good: a product that could help hardened smokers kick the habit. Not a recreational product – especially not one targeted at kids. If vapes are therapeutic goods then it is entirely appropriate that Australia should regulate them as therapeutic goods, instead of allowing them to be sold alongside chocolate bars in convenience stores, often down the road from schools.

It's now clear vapes are being used to recruit a new generation to nicotine addiction, and it's working. One in 6 high school students, and 1 in 4 young Australians aged between 18 and 24 are vaping. Australian Health Ministers are not going to stand by and let our kids get hooked on nicotine.

Before the Federal Parliament there is currently world leading legislation to ban the sale, supply, manufacture and commercial possession of non-therapeutic vapes. ... All Health Ministers have today urged the Australian Parliament to pass the Albanese Government legislation, to ensure consistency and coordinated action to protect the future generations of Australians."

The present amendment Bill has arisen out of discussions between all nine Australian governments from 2022 to 2024, with the result that rather than see each jurisdiction have their own legislative solutions to supply-side control challenges, the Commonwealth should legislate for the whole nation, modernising the relevant parts of the Therapeutic Goods Act to reflect the national policy consensus. In the particular case of controls over *importation* of goods, the Commonwealth is the correct level of government to legislate.

In the absence of this Bill, the underlying present Therapeutic Goods Act regulatory position would continue. Under those arrangements we have nonetheless seen a dramatic increase in the uptake of vaping, particularly in young people, which will contribute to a severe burden of chronic disease for future generations.

Failure to pass the Bill would likely also result in fragmentation of the agreed uniform national approach in respect of the supply issues, as states and territories are left to face the enforcement challenges separately. Meanwhile, the nicotine industry has not been idle in attempting to subvert the agreed position of governments through both lobbying and through public influence campaigns. Australia is widely seen as a world leader in the global battle against nicotine products and the industries that create, retail and market them, primarily to young people. Whilst the industry's strategies are framed internationally, the industry pays very close attention to Australian policy developments. At every turn in recent years the industry has sought to influence policy-makers in Australia, typically from behind several layers of concealed influence, and this is certainly so in regard to the present Bill and the Senate's immediate inquiry into it.⁶

We note, as no doubt all Senators know, that the tobacco and nicotine industry is unique in the world in that a specific international treaty has been made in which nations commit to rejecting any influence of the industry over political and government policy-making. This came about because the nicotine industry is responsible for the greatest degree of individual death and harm worldwide of any class of manufactured products. The *Framework Convention on Tobacco Control* (2005) lays out detailed programs for nations to confront this global challenge.⁷ We commend government agencies, including the Parliament, for their efforts to apply the Convention's requirements to the conduct of recent and current government consultations and parliamentary inquiries, so as to make transparent and constrain all forms of tobacco industry influence, direct or indirect, on Australian policy-making.⁸

National policy has *not* established personal use 'prohibition'

A misleading debate has emerged that the use by individual Australians of vaping products is subject to a regime of personal use "prohibition". Our current law is not comparable to previous historical uses of the term focussed on personal use of harmful products, such as the prohibition of consumption of alcohol in the United States in the early 20th century, or the prohibition of other drugs in Australia and other countries from later in the 20th century onward.

We note that the Commonwealth Government in announcing its recent reforms has been very clear, consistent with the uniform national policy consensus of all governments, to refute any policy intention to impose criminal sanctions on individuals for actions relating only to personal use of products.

The current Therapeutic Goods Act restrictions applying to vaping products are fundamentally addressed to the *supply* side of the trade in vaping products, not the consumption side. The personal consumption and possession of vaping products has not been subject to any prohibitive policies or prohibitive legislation focused on *individual vape users* in any Australian jurisdiction.

The present amendment Bill does not create any new *personal use* offences relating to vaping products. Moreover, we note the deliberate inclusion – in the part of the Bill dealing with commercial possession offences – of an exemption from offences for acts of possession of vaping products "for use by the person personally" (see proposed clause 41QD(9) on page 22 of the Bill).

The closest that any existing legislation in Australia comes to imposing offences on individuals for personal use are suggestions that either of the following two scenarios might apply:

- laws restricting *commercial possession for retail purposes* (at both Commonwealth and in some cases at state/territory level) might be interpreted very broadly to capture lesser acts of possession by individuals for personal (non-commercial use), or
- laws enacted to govern the *safe handling of medicines and poisons* (primarily at state and territory level) might be interpreted very broadly such that their restrictions on inappropriate *possession* of

controlled substances (which would include vaping products in their capacity as therapeutic goods) might capture lesser acts of possession of vaping products by individuals for personal use.⁹

Such interpretations of the retail supply control and safe handling laws clearly exceed the intended objects and application of those laws. Any unintended prosecution risk can be managed by government policy direction to relevant health and law enforcement agencies. Alternatively, amendments to the relevant laws could put the risk of criminalisation of individual possession and use of vaping products beyond doubt. We note that at least one jurisdiction (the ACT) has already announced its intention to make amendments to its safe handling of medicines and poisons legislation to exclude this risk of misapplication of the law.

To the extent that the commercial possession provisions of this Bill, or any other part of the Therapeutic Goods Act, are thought to carry any remaining penalty risks for vaping product personal use by individuals, this could also be further clarified by appropriate amendments.

An open market would be disastrous for health, especially that of young people

There are fundamentally two different ‘markets’ for vaping products, requiring two different policy responses:

1. vape use by nicotine-addicted smokers, typically at older age cohorts, for whom we have correctly established a medically-assisted supply chain via pharmacies
2. recreational consumption, largely by younger Australians who are being targeted by the nicotine industry to become a new generation of addicted customers.

The policy response for the addicted smoker category is now broadly in place, and the current Bill is not concerned with altering those arrangements.

The response to the second challenge – protecting children and young adults from becoming a new nicotine-addicted population – is the primary concern of this Bill. The Bill delivers key elements of the national strategy by significantly improving the response to supply-side factors including importation, manufacture, distribution, commercial-scale possession, advertising, retailing and other aspects of supply.

Needless to say, the nicotine industry’s effort to create a new addicted consumer population is already substantially advanced. The alarming rise in youth recreational vaping gives rise to claims that the current policy regime has ‘failed’. The argument is designed to beguile policy-makers into believing that ‘the horse has bolted’ and that governments should now surrender control of the how vaping products are supplied to young Australians.

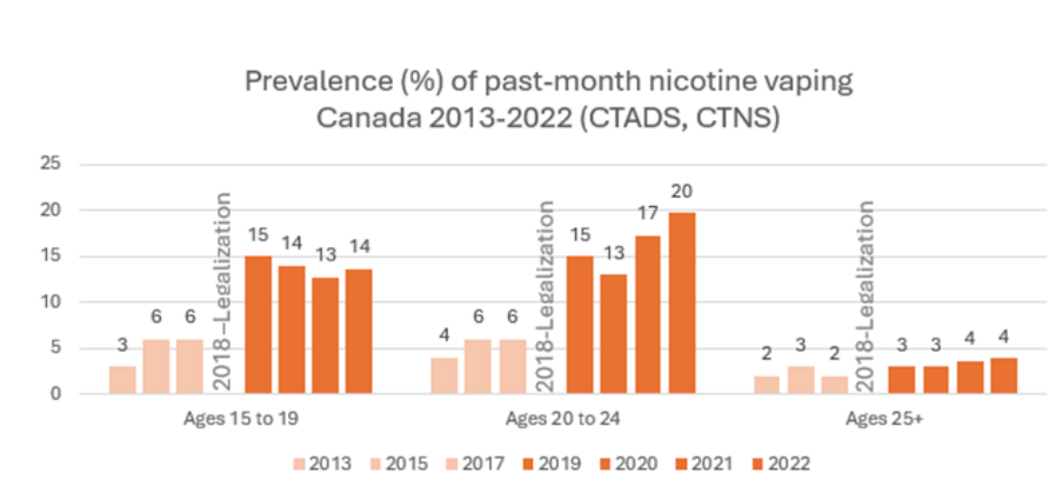
But the policy design that dates from the underlying coverage of vaping products by our therapeutic goods law, and the policy direction in 2019 which clarified the ‘prescription model’, are in fact evidence-based and carefully thought out in terms of resisting an epidemic growth in rates of addiction. The problem we face is not that the national policy consensus was incorrectly chosen, but that hitherto it has been imperfectly implemented and enforced. This is what the present Bill is crafted to address.

An open retail market would lead rapidly to a public health disaster

The nicotine industry, including its retail sector, argue for a radical alternative to the national strategy: an open market of vaping products. To be in any way compatible with our health goals for young Australians, such a proposition would need to be supported by clear evidence that an open market would be able to reduce nicotine use, and new uptake, of smoking or vaping products. The suggestion is absurd on its face. The commercial imperatives of such a retail market would be to increase demand as much as possible.

Such an open market policy would also need to have a coherent strategy to confront the dramatic increase over the past half decade in the nicotine industry’s promotion of vaping products (in particular disposable products) specifically targeted to young people. No evidence from Australia or anywhere else in the world provides any indication that a demand reduction outcome could be achieved through a market policy that allows the nicotine industry growth strategy to dominate.

To help us predict what might occur in Australia from an open market, a clear lesson is available from the outcomes of the policy approach adopted in Canada. Nicotine vaping products were not legal for general sale in Canada until 2018, when federal legislation adopted a ‘legalization’ approach. As the chart below shows, the immediate result was a marked increase from 2019 in vaping use by younger people (ages 15-24), together with a more moderate increase (at lower levels) by people aged 25 and older.¹⁰ Subsequent government initiatives aimed at reducing youth vaping, including attempting to specifically prohibit underage use of products, have – as the data clearly indicate – not been at all effective to help mitigate the commercial drivers promoting such addictive products. In fact this data clearly shows that the legalization framework adopted in Canada in 2018 has been a public health disaster in terms of nicotine use among (particularly) young people in Canada.



Prevalence of past-month nicotine vaping in Canada between 2013 and 2022—before and after deregulation of sale—ages 15 to 19 and 20 to 24 compared to ages 25 and older; Source: CTADS and CTNS; Cancer Council Australia.

Since uptake of vaping by young people has also been found (in several meta-analyses of international evidence in longitudinal studies) to be associated with a three-times greater likelihood of users subsequently taking up smoking,¹¹ such an approach would threaten to reverse the hard-won gains currently seen in commercial tobacco use and addiction in our country.

There is no retail market that we can trust

Alternative policy proposals for an open market, perhaps one that is described as ‘regulated’, simply will not work.

An open market strategy would require a retail sector willing and able to adhere to policy strictures regarding product sale to children, as well as product controls on nicotine content, presence of other harmful chemicals, packaging and labelling, and so on. Yet the retail operators that currently exist have already demonstrated a willingness to defy every current regulatory stricture with contempt. Searches and seizures in the past year, as enforcement efforts have scaled up, have shown the most deplorable dishonesty and defiance of the current law. Retailers who have consistently flouted existing laws in the retailing of addictive vaping products have lost their social license to operate. The proposition that in a less regulated market the retail sector would meekly adhere to what strictures our governments might choose

to require simply cannot be believed. There is no retail sector which could be trusted to engage in an 'open' market for vaping products.

This is precisely why the current regulatory mechanism for delivery of therapeutic-purpose vaping products to smokers seeking to quit nicotine addiction has utilized the pharmacy sector as its supply channel. The pharmacy sector is well-regulated, staffed by people with relevant professional and ethical training, and well accustomed to administering tightly controlled supply chains for therapeutic goods.

It should also be noted that the 'small retailers' of nicotine products are in practice the retail face of the much larger overall nicotine products industry. Such retailers are presented in the course of public influence campaigns as innocent small business stakeholders. Many retailers claim to have no political association with the tobacco industry. But any retailer who is prepared to sell such a powerfully addictive and harmful product line such as 'recreational' use nicotine vaping products cannot claim to be innocent of the industrial interests it is part of, nor of the social harm they cause.

Moreover, the use by the nicotine industry of 'retailer association' entities in their political lobbying is infamous worldwide. We would again urge the Committee and the Parliament to apply the cautions set out in the Framework Convention on Tobacco Control to any representations made by stakeholders that are part of the nicotine supply chain.

The fact that an illegal market exists is not an argument for surrendering to it

Opponents of the Australian policy consensus have claimed that the current policy regime has caused the creation of a 'black' market, in some cases associated with incidents of violent crime in pursuit of profit.

The specific motivation for illegal (and in some cases violent) conduct is not that the products are *unlawful*, it is that they are *lucrative*. The driver of that situation is growth in demand, fueled by highly aggressive industry promotion¹² and the fact that the products in question are deliberately designed to be addictive.¹³

The proposed response that we should surrender to the interests of the industry driving and supplying this illicit market is simply perverse. In no other similar policy domain is the 'law and order' response to criminal activity simply to repeal the laws and give up on order.

The 'surrender' position cannot in any way be reconciled with the paramount goal of preventing nicotine addiction and demand growth, especially among young people. The overriding policy imperative must be to keep demand as low as possible, especially by discouraging uptake. Key means of doing so include comprehensive denormalization, strict prohibition of marketing, and strong constraints on supply. As the Canadian data above clearly shows, surrendering to an 'open market' would have the very opposite result to our goals.

An open retail market would also increase the environmental impact

The quantity of vaping products consumed in Australia also comes with a dramatic environmental impact, in terms of the waste disposal of electronic devices containing lithium batteries, as well as a wide variety of toxic chemicals.

Regulated products supply can support policies to control the toxicity of chemical and other components of therapeutic-use vaping products, or to establish systems for waste recovery and disposal of vaping products devices and ingredients.

The strategic goal of reducing this environmental toxicity provides another powerful reason to adopt policies to reduce the total quantity of vaping products consumed in Australia.

Content of the Bill

The bill is designed to improve the national policy framework for supply-side issues

The Bill's explanatory memorandum is clear that that Bill revises the existing Act "to prohibit the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable vaping goods." The Bill revises, modernises and improves the current Therapeutic Goods Act regulations to streamline implementation by enforcement agencies of the national approach.

Actions relating to importation, supply, and advertisement have been regulated under the Act for some years. In regard to overall advertising control, the *Public Health (Tobacco and other products) Act 2023*, which came into force earlier this month, has also enhanced the overall regime of controls significantly.

As the two-decade history of the legal status of vaping products outlined above shows, the current bill does not initiate a process of 'banning' a retail market for vape products in Australia. The 'market' for vaping products, at least those containing nicotine (as almost all vaping products do) has not been a legally 'open' market since the products first came on the scene.

In regard to potential *manufacture* of products in Australia, and in relation to *commercial possession*, the Bill's provisions cover new ground not addressed by the present regulations. This is part of the national policy consensus that manufacturing and commercial possession, when not associated with the management of smoking nicotine addiction and delivered through the regulated pharmaceutical supply chain, should be prohibited.

State and territories governments, enforcement agencies and judicial officers have also raised issues with the effective enforceability of the current arrangements for general supply-related control of vaping products (outside the therapeutic framework supporting smoking cessation) across Australia. This Bill assists such agencies greatly in carrying out enforcement efforts.

The bill supports the existing regime that vaping products can legally be used for the purpose of quitting smoking

The position in place for nearly 20 years governing the legal status of vaping products has very carefully preserved a place for vaping products to be used for smoking cessation as 'therapeutic goods'.

There is at present only uncertain evidence on the efficacy of vaping-assisted quitting, and mixed views among health care professionals about its appropriateness as a quitting strategy. However, many nicotine-addicted Australians seek this pathway to quitting. Medical professionals seek the best interests of their patients in respect of quitting their addiction, and if a client is persuaded that vaping products are appropriate for them, they can be assisted under current laws to make use of them.

The consensus framework of all nine governments, and the recent reforms to regulations relating to content, packaging and other matters relevant to quitting-focused vaping products, directly assist such health interventions to be as safe and effective as possible.

None of the provisions in the present Bill detract in any way from the vaping-assisted quitting framework established by other existing laws and regulations.

The rejection of this bill would serve no desirable policy goal

Overall, there is no part of the current regulatory framework in Australia which would be better off for the delay or rejection of the current Bill. To reject the Bill would be to reject a timely effort to clarify the laws governing supply-side circulation of illegal vaping products, for which all governments have agreed that the Commonwealth should legislate.

In the absence of this Bill, national control of supply-side matters will remain covered by existing Therapeutic Goods Act regulations as well as the limited provisions of current state and territory legislation. Such a result would only hinder the work of health and enforcement agencies. States and territories committed to tighter control of vaping products circulation would face pressure to legislate alone, diminishing the coherence of the national response.

The best way forward

PHAA strongly supports this Bill. Our overall advice to Senators is to support the national consensus on addressing the vaping epidemic and helping to protect the health of all Australians by:

1. Reaffirming the paramount goal – agreed by all governments – of **protecting young people** from the massive health impacts of nicotine addiction, whether through vaping or smoking,
2. Also supporting the goal of a well-regulated **smoking cessation framework** through which current smokers seeking to quit can do so with the current wide range of nicotine replacement products, as well as vaping products. The Bill will strengthen the regime under which vaping products are regulated for their specific content, labelled and supplied honestly, made available through reliable public sources, and with medical advice fully incorporated into their cessation efforts.
3. Help confront the circulation of illegal (and more hazardous) vaping products by putting in place **modernised, comprehensive enforcement legislation**.
4. Ensuring that the various **agencies responsible** for implementing the national policy response – including the TGA, Border Force, health regulators and police forces across all governments – are all tasked and properly resourced to implement more easily enforceable laws.
5. **Protecting our environment** from the toxic impact of vaping products to the greatest extent possible.

We thank you for your attention to this vital national health issue. Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.



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19 April 2024

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