

POSITION STATEMENT ON TOBACCO HARM REDUCTION

Smoking tobacco cigarettes is one of the most harmful ways to use nicotine. Nicotine products that do not involve the inhalation of combusted tobacco, such as low nitrosamine smokeless tobacco and vaporised nicotine products, are likely to be much less harmful because they expose users to far fewer toxic chemicals.^{1 2} Smoking in Australia and other high income countries is increasingly concentrated among populations that experience greater social disadvantage and discrimination. These smokers should be a high priority for increasing access to reduced risk nicotine products because they experience greater difficulty quitting smoking, greater vulnerability to tobacco-related diseases and often have poorer health outcomes than more advantaged patients.

Accordingly, the undersigned Australian health and medical organisations support a risk-proportionate regulatory approach that allows Australian adults to legally access non-therapeutic reduced risk nicotine products. This is in line with Australia's National Drug Strategy. It also accords with approaches endorsed by international government and non-government health and medical organisations, including, but not limited to: The American Cancer Society, Cancer Research UK, Action on Smoking and Health UK, Royal Society for Public Health, Royal College of Physicians, British Medical Association, Public Health England, Health Canada, New Zealand Ministry of Health and the US Food and Drug Administration.

- Signatories

Tobacco Harm Reduction

Harm Reduction is one of the three pillars of Australian drug policy, along with Demand Reduction and Supply Reduction.³ The National Drug Strategy states that the same approach should be adopted for all substance use, including tobacco, and that strategies should be equally balanced across these the three pillars. Australia has been a leader in implementing Harm Reduction policies for substances other than tobacco and other health issues, such as HIV prevention. Examples include clean needle and syringe programs to prevent the spread of blood borne viruses through sharing injection equipment, promotion of condom use and increasing access to condoms (e.g. condom vending machines) and pre-exposure prophylaxis treatment with antiretroviral drugs. These strategies are all essential components of Australia's comprehensive response to HIV.

Internationally, there is good evidence that the wide availability of non-therapeutic reduced risk nicotine products is beneficial to public health.⁴ Sweden has one the lowest smoking prevalence and lowest rates of tobacco-related disease among high-income countries. It is widely acknowledged that the availability of low nitrosamine smokeless tobacco, in the form of Swedish snus, has been a major contributor to this achievement.⁵

The current Australian policy approach to harm reduction for tobacco users is inconsistent with the National Drug Strategy. It is also inconsistent with the goals of the Ottawa Charter for Health Promotion such as increasing "the options available to people to exercise more control over their own health and over their environments, and to make choices conducive to health", "ensuring safer and healthier goods and services" and making "the healthier choice the easier choice."⁶ The current Australian policy approach to reduced risk nicotine products is inconsistent with these principles. It is ethically questionable to prohibit access to lower risk nicotine products that might be acceptable substitutes for tobacco cigarettes, while permitting tobacco cigarettes to be widely sold.⁷

Prohibiting access to lower risk alternatives to tobacco cigarettes is increasingly recognised internationally as poor public policy. Australia's policy is out of step with our international

POSITION STATEMENT ON TOBACCO HARM REDUCTION

counterparts, such as the United Kingdom, the United States of America, Canada, New Zealand and Europe (both EU and non-EU countries). These countries have chosen to regulate non-therapeutic nicotine products by developing appropriate quality standards for manufacture, packaging and labelling to minimise the risk of using these products and to maximise the opportunities for smokers to switch to a lower risk nicotine delivery system. Australia should do the same.

Populations with high smoking prevalence

Tobacco Harm Reduction is an important social justice issue because smoking prevalence in Australia is unevenly distributed across the population.⁸ Populations that are more likely to smoke are also those who are more likely to experience social disadvantage, stigmatisation and marginalisation in mainstream Australian society. These include LGBTIQ people, people living with HIV, people with substance use disorders and people living with mental illnesses. Many of these smokers experience greater difficulty quitting smoking.

Australian policy on e-cigarettes that gives priority to preventing uptake of smoking among youth perpetuates the discrimination that these populations often experience and risks exacerbating health disparities because their health needs have been given little weight in policy making on tobacco harm reduction.⁹ Allowing access to lower risk ways of using nicotine could substantially reduce smoking-related diseases among these populations for whom smoking causes a high burden of premature morbidity and mortality. It will also reduce the large financial burden of smoking in these populations if these products are taxed at a lower rate than smoked tobacco.

Children and Youth

Australia has one of the world's lowest rates of youth smoking. This low youth smoking prevalence is often cited as a reason to prohibit adult smokers from accessing reduced risk non-therapeutic nicotine products. Youth use of nicotine in any form is undesirable and preventive efforts are needed to protect youth from developing addiction to nicotine. However, these concerns do not justify a zero tolerance approach toward reduced risk nicotine products. Importantly, the same approach has not been adopted to smoked tobacco. Indeed, the low youth smoking prevalence has been achieved without prohibiting sale of smoked tobacco to adults. Potential use of condoms by underage youth is not considered a justification for banning adult access to this harm reduction product.

The argument that allowing the sale of reduced risk nicotine products to adults will increase youth smoking prevalence is inconsistent with evidence from countries that allow the sale of e-cigarettes. In these countries youth smoking has decreased over the same time period that access to reduced risk nicotine products has increased. Close monitoring of youth smoking and nicotine use is warranted, but prohibition of sales to adults is not.¹⁰ Furthermore, children and youth living in households of adult smokers will benefit from these adults switching to reduced risk nicotine products which produce lower or no second-hand emissions.

Regulation as a therapeutic good is not a viable option for reduced risk nicotine vaping or smokeless tobacco products

Current Australian policy only allows nicotine extracted from tobacco to be sold as an approved therapeutic good, such as a smoking cessation aid. The only non-therapeutic nicotine product permitted to be sold is tobacco prepared and packed for smoking, the most harmful way to use nicotine. While it is theoretically possible for a nicotine vaping product or smokeless tobacco product to be approved as a therapeutic good, there are no approved vaporised nicotine products or

POSITION STATEMENT ON TOBACCO HARM REDUCTION

smokeless tobacco products available in Australia. The fact that these products can be sold without therapeutic goods approval in most of the world limits commercial interest in obtaining approval to sell them as a therapeutic good. While therapeutic goods approval would result in these products being manufactured to a very high quality and good safety assurance, only allowing approved products to be sold risks the perfect being the enemy of the good.

Furthermore, products that are approved as therapeutic goods may not be appealing to smokers as substitutes for cigarettes because the regulatory framework for therapeutic goods is not likely to produce a product that can substitute for cigarettes. A good example is the low use of currently approved nicotine replacement therapies as long-term cigarette substitutes. Any vaporised nicotine product that was approved as a therapeutic good would only be available on medical prescription. This presents a substantial barrier to e-cigarettes competing effectively with cigarettes which are widely available in the general retail environment.

The Precautionary Approach/Principle

A 'precautionary approach' has been invoked as justification for the current ban on sale of non-therapeutic nicotine products.¹¹ The precautionary principle originated in the environmental protection field. The policy of banning adult access to non-therapeutic reduced risk nicotine products is inconsistent with a precautionary approach for a number of reasons.

Firstly, these products are replacing more harmful existing products. Products such as e-cigarettes and low nitrosamine smokeless tobacco are lower risk delivery systems for a substance (nicotine) that is legally (and widely) available in a much more harmful delivery system (tobacco cigarettes). The ban has the perverse effect of favouring a more harmful over a less harmful nicotine product.

Secondly, precautionary measures should be taken (e.g. limits on nicotine strength, child-resistant packaging, accurate labelling), but a precautionary approach does not require or justify a zero risk approach. Prohibition is a disproportionate policy response. The following quotes from Australian case law¹² provide guidance on the appropriate application of the Precautionary Principle:

- "The precautionary principle should not be used to try to avoid all risks."
- "A zero risk precautionary standard is inappropriate"
- "Measures based on the precautionary principle must not be disproportionate to the desired level of protection and must not aim at zero risk, something which rarely exists"
- "The precautionary principle embraces the concept of proportionality"
- "The selection of the appropriate precautionary measures must involve examining both sides of the ledger: the costs associated with the project, process or product (which tends to increase the degree of precaution) as well as the benefits of the project, process or product (which tends to decrease the degree of precaution commensurate with realising the benefit)"
- "The precautionary principle, where triggered, does not necessarily prohibit the carrying out of a development plan, programme or project until full scientific certainty is attained."

Risk proportionate regulation is needed

Applying regulation that is proportionate to reduced risk nicotine products (e.g. see New Zealand Ministry of Health statement¹³) is a more coherent and legitimate application of the Precautionary Principle.

Risk proportionate regulation could include nicotine content limits, manufacturing quality standards, packaging and labelling requirements, and sales and advertising restrictions, such as age limits and

POSITION STATEMENT ON TOBACCO HARM REDUCTION

retailer licensing. Policies that encourage smokers to switch to lower risk products, such as lower taxation compared to smoked tobacco could achieve more equitable public health outcomes.

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¹ National Academies of Sciences, Engineering, and Medicine. "Public health consequences of e-cigarettes." Washington, DC: The National Academies Press. doi 10 (2018): 24952.

² Tobacco Advisory Group of the Royal College of Physicians. "Nicotine without smoke—tobacco harm reduction." Royal College of Physicians. 2016.

³ National Drug Strategy 2017-2026.

⁴ Gartner CE, Hall WD, Vos T, Bertram MY, Wallace AL, Lim SS. Assessment of Swedish snus for tobacco harm reduction: an epidemiological modelling study. *The Lancet*. 2007 Jun 16;369(9578):2010-4.

⁵ Foulds J, Ramstrom L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tobacco control*. 2003 Dec 1;12(4):349-59.

⁶ WHO. The Ottawa Charter for Health Promotion. First International Conference on Health Promotion, Ottawa, 21 November 1986.

⁷ Hall W, Gartner C, Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction*. 2015 Jul 1;110(7):1061-7.

⁸ Bonevski B, Borland R, Paul CL, Richmond RL, Farrell M, Baker A, Gartner CE, Lawn S, Thomas DP, Walker N. No smoker left behind: it's time to tackle tobacco in Australian priority populations. *The Medical Journal of Australia*. 2017 Aug 21;207(4):141-2.

⁹ Hall W, Morphett K, Gartner C. The Australian ban on nicotine-containing e-cigarettes is ethically indefensible. *Neuroethics*: submitted manuscript.

¹⁰ Glasser et al. Patterns of E-Cigarette Use Among Youth and Young Adults: Review of the Impact of E-Cigarettes on Cigarette Smoking. *Nicotine & Tobacco Research*, 2018, 1–11 doi:10.1093/ntr/nty10

¹¹ Department of Health. Principles that Underpin the Current Policy and Regulatory Approach to Electronic Cigarettes (E-Cigarettes) in Australia. 11 January 2018.

<http://www.health.gov.au/internet/main/publishing.nsf/Content/principles-underpin-current-policy-regulatory-approach-electroniccigarettes-eeCigarettes-australia>

¹² Hon. Justice Brian J Preston, (2006), 'Telstra Corporation Limited v Hornsby Shire Council [2006] NSWLEC 133', *Land and Environment Court of New South Wales*. Paragraphs 125-183. <https://www.caselaw.nsw.gov.au/decision/549f8a6b3004262463ad5606>

¹³ Ministry of Health. Vaping, smokeless, including heated tobacco. Update 6 June 2018.

<https://www.health.govt.nz/our-work/preventative-health-wellness/tobacco-control/vaping-smokeless-including-heated-tobacco>