

SUBMISSION

Friday, 12 April 2024

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

Community Affairs Legislation Committee

Online submission

Introduction

The AMA welcomes the opportunity to provide a submission to the Community Affairs Legislation Committee Inquiry: Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024 (herein referred to Vaping Reforms Bill 2024).

Almost a decade ago, the AMA released a Position Statement which raised serious and legitimate concerns about e-cigarettes (herein referred to as vapes) <https://www.ama.com.au/position-statement/tobacco-smoking-and-e-cigarettes-2015>. Vapes were originally marketed as smoking cessation devices to help long-term smokers quit cigarettes. With their bright packaging and wide-range of flavours, the AMA warned these devices could increase the appeal of cigarettes to children, young people and the wider population and that the continued “normalisation” of vapes would undermine population health. In 2024, rates of vaping in children and young adults continue to rise. Alarmingly, vapes are being taken up by children and young adults as their first nicotine-based product. They are not trying to quit, as they have never smoked before.

The AMA strongly supports the Vaping Reforms Bill 2024. A single consistent framework that applies nationally to reduce rates of vaping and prevent long term adverse effects on population health is urgently required. The Bill will reduce widespread availability of vapes by controlling all levels of the supply chain. The Bill amends the Therapeutic Goods Act 1989 (the TG Act) to prohibit the importation, domestic manufacture, supply, commercial possession and advertisement of non-therapeutic and disposable vaping goods. Importantly, the Government’s reforms will support people to cease smoking and/or vaping by retaining access to prescription vapes and making these more accessible to patients where clinically appropriate through any GP. GPs are highly trained and experienced in managing addiction with their patients and are experts in smoking cessation. With new clinical guidelines, GPs are ready to continue helping patients to quit.

1. Vapes and new technologies are a major threat to Public Health

The current state of evidence regarding the direct harms vapes pose to human health, their impacts on smoking initiation, continuation and cessation, their uptake among youth and young adults, and their dual use with conventional tobacco products justifies a continuing precautionary approach. The evidence continues to reinforce a widespread and serious concern among public health policy makers and medical practitioners at the increasing marketing and use of vapes, and the use of vapes by youth and young adults.

According to the National Drug Strategy Household Survey 2022-23, Australia recorded its lowest frequency of people smoking daily at 8.3 percent.¹ Strong and comprehensive action on smoking is working. By contrast, the current laissez-faire approach to vaping has led to an alarming increase in the rate of vaping in young people. Current use of vapes among people aged 14 and over nearly tripled between 2019 (2.5 percent) and 2022–2023 (7.0 percent); it quadrupled among people aged 18–24 (from 5.3 percent to 21 percent) and it increased more than five-fold among people aged 14–17 (from 1.8 percent to 9.7 percent).

Younger people and children are increasingly becoming addicted to vaping because of their ease of access, misinformation about their safety, and the pernicious marketing of vapes to young people through flavours and packaging. While proponents push vaping as a smoking cessation tool, the evidence demonstrates that people who vape are three times more likely to smoke than people who have never vaped, and that former smokers who vape are more likely to relapse.² We now have a situation where smoking rates for 14-17 year olds in Australia is trending upwards.³

Research led by Professor Emily Banks and the National Health and Medical Research Council has clearly demonstrated that for nonsmokers, there are multiple health risks associated with vaping.⁴ Substances commonly found in vapes include diacetyl, which damages small passageways in the lungs, formaldehyde, which is known to contribute to lung and heart diseases, and acrolein, which is often used as a weed killer. There is conclusive evidence that vapes and their constituents cause poisoning, injuries and burns and immediate toxicity through inhalation, including seizures, that their use leads to addiction and that they cause less serious adverse events, such as throat irritation and nausea.

¹ <https://www.aihw.gov.au/reports/illicit-use-of-drugs/national-drug-strategy-household-survey/contents/tobacco-and-e-cigarettes-vapes>

² Baenziger et al., March 2021, E-cigarette use and combustible tobacco cigarette smoking uptake among nonsmokers, including relapse in former smokers: umbrella review, systematic review and meta-analysis, BMJ Open

³ Wakefield et al. May 2023, Current vaping and current smoking in the Australian population aged 14+ years: February 2018-March 2023.

⁴ https://openresearch-repository.anu.edu.au/bitstream/1885/262914/1/Electronic%20cigarettes%20health%20outcomes%20review_2022_WCAG.pdf

As more time passes, further evidence is coming to light about the extensive dangers of vaping and long-term health risks. Potential adverse effects include negative impacts on adolescent brain development, and amplification of mental health conditions including stress, anxiety, and depressive symptoms.⁵ Parents, teachers, and doctors are reporting that nicotine-dependence is impacting learning behaviours and wellbeing in schools.⁶ In 2020, the Centres for Disease Control and Prevention (CDC) confirmed 2,807 cases of vaping-associated lung injury (EVALI) and 68 deaths attributed to that condition.⁷ Data collection was stopped due to the public health response to COVID-19 pandemic. Emerging data suggests links to chronic lung disease and asthma⁸, as well as associations between dual use of vapes and smoking with cardiovascular disease.⁹

2. The Vaping Reforms Bill 2024 will stop the exploitation of regulatory loopholes by the vape industry

The vape industry are intent on market expansion. The global vape market was valued at USD 28.17 billion in 2023 and is expected to grow at a compound annual growth rate - of 30.6 percent from 2023 to 2030.¹⁰ As tobacco control efforts expand, the tobacco and vaping industries have responded with a variety of messages and tactics to protect their business interests including lobbying and shaping the evidence base to support product use or “harm reduction” messages.¹¹ In Australia, several of the multinational tobacco corporations are lobbying government through submissions to legislative reviews, participating in public inquiry hearings, making political donations, funding third parties to lobby on their behalf and meeting privately with parliamentarians.¹²

Any proposals to allow for “more-tightly” regulated market will ensure the health of Australians – in particular children and young Australians – is exploited for profits at all stages of the supply chain with

⁵ Truong M and Cotton E. The impact of vaping on adolescent mental health: Policy and Practice Paper. (2023) Australian Institute of Family Studies

⁶ <https://www.sydney.edu.au/news-opinion/news/2023/05/02/vaping-and-behaviour-in-schools-what-does-the-research-tell-us.html>

⁷ https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html

⁸ Chatziparasidis G. And Kantar A. Vaping in Asthmatic Adolescents: Time to Deal with the Elephant in the Room *Children (Basel)*. 2022 Mar; 9(3): 311.

⁹ American College of Cardiology (2024) Study Links E-Cigarette Use with Higher Risk of Heart Failure.

¹⁰ <https://www.grandviewresearch.com/industry-analysis/e-cigarette-vaping-market>

¹¹ Savell E, Gilmore AB, Fooks G. How does the tobacco industry attempt to influence marketing regulations? A systematic review. *PLoS One*. 2014;9(2):e87389

¹² Watts, C et al., How tobacco companies use the revolving door between government and industry to influence policymaking: an Australian case study. *Public Health Res Pract*. 2023;33(4):e33122305

the Australian public covering the health costs into the future. Under the current arrangements we have repeatedly witnessed (1) misleading nicotine labelling; (2) harmful constituents within the vape liquid; (3) retail outlets strategically positioned near schools and in lower socio-economic areas and (4) child-friendly marketing. These tactics are discussed in turn below:

2.1. The majority of 'non-nicotine' vaping products contain nicotine, and these are available in shops and online, which completely undermined the TGA regulatory framework and mislead customers into purchasing an addictive product.

Nicotine is a highly addictive substance.¹³ Most Australian states and territories (with the exception of New South Wales) follow the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).¹⁴ New South Wales has established its own NSW Poisons List which reflects the SUSMP with respect to nicotine. Nicotine for human consumption is listed in the SUSMP as a prescription only medicine in the schedule 4 (S4) classification, except when used as an aid in the withdrawal from tobacco smoking in preparations intended for oromucosal or transdermal use (e.g. nicotine patches, gum or mouth sprays). In the schedule 7 (S7) classification, nicotine is listed as a poison, except in preparations for human therapeutic use or in tobacco prepared and packed for smoking. Nicotine used for vapes falls within S7 classification if it is not treated as a therapeutic good. Under the existing regulations, vapes containing nicotine cannot legally be sold in any Australian state or territory. Unfortunately, what has been found is that most vapes marketed as being non-nicotine based contain nicotine with easy access to these through retail outlets.

The frequency with which nicotine is detected in e-liquids labelled "nicotine-free" is disturbing.¹⁵ In a 12-month Australian-first research project, conducted on behalf of NSW Health, the team from the University of Wollongong's School of Chemistry and Molecular Biosciences tested 750 vapes, including 428 seized from retailers and 322 surrendered by New South Wales high schools.¹⁶ Approximately, 97.5 percent of the devices contained nicotine despite most not listing it as an active ingredient, with an average concentration of 40 milligrams per millilitre (twice the dose proposed to be allowed by the TGA under a stronger TGO 110). To date, there have been no applications to the TGA for assessment and registration of vapes and associated products onto the Australian Register of Therapeutic Goods (ARTG).

¹³ Benowitz NL. Pharmacology of nicotine: addiction, smoking-induced disease, and therapeutics. *Annu Rev Pharmacol Toxicol* 2009; 49: 57-71.

¹⁴ Australian Government Department of Health, Therapeutic Goods Administration. The poisons standard (the SUSMP). Canberra: Commonwealth of Australia, 2015. Available at www.tga.gov.au/publication/poisons-standardsusmp#susmp [Accessed 5 May 2015].

¹⁵ Chivers, E. et al., Nicotine and other potentially harmful compounds in "nicotine-free" e-cigarette liquids in Australia (2019) *Medical Journal Australia*

¹⁶ <https://www.theillawarraflame.com.au/news/fears-for-teens-health-as-uow-researchers-find-banned-substances-in-vapes#:~:text=In%20a%2012%2Dmonth%20Australian,New%20South%20Wales%20high%20schools.>

2.2. Non-nicotine vaping products also contain a range of harmful chemicals that are an immediate public health concern.

The non-nicotine constituents of e-cigarettes include solvents – water, propylene glycol and vegetable glycerine – and flavourings, as well as multiple other chemicals. There are many thousands of e-liquids on the market and over 15,000 flavours were identified for sale online in 2017.¹⁷ The presence of metals (such as chromium, nickel and lead) and carbonyls (such as formaldehyde, acetaldehyde, acrolein and glyoxal) raise serious health concern. Exposure to some metals may cause serious health effects, including diseases of the nervous, cardiovascular and respiratory systems.¹⁸ From the ANU Review, Professor Emily Banks reported 38 chemicals found in e-cigarette liquids are listed as poisons on the Australian Poisons standard.¹⁹

2.3. Accessibility of retail and online sales to minors

Implementation of the Vape Reform Bill 2024 will put an end to the lawful supply of any type of vape by tobacconists, vape shops and convenience stores. Despite extensive warnings about the reforms to vaping in Australia, and strong opposition from communities, commercial retail is still growing. Between 1 January 2023 and 30 June 2023, 633 retailers notified NSW Health that they were selling vaping products. In the same period last year, 326 retailers notified NSW Health that they were selling these products.²⁰

The locations of these retailers so close to schools are both deliberate and predatory. There is no specific requirement in New South Wales or Victoria to inform local councils of the intent to sell tobacco or smoking-related products. A report commissioned by Cancer Council WA found 88 per cent of stores that sold vapes as their main source of business were located within one kilometre of a school.²¹ Vape store densities were nearly seven times higher in the most socio-disadvantaged areas compared to everywhere else. The Western Public Health Unit (WPHU) in Victoria created the Out and About Project to better understand the accessibility of vapes within the WPHU catchment, by mapping the number, type and location of vape retailers in one Local Government Area, Brimbank (LGA).²² Vapes were available for sale at 57 retailers, with 70 percent located within 1 kilometre of a school (median distance 741m). This is a deliberate ploy by vape retailers to be in close proximity to settings that are frequented by children and young people, such as schools and sport, recreation and leisure facilities.

¹⁷ Hsu G, Sun JY, Zhu S-H. Evolution of electronic cigarette brands from 2013-2014 to 2016-2017: analysis of brand websites. *Journal of Medical Internet Research* 2018; 20(3): e80

¹⁸ SCHEER (Scientific Committee on Health, Environmental and Emerging Risks). Scientific Opinion on electronic cigarettes, 16 April 2021. Luxembourg: European Commission, 2021.

¹⁹ Health impacts of electronic cigarettes | National Centre for Epidemiology and Population Health (anu.edu.au)

²⁰ <https://www.theguardian.com/australia-news/2023/nov/29/nsw-vape-sales-retailers-increase-government-ban-2023>

²¹ <https://www.journals.elsevier.com/australian-and-new-zealand-journal-of-public-health>

²² <https://www.wphu.org.au/wp-content/uploads/2023/11/WPHU-Vaping-Out-and-About-Investigation.pdf>

- 2.4. Industry marketing tactics to lure children and young people through bright coloured packaging, sleek-looking vapes and the availability of multiple flavours.

Vaping companies utilise marketing methods that distinctly target young people. Some vapes are promoted in confectionery flavours that are designed to appeal to young people whilst appearing relatively harmless. Surveys in New Zealand have indicated high proportions of users' state flavour as a main reason behind their vaping.²³ Vaping companies spend most of their marketing budget on magazine and television advertising. Analysis showed that more than half of vaping adverts in the USA included features to appeal to youth, such as animation, content related to positive sensations, young actors, humour, promoting mood and individuality. This study also showed the significant budgets the industry uses for marketing, one brand alone (Juul) spent over USD 100 million in 2019.²⁴ Although the restrictions on television and radio advertising in Australia are much stronger and would prevent this kind of advertising legally, this shows the importance of targeting the youth market to these companies. Studies have shown social media content highly influences young people's decisions to take up vaping. Use of Snapchat, Instagram, and Facebook were all significantly associated with higher rates of vaping advertisement exposure via smartphones. Exposure to vaping advertisements on smartphones was associated with ever vaping (AOR: 1.30, 95% CI = 1.05–1.60). Of the social media platforms examined, only Snapchat use frequency was associated with higher odds of ever vaping (AOR: 1.22, 95% CI = 1.10–1.36).²⁵

3. The Vaping Reforms Bill 2024 will cement Australia as a leader in tobacco and vape control.

Many countries are shocked and activated by the rapid uptake of vaping by young people. According to a report from the World Health Organization, vapes are banned in 33 countries.²⁶ An additional 87 countries regulate the sales of vapes. Mounting pressure from Scottish and Welsh Governments to curb the increasing rates of vaping in young people resulted in the UK calling for a ban on disposable vapes in January 2024. Ireland is seeking people's views ahead of a potential ban while many health and environmental associations are urging their governments to act. France²⁷ and Germany also intend to take action against disposable vapes. In New Zealand, vaping rates among the youth continue to rise despite the roll-out of new regulations including increased fines and imposed restrictions on retailers near schools.

²³ Gendall P, Hoek J. Role of flavours in vaping uptake and cessation among New Zealand smokers and non-smokers: a cross-sectional study. *Tob Control* 2021; 30: 108–110.

²⁴ Hoetger C, Wall C, Rudy A, et al. Content Appealing to youth and spend characteristics of electronic cigarette video advertisements. *J Public Health (Oxf)* 2022; 44: 129–137

²⁵ Massey et al., Vaping, smartphones, and social media use among young adults: Snapchat is the platform of choice for young adult vapers. *Addictive Behaviors*. 2021

²⁶ <https://iris.who.int/bitstream/handle/10665/372043/9789240077164-eng.pdf?sequence=1>

²⁷ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000047663185>

Among 15–24 year-olds, regular use (at least monthly) has increased from 4.9 percent (2017/2018) to 27.1 percent (2022/2023).²⁸ The government recently announced that it will impose a ban on disposable vapes, however this will not be enough to stem the rise in vaping in New Zealand’s youth.

4. GPs support the prescription model for vape access

The AMA and its members strongly support the new Vaping Reforms that began rolling out in 2024. As part of the first phase (1 January 2024), doctors have been able to prescribe therapeutic vapes for smoking cessation or the management of nicotine dependence without applying to the TGA for pre-authority or approval through a new Special Access Scheme C pathway. This has reduced the administrative burden on prescribers while facilitating legitimate access to therapeutic vapes as part of a medically supervised smoking cessation strategy.

Addiction is complex. The right management approach will differ from person to person. GPs have a lot of tools and resources at their disposal to work with the patient to determine the best approach for everyone. As a medical community, open dialogue with patients to determine if support is needed for nicotine addiction will always be recommended and TGA approved Nicotine Reduction Therapies (NRTs) and behavioural support are at the ready, depending on the level of intervention needed.

5. Conclusion

The Australian Government has listened to public health and medical experts to urgently intervene on this blight by cynical actors making a profit at the expense of young Australians. Regulation, imposed in 2021 by the former Coalition government did not abate the rising rate of nonsmokers taking up vaping because it was not sufficiently comprehensive in its approach to tackling this issue. The AMA applauds this national approach that will tackle all levels of the supply chain. Coupled with harsher penalties for those doing wrong and stronger border control, the AMA is confident these reforms will be successful.

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²⁸ Hardie L, McCool J, Freeman B Industry response to New Zealand’s vaping regulations *Tobacco Control* Published Online First: 01 March 2024