



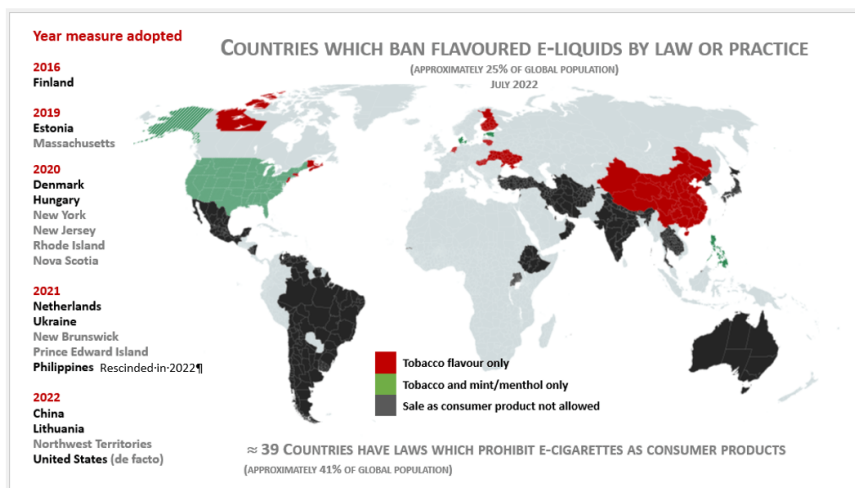
Response to the TGA Consultation paper: Potential reforms to the regulation of nicotine vaping products (NVPs)

The Australian Council on Smoking and Health (ACOSH) is an independent, non-government, not for profit coalition of prominent health, education, community, social service and research bodies with a shared concern about smoking and health. ACOSH works through advocacy and collaboration on comprehensive strategies to achieve a tobacco-free Australia by 2030.

It is an historical anomaly that tobacco is available as a consumer product, a consequence of the harms of tobacco use being identifying many years after its uptake. Tobacco use remains the leading cause of preventable disease and early death in Australia. Smoking-caused diseases kill more than 20,000 people every year. Smoking is responsible for killing two-thirds of regular consumers.¹

The commitment of all Australian governments² to maintaining a precautionary approach to e-cigarettes is supported strongly by ACOSH given increasing research into the harms of e-cigarette use and evidence that e-cigarette use by young people can be a gateway to smoking and nicotine addiction.³

More than half world's citizens live in countries whose health authorities do not approve the sale of flavoured e-cigarettes. Approximately 40% of the global population lives in countries where e-cigarettes cannot be sold at all as consumer products.⁴



¹ Winstanley, MH & Greenhalgh, EM. 3.0 Introduction. In Scollo, MM and Winstanley, MH [editors]. Tobacco in Australia: Facts and issues. Melbourne: Cancer Council Victoria; 2019. www.tobaccoinaustralia.org.au/chapter-3-health-effects/3-0-background

² See [Policy and regulatory approach to electronic cigarettes \(e-cigarettes\) in Australia | Australian Government Department of Health and Aged Care](#).

³ Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. *Report for the Australian Department of Health*. National Centre for Epidemiology and Population Health, Canberra: April 2022. <https://openresearch-repository.anu.edu.au/handle/1885/262914>

⁴ Physicians for a Smoke-Free Canada <https://smoke-free.ca/update-on-e-liquid-flavour-restrictions/>

Use of e-cigarettes for smoking cessation

Australian health authorities have identified a possible and limited role for NVPs in smoking cessation.

National Health and Medical Research Council (NHMRC CEO statement 2022)⁵

For some smokers, using nicotine e-cigarettes may assist them to quit smoking. There are other proven safe and effective options to help smokers quit. E-cigarettes are not proven safe and effective smoking cessation aids.

RACGP Supporting smoking cessation: A guide for health professionals⁶

Recommendation 15:

For people who have tried to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend along with behavioural support.

Conditional recommendation for intervention, low certainty

The recently published Cochrane report on e-cigarettes concluded that the relative risk for success between E-cigarettes and NRT is 1.63 (10 vs 6 successes per 100 tries). The relative risk for failure between NRT and E-cigarettes is 1.04 (94 vs 90 failures per 100 tries).⁷

While there is little difference between the success and failure rates, the safety of NRT has been assessed but no e-cigarettes have been submitted to the TGA for evaluation of quality, safety and efficacy (for smoking cessation).

ACOSH shares the concerns of the TGA⁸ that existing requirements for NVPs are not meeting the aim of preventing children and adolescents from accessing NVPs, whilst allowing smokers to access these products for smoking cessation with a doctor's prescription.

In practice, across Australia,

- children and adolescents are continuing to obtain NVPs in higher numbers; and
- adults are accessing NVPs without a prescription, rather than through lawful supply channels with a prescription from an Australian doctor.

⁵ National Health and Medical Research Council CEO statement 2022 www.nhmrc.gov.au/health-advice/all-topics/electronic-cigarettes/ceo-statement

⁶ RACGP Supporting smoking cessation: A guide for health professionals www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/supporting-smoking-cessation/recommendations

⁷ Electronic cigarettes for smoking cessation. Cochrane Library www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/full

⁸ TGA Potential reforms to the regulation of nicotine vaping products. Consultation paper <https://consultations.tga.gov.au/medicines-regulation-division/proposed-reforms-to-the-regulation-of-nicotine-vap/>

Restricting illegal supply of e-cigarettes

ACOSH supports comprehensive restrictions to shut down the avenues of illegal supply of NVPs. Without an integrated approach on NVPs and non-nicotine e-cigarettes, the concealment of nicotine in products will continue to undermine the effectiveness of any TGA reforms to end illegal access to NVPs.

To achieve this outcome, the following options in the consultation paper are supported:

1. ACTION NEEDED AT THE BORDER Support Option 4

Federal government to introduce an amendment of the Customs Regulations to declare all vaping products (NVPs and non-nicotine products and devices) prohibited imports. An import permit would be required to demonstrate that the import falls within one of the exemptions for accessing unapproved therapeutic products.

Additional Actions Required:

Therapeutic goods controls to deal with the domestic manufacture and supply of NVPs.

Federal, State and Territory government action to ban and enforce prohibition of the importation, manufacturing and supply of all vaping products.

REINFORCING THE TGA PRESCRIPTION PATHWAY

Ending the Personal Importation Scheme would:

- Require prescriptions for NVPs to be through a medical practitioner with approvals under the Authorised Prescriber (AP) scheme or Special Access scheme (SAS);
- Mean all NVPs would be accessed through local pharmacies (online or physical) ensuring that patients receive pharmacists' advice; and
- Close a loophole that may be exploited through the allowance of 15 months NVPs supply.

As a stand-alone measure Option 2 is not supported as it would not be effective in ending the most common avenues of illegal supply of vaping products.

E-cigarette product controls

2. PRE-MARKET ASSESSMENT OF NVPs Support Option 3

Ensuring the quality, safety and efficacy of prescription products:

- Would be undermined by a pre-market assessment process proposed in Option 2, setting a dangerous precedent and lowering the bar for TGA regulation;
- Is best achieved by Option 3 to establish a regulated source of NVPs through the evaluation of quality, safety and efficacy (for smoking cessation); and
- Is an expectation of Australian consumers, therefore it is likely that a pathway that did not undertake a full safety analysis of products or evaluation of efficacy would be misunderstood by consumers as an "endorsement by the TGA".

Recognising the barriers to access that this poses to the current prescription pathway, Option 1: Make no changes, would be the alternative option preferred if Option 3 is not adopted.

3. MINIMUM QUALITY AND SAFETY STANDARDS FOR NVPs

Support Option 7

Measures to reduce the appeal and harm of vaping products through amendments to TGO 110 or by changing the terms of the exemptions under which unapproved NVPs are currently imported:

- Prohibit all flavours (except tobacco) and additional ingredients;
- Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging;
- Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent);
- Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent); and
- Remove access to disposable NVPs.

Option 7 is supported to complement Option 4, a ban on importation of vaping products and devices, not as a standalone option that would be ineffective in curbing illegal access to NVPs.

4. CLARIFYING THE STATUS OF NVPs AS 'THERAPEUTIC GOODS'

Yes support

This would enable the TGA to take regulatory action in relation to NVPs that contain nicotine, but are not labelled as such, under the therapeutic goods legal framework.

ACOSH support restrictions on access to NVPs to reduce use, except by smokers for smoking cessation with a doctor's prescription, as an important and vital investment in the prevention of future harms.

As concluded in the systematic review of global evidence conducted by the National Centre for Epidemiology and Population Health, [Electronic cigarettes and health outcomes](#):

There is strong or conclusive evidence that nicotine e-cigarettes can be harmful to health and uncertainty regarding their impacts on a range of important health and disease outcomes. Based on the current worldwide evidence, use of nicotine e-cigarettes increases the risk of a range of adverse health outcomes, including: poisoning; toxicity from inhalation (such as seizures); addiction; trauma and burns; lung injury; and smoking uptake, particularly in youth.

Their effects on most other clinical outcomes are unknown, including those related to cardiovascular disease, cancer, respiratory conditions other than lung injury, mental health, development in children and adolescents, reproduction, sleep, wound healing, neurological conditions other than seizures, and endocrine, olfactory, optical, allergic and haematological conditions.

Nicotine e-cigarettes are highly addictive, underpinning increasing and widespread use among children and adolescents in many settings.

Less direct evidence indicates adverse effects of e-cigarettes on cardiovascular health markers, including blood pressure and heart rate, lung function and adolescent brain development and function.

The commonest pattern of e-cigarette use is dual e-cigarette use and tobacco smoking, which is generally considered an adverse outcome.

There is limited evidence of efficacy of freebase nicotine e-cigarettes as an aid to smoking cessation in the clinical setting. E-cigarettes may be beneficial in some smokers who use them to quit smoking completely and promptly, with uncertainty about their overall balance of risks and benefits for cessation.

Current evidence supports national and international efforts to avoid e-cigarette use in the general population, particularly in non-smokers and youth.

Better evidence is needed on health impacts, the overall balance of quality, safety and efficacy of e-cigarettes as potential aids for smoking cessation, and effective regulatory options.