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Perspective

A prescription model for vapes: the way we 'do' medicines policy in Australia

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Key points

- Reforms before the Australian Parliament aim to strengthen the prescription model for the regulation of vaping (e-cigarette) products
- The prescription model has been in place for some years but has not operated effectively because of an anomalous regulatory distinction between nicotine and non-nicotine vaping products, which has hindered its enforcement
- A failure to enact these reforms would not legalise the retail supply of vapes in Australia but would delay measures to improve enforcement efforts
- Successful implementation of the prescription model for nicotine vapes could help to prevent future nicotine addiction, facilitate the effective use of

Abstract

On 2 May 2023, the Australian Federal Government announced a suite of reforms aimed at ensuring the effectiveness of the prescription model of regulation of vaping (or e-cigarette) products in Australia. These reforms are intended to protect Australians, particularly young people, from the harms of vaping and nicotine dependence. The ensuing public debate on the issue has often created the impression that the options under consideration are to either retain 'recently introduced' prescription regulation or to 'revert to' a retail supply approach. However, the sale of nicotine vapes by retailers such as tobacconists and convenience stores has never been lawful in Australia. The reforms do not seek to change the way nicotine vaping products are regulated, but rather to ensure that the existing prescription model can be effectively enforced and can function as originally intended. This paper describes the historical context and rationale for strengthening prescription regulation of vapes in this country.

Key points (continued)

vaping products and prevent illegal sales, setting a global benchmark for regulating vaping products to protect public health

Introduction

In May 2023, the Australian Government announced a suite of reforms that aim to ensure the effectiveness of the prescription model for the supply of vaping (or e-cigarette) products in this country (see Box 1). These reforms were announced after extensive consultation and assessment by the Australian Government Therapeutic Goods Administration (TGA). A Bill amending the *Therapeutic Goods Act 1989* ('the Bill') to enact several of the proposed measures is being considered by the Australian Parliament at the time of writing.[1]

Box 1. Australian vaping reform measures

- Easier vape prescription processes for doctors and nurse practitioners (commenced 1 January 2024)
- End to the sale and import of single-use, disposable vapes (the prohibition on import commenced 1 January 2024)
- End of importation of all non-therapeutic vaping products (regardless of nicotine content) (implemented 1 March 2024)
- Closing down the sale and manufacture within Australia of all non-therapeutic vapes regardless of nicotine content (to commence the later of 1 July 2024 or the day after the Act receives Royal Assent if passed)
- Stronger minimum quality standards for therapeutic vapes, including restricted flavours (introduced 1 March 2024), lower maximum nicotine concentration and pharmaceutical-style packaging (to commence 1 December 2024).

Medicines and poisons policy in Australia

When considering the proposed vaping reforms, it is important to understand Australia's standard approach to the regulation of medicines and poisons, which may be more robust than that regulation in some other countries.[2]

Medicines policy in Australia:

- Requires manufacturers to provide evidence of the effectiveness of medicines for which they are making therapeutic claims
- Ensures quality and high standards of manufacturing
- Strictly controls the supply of drugs and poisons, to minimise risks to consumers
- Promotes quality of prescribing and use of medicines to maximise benefits and minimise harms
- Ensures access, through its Pharmaceutical Benefits Scheme, to approved drugs at an affordable cost to the whole community.[3]

Treatment of nicotine in the context of Australia's medicines policy

When vaping products first started arriving in Australia in the late 2000s, nicotine liquids were automatically subject to regulation by the TGA. From 2012, nicotine that was not in "tobacco prepared and packed for smoking" and not in products for "therapeutic use" was classified in Australia as a 'schedule 7 (S7) dangerous poison'[4] and subject to a high level of control. For instance, permits and/or licences are generally required to sell or purchase products containing an S7 substance in Australia.[5] Where a supplier's labelling or advertising stated or implied it was for therapeutic use, the nicotine in vaping products was classified as a 'Schedule 4 – prescription-only' substance. This meant that nicotine e-cigarettes (now more commonly referred to as 'vapes') could not be supplied unless: a) assessed and approved by the TGA and entered on the Australian Register of Therapeutic Goods; or b) purchased under the special avenues the TGA has in place for (all) unapproved therapeutic goods, all of which require a medical prescription. Vapes that did not contain nicotine, by contrast, did not fall within the remit of the TGA (unless they were marketed as therapeutic products) and were left unregulated. After calls for regulation of non-nicotine vaping products by health groups[6], tobacco control legislation was rapidly amended so that within a couple of years, no state or territory allowed the supply of non-nicotine vapes to anyone aged under 18 years.[7] However, all Australian jurisdictions other than Western Australia continued to allow the general retail sale of non-nicotine vapes to people aged over 18 years.

Continuing pressure to deregulate

Since vaping products first arrived in Australia, it has always been possible to access nicotine vapes for therapeutic use with a prescription. The use of vaping products started increasing gradually from 2012 onwards. Pressure grew over the late 2010s from those who wanted the general sale of nicotine vapes legalised in Australia. Applications in 2016 and again in 2017 to remove nicotine in vaping products from S7 of the Poisons Standard were not supported by the TGA's independent expert scheduling committee. Meanwhile, amidst growing disquiet about vaping risks to users, reviews of evidence of the health effects of e-cigarette use were commissioned by the Australian Government from the University of Sydney in 2016[8], the National Health and Medical Research Council (NHRMC) in 2017 and again in 2022[9], the Commonwealth Scientific and Research Organisation (CSIRO) in 2018[10], the National Industrial Chemicals Notification and Assessment Scheme in 2019[11], and the Centre for Epidemiology and Population Health at the Australian National University in 2020[12] In addition, health groups became ever-more concerned about increasingly aggressive global marketing of vapes to young people.[13]

The regulation of vapes demanded political attention, with continuing agitation by proponents for the general sale of e-cigarettes on the one hand, alongside community concern about growing vape use among young people on the other. Parliamentary inquiries examined the issue in South Australia in 2016, in Western Australia in 2017 and again in 2018 and the Northern Territory in 2018. The Australian Senate held an inquiry into e-cigarette use and marketing in 2016, followed by a House of Representatives inquiry in 2018 and a further Senate inquiry in 2020. After considering extensive evidence and hearing representation from many groups with ranging opinions, none of these inquiries recommended changing the scheduling to make nicotine vaping products available for general sale in Australia. In communiques released by the Ministerial Council on Drug Strategy in 2017 and 2019, the Australian Government, in conjunction with all state and territory governments, stated a commitment to maintaining a "precautionary approach" regarding the regulation of vapes.[14]

The question of scheduling of nicotine in vapes was assessed again in 2020. Once again, the TGA and its independent expert scheduling committee considered local and international evidence and undertook extensive consultation. This led to Australia's Poisons Standard being amended, commencing in October 2021, to essentially remove nicotine for non-therapeutic human use from S7, so that nicotine in any vaping product for human use would be classified as a 'Schedule 4 prescription-only' medicine, regardless of whether the intended purpose was therapeutic or non-therapeutic use (i.e. recreational use). Far from being a new 'ban' on the sale of nicotine vapes as many have suggested, this simplification of scheduling simply addressed some uncertainty among stakeholders regarding when a vaping product would be considered to be for 'therapeutic use'. It also clarified that a prescription was required to legally import nicotine-containing vaping products under the 'personal importation scheme'.

Advantages of prescription regulation of e-cigarettes

The main purpose of simplifying the scheduling of vapes in 2021 was to ensure that people who did not currently smoke, particularly young people, were not sold products that were likely to result in nicotine addiction. Australia was already seeing growing use of vapes among teenagers, which was of concern given evidence about the effects of nicotine on the developing brains of young people.[15] Respiratory effects, contamination of vaping liquids resulting in lung injury, nicotine toxicity, and trauma and burns from explosions all pose immediate risks.[15] Numerous international reviews of longitudinal cohort studies – including those that controlled for several other factors that correlate with risk-taking behaviours – have found that nicotine naïve young people who take up vaping are up to three times as likely to subsequently take up traditional cigarette smoking.[15] Vaping is thus a threat to decades of successful tobacco control in Australia, with both immediate- and long-term costs to individual users and the healthcare system.

The supply of vapes via prescription has many advantages. Consultation with a health professional ensures that those thinking about using vapes get independent medical advice and can make an informed decision based on their particular circumstances (including age, level of addiction to nicotine, smoking cessation history and other health conditions). As with other substances of addiction, the prescription status for nicotine in vaping products was intended to ensure that supply and use are in line with best and safe clinical practice. This was deemed to be a reasonable and proportionate approach considering the highly addictive nature of nicotine, and the fact that no nicotine vaping products had yet been assessed and approved by the TGA for quality, safety and efficacy. The scheduling simplification also ensured that no-one using vapes containing nicotine would be subject to the penalties applicable for possession of an S7 poison, as long as they had a valid prescription for its use.

Evidence from randomised clinical trials[15,16] suggests that vapes can help some smokers quit using tobacco. However, those trials have all included clinical supervision and/or behavioural support. The effectiveness of vaping as a smoking cessation aid in the absence of such support has not been investigated in well-designed studies. Further, a high proportion of participants who stop smoking are reported to still be vaping at the end of such trials. Vapes have not been demonstrated

to be superior to best practice smoking cessation treatments such as behavioural counselling combined with varenicline or combination (short- and long-acting) nicotine replacement therapy.[16,17] Consultation with a prescriber ensures that people are aware of these first-line, therapeutically approved approaches for quitting smoking, which carry a lower risk of ongoing nicotine addiction than vaping, and for which costs are subsidised in Australia.

People who use vapes on an occasional basis – the most common pattern of use – rather than daily[18] do not tend to be more likely to give up smoking compared to people who never use vapes. And several studies have found that people who continue to regularly smoke tobacco along with vaping (again a common pattern of use), do not increase their chances of quitting.[19] The vape prescription model in Australia can help ensure that people who use vapes to quit smoking use them in the most effective way possible. Consistent with that aim, and with the overall pattern of findings from the literature, data from the Victorian Smoking and Health Survey conducted in 2022 showed that among people who vape, those who had a prescription were six times more likely than those without a prescription to be ex-smokers (as opposed to continuing smokers or never smokers) (Odds Ratio 6.18; (95% Confidence Interval: 2.96, 12.88).[20]

Evidence is rapidly accumulating of long-term risks of chronic disease associated with vaping, including impaired lung function and increased risk of periodontitis. When used in pregnancy, there is a higher risk of low birth weight.[21] In addition to helping consumers make informed choices about whether to use nicotine vapes and whether to try other treatment options to quit smoking, supply via prescription ensures evidence-based care for people with continuing nicotine addiction. It enables monitoring of adverse events that result from certain patterns of use, or from new products that come onto the market. Reporting of adverse events, as well as case reports by doctors, could facilitate the identification of potential longer-term health effects that could be investigated in future studies.

Securing better regulatory control of non-nicotine vapes

The latest data from Australia's National Drug Strategy Household Survey suggest that large numbers of young people are vaping and that few Australians who buy vapes currently have a prescription to do so.[22] So it is clear that the objectives of the 2021 simplification of vape scheduling are currently not being achieved. The reforms introduced early in 2024 streamline prescribing arrangements and end the importation of the type of vaping products most attractive to young people.

As highlighted elsewhere[23], non-nicotine vapes (which remain largely unregulated) have been widely used across Australia as a 'Trojan horse' to conceal the illegal importation and sale of nicotine vapes, including by some retailers. The reforms currently before the Australian Parliament will close this loophole, and are the final piece in the package of reforms aimed at ensuring the prescription model can finally operate as intended.

Many countries around the world now have very high rates of youth vaping, and many are considering some of the same measures as those in the current Australian package of reforms.[24] For instance, a ban on the importation and sale of disposable vapes is already in place in New Zealand and is set to be introduced in the UK, France and Germany. Reforms underway in Australia are also in line with guidance issued by the World Health Organization in December 2023.[25]

Conclusion

Vaping products in Australia have not been singled out for particularly harsh regulatory treatment. Rather they have been regulated in the same way as every other therapeutic good in Australia. Australia's prescription model has not failed because 'prohibition doesn't work'; rather the prescription model has not had the opportunity to operate effectively because the anomalous regulatory distinction between nicotine and non-nicotine vaping products has prevented it from being properly enforced.

The current reforms are about ensuring the prescription model works as intended.

Failure to support the current Bill would not legalise the retail supply of vapes in Australia. However, failing to pass the Bill would delay the introduction of measures that could otherwise start within a matter of weeks to improve enforcement efforts across all levels of government.

The Australian Parliament's decision on these important reforms will be closely watched by parents and educators who are appalled by the recent escalation in nicotine use among young Australians. It will also be observed by public health authorities in other countries that have frequently looked to Australia as an exemplar of tobacco control. If a fully implemented prescription model for nicotine vapes proves effective in preventing the development of nicotine addiction, in facilitating the most effective use of vaping products and in preventing illegal sales, then it could be rapidly emulated all over the world.

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Author contributions

All authors were engaged in the development, writing and/or editing of the paper.

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