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# Australia tightens its prescription-only regulation of e-cigarettes

## New measures close loopholes that facilitate non-therapeutic use

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Australia recently announced further tightening of e-cigarette regulations introduced in 2021 that designated all e-cigarettes containing nicotine as prescription-only medicines.[1] Since 2021, only authorised practitioners can prescribe e-cigarettes dispensed by pharmacists, although any doctor can prescribe e-cigarettes for patients to import themselves for personal use (that is, "to be sent to them from an overseas supplier or family/friend"[2]). Nicotine-free e-cigarettes continued to be sold as consumer products similar to tobacco.

However, many retailers have continued selling nicotine containing e-cigarettes "under the counter," few adults use the prescription pathway, and use of e-cigarettes by young people seems to have increased.[3-5]

The proposed measures aim to close loopholes that facilitated illicit sales and include only allowing pharmacies to import e-cigarettes, regardless of nicotine content, and banning single use disposable and flavoured e-cigarettes, which are popular among young people. These measures will end the sale of nicotine-free e-cigarettes as consumer products and stop all personal importation of e-cigarettes for either recreational or therapeutic purposes such as by purchasing from international online stores. To maintain access for adults quitting smoking, all medical practitioners will be able to prescribe e-cigarettes without needing special authorisation.

Although these new measures are restrictive, they still allow controlled access to e-cigarettes through a medicinal pathway. Twenty six countries have banned sale of all types of e-cigarettes, regardless of nicotine content. India also bans importation of e-cigarettes, and Singapore bans possession and use.[6]

Is Australia's prescription based model a reasonable approach to regulating e-cigarettes? The model aims to make e-cigarettes available for smoking cessation while protecting young people from the risk of nicotine addiction through vaping. So, the regulatory model is reasonable in its intent.

### Will it work?

However, whether Australia's model will achieve these aims is unclear. Prevention of illicit importation and supply may remain challenging. The current lack of regulatory approval for e-cigarettes in any jurisdiction has probably undermined the credibility of e-cigarettes as smoking cessation aids among consumers and healthcare professionals.[7] Healthcare professionals are generally reluctant to endorse e-cigarettes for quitting because of continuing uncertainty about risks. This is problematic since professional counselling increases the efficacy of pharmaceutical smoking cessation aids.[8]

Pharmacy-only supply of e-cigarettes under the Australia model may enhance the credibility of e-cigarettes for smoking cessation among healthcare professionals and adults who smoke.

Potential disadvantages of a prescription based model are the added costs and inconvenience associated with medical consultations, for both consumers and the health system.[9] Further refinement of the Australian regulatory framework may be warranted. One option is to maintain restrictions such as pharmacist-only supply of e-cigarettes but remove the need for a medical prescription, similar to the framework used for medicines containing pseudoephedrine.[10] This could limit purchasing by young people while improving access for adults who smoke. Community based pharmacists are an accessible and trusted source of health advice in Australia and can provide counselling in the use of the full range of smoking cessation medicines and referral to the Quitline for behavioural support.[11]

An alternative to the prescription model is to sell e-cigarettes as consumer products but with restrictions on marketing and retail availability. The advantages and disadvantages of the consumer product model relative to other regulatory approaches are hotly debated. Proponents claim it enhances smoking cessation rates and accelerates reductions in smoking prevalence, while critics argue it results in unacceptable youth uptake of vaping and low quit rates.

Implementing new regulatory frameworks for e-cigarettes presents an opportunity to ensure that smoked tobacco—which accounts for most of the health burden from nicotine products—is subject to the toughest regulatory restrictions. While Australia has recently announced a new national tobacco strategy and commited to a menthol ban, stronger warnings on cigarette packs and sticks, and a 5% annual increase in tobacco excise for three years, the availability of smoked tobacco products remains largely unregulated.[12]

The new measures are welcome, but pale in comparison with the bold framework being implemented in New Zealand (Aotearoa),[13] which aims to rapidly end the cigarette epidemic by reducing nicotine to non-addictive levels in all commercial smoked tobacco products, decreasing the number of tobacco retail outlets by 90%, and introducing a tobacco-free generation policy whereby it will be illegal to sell smoked tobacco products to people born after 2008. New Zealand has chosen a consumer product model for e-cigarettes, although debate continues about whether this needs to be modified to reduce high rates of e-cigarette use among the youth.

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Overall, Australia's e-cigarette framework reflects the challenge of minimising use among young people, while helping adults quit smoking. This novel regulatory model should be seen against a backdrop of uncertainty: products and behaviours are evolving rapidly, and different jurisdictions are implementing different policies without good evidence about which approach maximises benefits and minimises harms. Only through implementing and evaluating these different approaches will we learn what works—or doesn't—for whom and in what contexts. In the meantime, the priority should continue to be strengthening restrictions on smoked tobacco products to accelerate declines in smoking prevalence.

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1 Ministers Department of Health and Aged Care. Taking action on smoking and vaping. 2023. https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/taking-action-on-smoking-and-vaping

2 Australian Government Department of Health and Aged Care. Personal importation scheme. 2023. https://www.tga.gov.au/products/unapproved-therapeutic-goods/personal-importation-scheme

3 Watts C, Egger S, Dessaix A, etal. Vaping product access and use among 14-17-year-olds in New South Wales: a cross-sectional study. *Aust N Z J Public Health* 2022;46:-20. doi: 10.1111/1753-6405.13316. pmid: 36156328

4 Australian Government Department of Health and Aged Care. Nicotine vaping product access. 2023. https://www.tga.gov.au/products/medicines/prescription-medicines/nicotine-vaping-products-hub/nicotine-vaping-product-access

5 Davey M. Australian youth vaping rates higher than previously thought, study suggests. *Guardian* 2023 Mar 27. https://www.theguardian.com/australia-news/2023/mar/28/australian-youth-vaping-rates-higher-than-previously-thought-study-suggests

6 Johns Hopkins Institute for Global Tobacco Control. Country laws regulating e-cigarettes. 2023. https://www.globaltobaccocontrol.org/en/policy-scan/e-cigarettes/sale

7 Benowitz NL, Warner KE, Myers ML, etal. How the FDA can significantly improve the public health—helping people to stop smoking. *N Engl J Med* 2023;388:-2. doi: 10.1056/NEJMp2301700 pmid: 37092791

8 US Department of Health and Human Services. *Smoking cessation. a report of the surgeon general.* US 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, 2020.

9 Mendelsohn C, Wodak A, Hall W. How should nicotine vaping be regulated in Australia?*Drug Alcohol Rev* 2023. doi: 10.1111/dar.13663. pmid: 37071577

10 Hattingh L. Pharmacy legal: Supplying and recording pseudoephedrine. *Australian Pharmacist.* 2014;33:-1.

11 Taing MW, Ford PJ, Gartner CE, Freeman CR. Describing the role of Australian community pharmacists in oral healthcare. *Int J Pharm Pract* 2016;24:-46. doi: 10.1111/ijpp.12241 pmid: 26809378

12 Australian Government Department of Health and Aged Care. National tobacco strategy 2023-2030. 2023. https://www.health.gov.au/resources/publications/national-tobacco-strategy-2023-2030?language=en

13 New Zealand Manatu Hauora Ministry of Health. Smokefree 2025 action plan. 2023. https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/smokefree-aotearoa-2025-action-plan

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