

How should nicotine vaping be regulated in Australia?

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Abstract

In Australia, nicotine vaping products are regulated as prescription-only medicines which can only be sold from a pharmacy, with the aim of preventing youth access and allowing use by adult smokers with a doctor's support. The Therapeutic Goods Administration has acknowledged that this policy has not achieved its goals. Instead, a thriving black market has developed which sells unregulated vape products to children and adults. Very few adult vapers use the legal prescription pathway. Regulation should find the optimal balance between facilitating legal access for adult smokers while restricting access by youth. The preferred approach is a tightly regulated consumer model with nicotine vaping products sold by licenced retail outlets with strict age-of-sale verification. Regulations should be proportionate to risk and reflect the lower harms of vaping relative to smoking. A consumer model would bring Australia into line with other Western countries and improve population health.

KEYWORDS

electronic cigarettes, public policy, regulation, smoking, vaping

Tobacco control has traditionally focussed on achieving complete smoking abstinence [1] but some smokers are unable or unwilling to quit on their own or using conventional treatments [2,3]. An alternative to complete quitting is to switch to one of the tobacco harm reduction options such as nicotine vaping products (NVP). Vaping is the most popular aid for quitting and reducing smoking used by Australian smokers [4].

There is now scientific agreement that vaping is more effective than nicotine replacement therapy as a quitting aid [5]. Although neither vaping nor nicotine replacement therapy are risk-free, vaping is a substantially safer alternative for adult smokers [6–9]. Switching completely to NVPs dramatically reduces toxicant exposure and biomarkers of harm and improves symptoms and clinical outcomes. The precise long-term effects of vaping have not yet been established but are likely to be far less harmful than from smoking [7].

Current Australian vaping policy is driven by alarmist and exaggerated media reports about youth vaping 'epidemics' [10]. However, most youth vaping is

experimental and transient and frequent vaping is most common among current or former smokers [11–13]. Regular vaping by never-smokers is rare. Rather than being a gateway to smoking [14], the evidence suggests that vaping diverts more young people away from smoking and is displacing smoking at the population level [15–17]. Very few young never-smokers who vape become dependent on nicotine [18, 19]. The evidence that nicotine harms the human adolescent brain is weak [20].

Four important principles should be considered in the regulation of NVPs. Firstly, the paramount objective must be reducing smoking-related death and disease.

Secondly, regulation of vaping should be proportionate to risk and reflect its lower harms compared to smoking [21]. As vaping is substantially less harmful than smoking, a lighter touch regulatory approach is required.

Thirdly, policymakers should also consider the harmful unintended consequences of regulation.

Fourthly, regulatory measures should be informed by evidence rather than by values, ideology, politics and opinion [22].

The challenge for policymakers is to find the optimal balance between facilitating access for adult smokers who are at substantial and more immediate risk from smoking, while restricting access to youth, for whom the risks of vaping are smaller and delayed [20]. Measures to protect non-smoking youth are essential, but excessive regulation which makes vaping less accessible, less appealing, more expensive, less consumer-friendly or less effective inadvertently perpetuates adult smoking and increases smoking-related death and illness [7].

1 | CURRENT AUSTRALIAN VAPING POLICY

Since 1 October 2021, nicotine liquid has been classified in Australia as an unapproved prescription-only medicine (Schedule 4) [23]. No NVPs are registered on the Australian Register of Therapeutic Goods [23].

Australians are permitted to import nicotine liquid for personal use or purchase it from an Australian pharmacy if they hold a valid doctor's prescription [24]. Possessing nicotine without a prescription is a criminal offence punishable by fines up to \$45,000 and/or 2 years jail [25].

These regulations were intended to achieve two goals: (i) firstly, to allow adult smokers access to regulated vaping products ideally through a pharmacy with a doctor's support; and (ii) to prevent youth vaping [23]. However, the Therapeutic Goods Administration has acknowledged that they have failed to achieve either objective [26].

Few doctors are prepared to prescribe unapproved nicotine products. Many are sceptical or uninformed about vaping and are discouraged from prescribing nicotine by health and medical authorities [27]. Fewer than 1% of doctors are publicly listed as nicotine prescribers [28] and over 90% of people who vape do not have a nicotine prescription [29].

Very few pharmacies stock nicotine liquids and the range of products is very limited. Only 2% of vapers are estimated to purchase nicotine from pharmacies with a prescription [29].

The de facto prohibition of NVPs has diverted users to a thriving illicit market [30]. Unregulated and incorrectly labelled products are freely sold to adults and young people and policing and enforcement are minimal. As a result, there has been a substantial increase in youth vaping, tax revenue has been lost and otherwise law-abiding citizens have been criminalised.

Proposals for more intensive enforcement of an approach already overwhelmingly rejected by consumers and health professionals will most likely boost black-market supply, intensify criminal activity and increase smoking (Data S1, Supporting information).

2 | HARMFUL UNINTENDED CONSEQUENCES

Well-intentioned flavour bans to reduce vaping by young people have often been counterproductive. For example, a ban on flavoured tobacco and vaping products in San Francisco in 2020 resulted in a more than doubling of smoking by high school students [31]. Among adults, vaping was reduced and smoking increased [32].

In the United States, flavours in pod-based products other than tobacco and menthol were banned nationally in 2019. One study reported that 14% of adult vapers returned to smoking [33]. The main impact on youth vapers was a shift to disposable products. Vaping and smoking behaviours remained unchanged [34, 35].

Increased taxation of NVPs has led to increased smoking by youth [36, 37], young adults [38] and adults [39]. This suggests that NVPs and cigarettes are economic substitutes.

Attempts to reduce youth vaping by restricting the age of legal sale have also perversely led to an increase in youth smoking [40–42].

Alarmist public health campaigns to deter youth from vaping can be harmful. In an experimental setting, a youth-targeted health warning was found to discourage adult smokers from using vaping to quit [43].

Proposals to reduce the nicotine content in NVPs risk detrimental effects. Higher concentrations of nicotine are needed for compact pod devices and disposables that are very popular transition devices for adult smokers. Higher nicotine levels are safer because they generate smaller aerosol volume and fewer toxicants [44–47]. Excessively low doses of nicotine may make NVPs less satisfying, especially for more dependent smokers, and lead to lower rates of switching [48]. Smokers often need higher doses of nicotine in the early stages of switching while learning to vape.

A blanket advertising ban on vaping inadvertently protects established cigarette brands. However, carefully targeted, responsible marketing to adult smokers can raise awareness of vaping, reduce the demand for traditional cigarettes, and increase switching to vaping as a lower-risk alternative [49, 50].

Exaggerated and misleading warning statements to discourage youth experimentation, even if technically correct, could deter adult smokers from switching to the safer product [51].

Prohibition and harsh regulation push drugs underground and often cause increased harm [52]. Prohibition of vaping in a variety of jurisdictions has led to continued use [53], increased cigarette sales [54] and a shift to illegal markets and more sales to youth [55].

TABLE 1 Elements of the consumer regulatory model [56–59].

Product standards	<ul style="list-style-type: none"> The current TGO 110 standards [59] are inadequate and need to be upgraded, for example, include all blacklisted ingredients on the TPD list [57]. Minimum standards for the manufacture and safety of vaping liquids and devices should include electrical, thermal, mechanical and chemical safety; standardised testing regimes; purity standards for ingredients; extended blacklist or dose limits on problematic ingredients; laboratory testing; and possibly emission testing. Limits to nicotine, for example, 20 mg/mL for freebase nicotine; 50 mg/mL for nicotine salt (as in New Zealand) [56].
Containers and labelling	<p>Mandatory standards for labelling: ingredient list; expiry date and batch number; PG:VG ratio; nicotine concentration; safety warning.</p> <p>Barcodes for tracing.</p> <p>Child-resistant refill containers which are leak proof, unbreakable (PET plastics) and have anti-spill protection.</p> <p>Removal of images that appeal to youth, for example, cartoons, appealing characters.</p> <p>Bottle size limits, for example, maximum 1800 mg nicotine per container (as in New Zealand) [56].</p>
Health warnings	<p>Health warnings comparing the risks to smoking, for example [58]:</p> <ul style="list-style-type: none"> 'This product may be addictive but is a far less harmful alternative for adult smokers'. 'If you are a smoker, switching completely to vaping is a much less harmful option'.
Notification system	Mandatory notification of compliance to standards prior to marketing
Flavours	<ul style="list-style-type: none"> Simple descriptions of flavour profiles. Prohibit descriptive flavour names and images that specifically appeal to youth and unsafe flavouring chemicals.
Public vaping	<ul style="list-style-type: none"> Some restrictions to apply, especially indoors.
Public messaging	<ul style="list-style-type: none"> Communicate the absolute and relative harms for vaping nicotine compared to smoking. Frame vaping as a less harmful alternative for adult smokers. Messaging to youth should emphasise that no nicotine-containing product is fully safe to use, all can be addictive, and youth should never start using any tobacco or nicotine product. All messaging should be accurate and avoid exaggeration of risks.
Advertising	<ul style="list-style-type: none"> Restricted advertising targeted at smokers who are unable or unwilling to quit with a 'switch' message. Banning all advertising that could appeal to young people, such as lifestyle ads associating vaping with positive imagery and adventure. Placement of advertising to minimise exposure to young people.
Monitoring	A system for reporting adverse effects and recall of unsafe products
Taxation	<ul style="list-style-type: none"> Proportionate to risk, similar to nicotine gum and patches. Maintain a significant differential between NVP and cigarette prices. High NVP prices lead to increased smoking as cigarettes and vaping products are economic substitutes.

Abbreviations: NVP, nicotine vaping product; PET, polyethylene terephthalate; PG, propylene glycol; TPD, tobacco products directive; VG, vegetable glycerine.

3 | PROPOSED REGULATORY FRAMEWORK

A carefully regulated consumer model would bring Australia into line with other western countries such as New Zealand [56] and the United Kingdom [57] (Table 1).

The United States approach has been less successful because of an overriding focus on protecting children rather than assisting adult smokers, restrictive pre-marketing approval requirements by the US Food and Drug Administration and unclear relative risk communication by governments in the face of widespread media advertising of vaping products [60].

The first step required is to exempt low concentrations of nicotine liquid up to 20 mg/mL freebase nicotine and nicotine salt 50 mg/mL from the Poisons Standard, as in New Zealand [56]. This enables them to be sold as

consumer products rather than medicines. This change could be made at the federal level or by State and Territory governments.

Nicotine liquids should be available from licenced retail outlets, such as specialist vape shops, pharmacies and general retail outlets, as for cigarettes and alcohol. The sale of vaping products where tobacco is sold exposes adult smokers to the safer alternative when they purchase tobacco.

Strict age verification at the time of purchase is required with harsh penalties for breaches and potential loss of licence. Consideration could be given to mandatory CCTV recording of sales as a condition of a sales licence. Online sales could be permitted by pharmacies and specialist vape retailers, with third party age verification on purchase and delivery.

All retailers would require a licence to sell nicotine liquids from state or territory health departments.

TABLE 2 Regulation and monitoring authorities.

Australian Competition and Consumer Commission
<ul style="list-style-type: none"> Standards for e-liquids, containers, labelling and health warnings Pre-market notification of nicotine liquids All notified products are recorded in a publicly available searchable database Post-market surveillance and reporting
State and territory health departments
<ul style="list-style-type: none"> Annual tobacco licences for retailers Supervision and enforcement of retailer compliance Spot checks for underage sales Advertising restrictions Public vaping restrictions Policing illicit sales by the black-market Public education about vaping Vape shop staff training and certification similar to the Responsible Service of Alcohol requirements
The Commonwealth government
<ul style="list-style-type: none"> Legislative changes Taxation Border control to intercept illicit imports Public education about vaping

Retailers would pay an annual licence fee, make annual reports and be subject to compliance checks.

A dual pathway which allows manufacturers to apply to the Therapeutic Goods Administration for medicines classification could engage additional smokers and give doctors more confidence to prescribe NVPs.

Under this model, the black-market would become less profitable and illicit sales would diminish over time, being largely replaced by a legal, regulated market.

Further details are listed in Table 1.

4 | REGULATORY AUTHORITIES

NVPs are consumer products designed to replace deadly cigarettes [61]. They are most appropriately regulated by the Australian Competition and Consumer Commission (ACCC) under dedicated consumer legislation. The ACCC can provide consumer protection and ensure that products comply with the legal requirements of the *Competition and Consumer Act 2010*.


The ACCC would be responsible for establishing and enforcing comprehensive standards for e-liquids, containers, labelling and health warnings. It would establish a pre-market notification system for nicotine liquids and a post-market surveillance system for reporting adverse events and faulty products. State and territory governments and the Commonwealth would also have specific responsibilities (Table 2).

5 | CONCLUSION

Regulations for vaping and tobacco smoking should focus on reducing the net public health harm. Policymakers need to find a balance between allowing ready access to NVPs for adult smokers while restricting access to youth. Harsh restrictions and bans are ineffective and often counterproductive.

The preferred regulatory approach is a pragmatic consumer model, regulated tightly and proportionate to risk. An overly restrictive approach to protect young people which reduces the access, effectiveness and appeal of vaping by adult smokers is likely to perpetuate illegal vaping product sales and tobacco smoking and have an overall profoundly negative effect on population health.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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