

**Submission regarding the interim decision to
amend the current Poisons Standard in relation
to nicotine**

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by

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(INNCO)



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The International Network of Nicotine Consumer Organisations (“INNCO”) submits the following comments to the Therapeutic Goods Administration (TGA) in connection with the proposed interim decision to amend the current Poisons Standard in relation to nicotine in order to allow access to nicotine-containing e-cigarettes only with a prescription. While we support the Australian Government and the TGA’s efforts to seek a means to allow legal access to nicotine-containing e-cigarettes by adults, we are concerned that the proposal is overly restrictive and will provide unnecessary and harmful barriers to access to these low-risk alternatives to smoking. Specifically, INNCO believes that as currently drafted, the interim decision will deprive many Australians who smoke meaningful and effective access to products that can dramatically lower their health risks and would actually protect the existing market in high-risk combustible tobacco products.

We disagree with many of the assertions made in the interim decision, and do not support a decision to allow access to nicotine-containing e-cigarettes only with a prescription. Rather, we urge the TGA and Australian government (i) to make nicotine-containing e-cigarettes and nicotine-containing liquids designed for use with e-cigarettes (e-liquid) available to adults of legal age without a prescription, and (ii) to establish risk-proportionate laws and regulations which provide quality and safety standards (including requiring child-resistant packaging). These recommendations are discussed in more detail in Section IV below.

INNCO, a global non-profit with more than 35 independent, autonomous consumer groups within its network, makes this submission in support of those who currently use e-cigarettes as well as the millions of Australians who will continue to smoke if this interim decision is implemented in current form. INNCO is a consumer organisation, representing the interests of consumers, not industry. INNCO unites the voices of consumer groups across six continents in our call for rights-based, risk-relative and balanced tobacco harm reduction (THR) policies as a legitimate human right. In connection with tobacco use, harm reduction in its most basic form embraces a range of policies, regulations and actions that reduce health

risks by providing safer replacements for high-risk products and/or by encouraging less risky behaviour. We note that THR strategies are not designed to supplant traditional tobacco control measures, but, rather, complement them.

I. Findings of the Interim Decision

A. The risks and benefits of the use of a substance

The interim decision states, “The Committee considered the available evidence, which does not support that e-cigarettes are a safer alternative to smoking cessation aids currently available and that there is currently insufficient evidence to conclude whether e-cigarettes can benefit smokers in quitting.” We respectfully submit that framing the issue in this medicalised manner ignores how e-cigarettes are currently being used by people who smoke, namely, as a lower-risk substitute for the unquestionably dangerous habit of smoking.

First, the question should not be whether e-cigarettes are a safer alternative to smoking cessation aids. Rather, the question should be whether e-cigarettes are a safer alternative to smoking. There is no doubt that smoking is an incredibly harmful behavior, resulting in a whole host of serious health problems. Likewise, there is no doubt that e-cigarettes, while not completely safe, are in fact markedly less harmful compared to smoking. As first noted by the Royal College of Physicians in 2016, vapor products are “unlikely to exceed 5% of the harm from smoking tobacco,” and therefore, “in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking.”¹ This position has been continuously reaffirmed, most recently in Public Health England’s 2020 update on vaping, in which it found that “vaping regulated nicotine products has a small fraction of the risks of smoking” and that “smokers should be encouraged to try regulated nicotine vaping products along with smoking cessation medications and behavioural support.”²

¹ Royal College of Physicians, “Nicotine without smoke: Tobacco Harm Reduction,” 28 April 2016, <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>.

² McNeill, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England.

The acceptance of the low-risk nature of THR products is growing. In fact, the World Health Organisation (“WHO”) Regional Office for Europe recently issued a report noting there is conclusive evidence that “completely substituting EN&NNDS for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes.”³ This echoes the findings of the National Academies of Sciences, Engineering and Medicine.⁴

Second, there is likewise no doubt that e-cigarettes can and do benefit smokers in quitting.⁵ Even the WHO Regional Office for Europe notes that there is evidence showing that “some smokers may successfully quit tobacco by using some type of ENDS frequently or intensively.”⁶ In a recent study involving 886 participants, researchers concluded that vapor products “were **more effective for smoking cessation than nicotine-replacement therapy**, when both products were accompanied by behavioral support” (emphasis supplied)⁷.

Earlier this year, the updated Cochrane Review “Electronic Cigarettes for Smoking Cessation” was released, including a review of more than 50 studies. In addition to reinforcing the relative safety of e-cigarettes, the 2020 Cochrane Review found with

³ Regional Office for Europe of the World Health Organization, “Electronic Nicotine and Non-Nicotine Delivery Systems: A Brief,” 2020, <http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/electronic-nicotine-and-non-nicotine-delivery-systems-a-brief-2020>

⁴ The National Academies of Science, Engineering, Medicine, “Public Health Consequences of E-Cigarettes.” Washington, D.C. The National Academies Press 2018, <https://pubmed.ncbi.nlm.nih.gov/29894118/>

⁵ See, for example, Sara Kalkhoran, MD, MAS, Yuchiao Chang, PhD, Nancy A Rigotti, MD, Electronic Cigarette Use and Cigarette Abstinence Over 2 Years Among U.S. Smokers in the Population Assessment of Tobacco and Health Study, *Nicotine & Tobacco Research*, Volume 22, Issue 5, May 2020, Pages 728–733, <https://doi.org/10.1093/ntr/ntz114>.

⁶ Regional Office for Europe of the World Health Organization, “Electronic Nicotine and Non-Nicotine Delivery Systems: A Brief,” 2020, <http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/electronic-nicotine-and-non-nicotine-delivery-systems-a-brief-2020>

⁷ Peter Hajek, Ph.D., Anna Phillips-Waller, B.Sc., Dunja Przulj, Ph.D., et al., “A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy,” *N Engl J Med* 2019; 380:629-637, DOI: 10.1056/NEJMoa1808779 14 February 2019.

moderate-certainty evidence that (i) e-cigarettes with nicotine are 70% more effective in helping smokers to successfully quit than nicotine replacement therapy (NRT) and (ii) 70% more effective in helping smokers to successfully quit than nicotine-free e-cigarettes.⁸

B. The purpose for which a substance is to be used and the extent of use of a substance

In its interim decision, only two purposes for nicotine are considered: NRT and conventional cigarettes. The interim decision also notes that e-cigarettes have not been approved by the TGA or any equivalent foreign medicines regulator as a smoking cessation aid. We respectfully question the manner in which this issue is framed. By framing the issue as such, e-cigarettes are forced to be considered only in the NRT category as a medicalised product. Approaching the issue in this manner allows no consideration for whether e-cigarettes can be used as a low-risk alternative to smoking. In fact, the approach taken in the interim decision actually helps protect the combustible cigarette market. We urge the TGA and Australian government to adopt an approach that puts e-cigarettes in direct competition with combustible cigarettes. Specifically, we support the adoption of tobacco harm reduction policies.

Harm reduction is not a novel concept. In fact, “harm reduction strategies” are specifically included within the definition of “tobacco control” in Article 1 of the WHO Framework Convention on Tobacco Control (“FCTC”).⁹ A growing number of countries have chosen to reduce smoking in their borders by adopting pragmatic harm reduction strategies that allow adult smokers to make informed choices to dramatically reduce their risks. We note that leading countries have regulated THR products rather than ban or

⁸ Hartmann-Boyce J, McRobbie H, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Butler AR, Hajek P. Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews 2020, Issue 10. Art. No.: CD010216. DOI: 10.1002/14651858.CD010216.pub4.

⁹ World Health Organization, “WHO Framework Convention on Tobacco Control,” 2003, https://www.who.int/tobacco/framework/WHO_FCTC_english.pdf.

medicalise them, and, as a consequence, smoking rates in those countries continue to decline.¹⁰

Given that these products do work to help many people completely replace their smoking habit and improve their health, they should be embraced as a humane and pragmatic solution to help reduce the smoking rate in Australia. It works against the interests of public health to make e-cigarettes more difficult to obtain than traditional combustible cigarettes, which are by far the most risky manner in which nicotine can be used.

C. The toxicity of a substance

The interim decision identifies risks in relation to the toxicity of nicotine, but fails to consider these risks in context. Specifically, in every instance, the potential risks associated with nicotine use via e-cigarettes must be compared to the potential risks of the indisputably dangerous habit of smoking. We further note that very few products or activities are “safe” in the absolute sense of the word. For example, even NRTs carry some risks, including nicotine overdose. To illustrate our concern, it may be helpful to consider the situation of a person who has been advised to undergo an abdominal CT scan to aid with diagnosis. If the patient only considers the risk of the CT scan itself (.5 deaths due to cancer per 1,000 people)¹¹, the patient may understandably decline the procedure. On the other hand, the risks associated with the CT scan are minimal as compared to the risks of not having the CT scan and allowing a potentially serious medical issue to go undiagnosed and untreated. Clearly, risk assessment does not occur in a vacuum, and it is critical that risks be examined in context.

D. The dosage, formulation, labelling, packaging and presentation of a substance

We agree with the finding that child-resistant packaging might reduce the risk of unintentional exposure to nicotine in children.

E. The potential for abuse of a substance

¹⁰ Examples of countries regulating rather than banning THR products include the United Kingdom, Canada, the United States of America, New Zealand, and various countries in the European Union.

¹¹ “Do CT scans cause cancer?” Harvard Men’s Health Watch, March 2013.
<https://www.health.harvard.edu/staying-healthy/do-ct-scans-cause-cancer>

The finding that e-cigarettes with nicotine carry a high risk of dependence lacks context. Specifically, it ignores the fact that the vast majority of people who use e-cigarettes are people who were formerly nicotine-dependent by virtue of their smoking habit. While nicotine dependence is certainly an issue to be considered, the fact is that e-cigarette use, even with nicotine, poses just a small fraction of the risk associated with smoking.

F. Any other matters considered necessary to protect public health

The interim decision notes Australia’s obligations under the World Health Organisation Framework Convention on Tobacco Control (FCTC) to reduce tobacco consumption, nicotine addiction and exposure to tobacco smoke, but fails to note that tobacco control strategies are specifically defined to include harm reduction strategies. Moreover, no attention is given to the fact that people switching from smoking to e-cigarette use will cause decreases in tobacco consumption and exposure to tobacco smoke.

The interim decision concludes that the proposed framework would “help prevent the introduction of non-smokers to nicotine via vaping.” It fails to note the perversity of requiring a prescription for use of e-cigarettes while allowing adults (presumably including non-smokers) to purchase high-risk combustible cigarettes.

II. Concerns About Youth Use

The interim decision concludes that “restrictions on the availability of e-cigarettes are necessary to mitigate the potential uptake of smoking in young adults who would otherwise be at low risk of initiating nicotine addiction.” Requiring that e-cigarettes only be available with a prescription does not only impact young adults; it also limits availability for adults who smoke. While protecting youth is certainly important, there are measures which can be taken that will protect youth without creating so many barriers for adult smokers to make the switch and reduce their risks. For example, ensuring that e-cigarettes are age-restricted and imposing significant sanctions on under-aged sales will provide significant barriers for youth. Finding a balance that protects youth without severely limiting access to adults who can reduce their risks by switching from smoking to e-cigarette use is critical, especially when one considers that combustible cigarettes are afforded widespread availability.

We also note that a great deal of attention has been paid to the so-called “gateway” concern, namely, that people who use e-cigarettes may transition from e-cigarette use to smoking. J.F. Etter examined the issue of whether e-cigarette use was causing a gateway to smoking, and found:

The gateway theory is not compatible with either (1) the decrease in smoking prevalence observed in adolescents in countries where vaping increased or (2) an increase in smoking among teenagers after age restrictions were imposed on e-cigarette purchases. A spurious gateway effect can be produced artificially by mathematical models in which a propensity to use substances is correlated with opportunities to use substances. Finally, neither nicotine medications nor smokeless tobacco produce gateway effects. Available data are compatible with a common liability model in which people who are liable to use nicotine are more likely to use both e-cigarettes and cigarettes.¹²

What is clear, however, is that if there is a gateway effect, it seems to be a one-way and quite beneficial movement from smoking to lower-risk e-cigarette use.

III. Practical Concerns Associated with a Prescription-Only Model

As stated previously, we are concerned that relegating e-cigarettes to a prescription-only model will serve to protect the traditional combustible cigarette market by perversely making low-risk e-cigarettes more difficult to obtain than high-risk combustible cigarettes. In order to reduce the smoking rate, e-cigarettes should be made more competitive with combustible cigarettes rather than less.

Requiring a prescription for e-cigarettes creates a hurdle that combustible cigarettes do not have. Moreover, we believe that the hurdle is potentially far greater than perhaps envisioned by the interim decision. At present, there are few physicians providing prescriptions for e-cigarettes. The Australian Tobacco Harm Reduction Association (ATHRA) maintains a directory of prescribing physicians, and the listing is, at best, meager.¹³ While it is fair to assume that the number will grow over time, given the strong anti-THR bias and messaging by traditional tobacco control adherents, including many physicians, it is not

¹² Etter JF. Gateway effects and electronic cigarettes. *Addiction*. 2018 Oct;113(10):1776-1783. doi: 10.1111/add.13924. Epub 2017 Aug 7. PMID: 28786147.

¹³ ATHRA presently lists only nine physicians as willing to write prescriptions on its website at <https://www.athra.org.au/doctors/>

likely that the number will grow sufficiently, at least not in the short- and medium-term, to ensure reasonable access. Meanwhile, combustible cigarettes will remain widely available and easily accessible.

Relegating e-cigarettes to a prescription-only model also ignores one of the factors that makes these products so promising in the battle to reduce the smoking rate. Specifically, there are a significant number of people who use e-cigarettes who are “accidental quitters.” These are people who tried an e-cigarette with no desire or intent to quit smoking, but nonetheless found themselves becoming “accidental quitters.” This phenomenon has been long-recognised in the consumer community¹⁴, but has recently gained attention from the scientific community.¹⁵ Having e-cigarettes available wherever combustible cigarettes can be purchased encourages people who smoke to try e-cigarettes as an alternative. Creating barriers by making e-cigarettes available only at pharmacies or ordered overseas--and then only with a prescription--virtually eliminates the “accidental quitter” phenomenon, in addition to posing barriers even for those who are motivated to quit.

Consumers are justifiably concerned about the criminalisation of a behavior that is far less damaging than smoking. While at first blush it may seem that pursuing a medicalisation route eliminates criminalisation concerns, we note that the issue, while somewhat ameliorated, will nonetheless persist. This stands in stark contrast to the current situation where adults are able to legally purchase combustible cigarettes without prescription and without criminalisation concerns. And, of course, all of the attendant problems associated with the black market will not only persist, but will likely grow.

IV. Reasonable Regulation Must Embrace Harm Reduction.

¹⁴ In its 2015 survey of members, consisting of more than 20,000 respondents, the Consumer Advocates for Smoke-free Alternatives Association (CASAA) reported that of the 17,186 respondents who quit smoking entirely using e-cigarettes, 64% said they started using e-cigarettes with the intention of quitting smoking, 25% started with the intention of merely reducing their smoking but ended up switching entirely, and 11% started using e-cigarettes without the intention of quitting or reducing smoking, but ended up switching entirely. <https://casaa.org/wp-content/uploads/CASAA-Vaping-Survey-Results-CVP-post-4-January-2016.pdf>

¹⁵ See Notley C, Ward E, Dawkins L, Holland R. The unique contribution of e-cigarettes for tobacco harm reduction in supporting smoking relapse prevention. *Harm Reduct J.* 2018;15(1):31. Published 2018 Jun 20. doi:10.1186/s12954-018-0237-7.

We urge the enactment of reasonable, proportionate regulation that is risk-relative and balanced.

- A. **Ensure products are not sold to minors** as an important first step in preventing youth uptake of nicotine-containing products.
- B. **Provide for accurate communication regarding relative risks** to allow adult consumers to make informed choices to eliminate or reduce their risk from smoking. Communications, whether from governmental agencies or contained on product labeling, should accurately and honestly state that while e-cigarettes are not risk-free, they are substantially lower risk than smoking.
- C. **Provide reasonable product standards that are attainable and ensure quality and safety**. We note that flavours are a key reason why e-cigarettes are such an effective alternative to smoking. The importance of flavours is recognised not only by the WHO Regional Office of Europe, but is supported by a growing body of research.¹⁶

V. **Conclusion**

There are currently more than 2 million people who smoke in Australia, and while Australia has achieved some very real success in reducing the smoking rate in years past, the fact is that smoking decline rates have been, at best, stagnant over the last few years using traditional tobacco control strategies. Serious consideration should be given to employing harm reduction strategies as a complement to traditional tobacco control measures in order to help reduce the smoking rate.

Regulation of e-cigarettes must be reasonable and proportionate, and relegating these products to a prescription-only model will result in fewer smokers quitting than if e-cigarettes were regulated as a general consumer good to compete head-on with high-risk combustible

¹⁶ See, for example, Farsalinos K, Romagna G, Tsiapras D, et al. Impact of flavour variability on electronic cigarette use experience: an internet survey. *Int J Environ Res Public Health*. 2013;10:7272–82. See also Russell, C., McKeganey, N., Dickson, T. et al. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* 15, 33 (2018). <https://doi.org/10.1186/s12954-018-0238-6>



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cigarettes. People who smoke need more options, not fewer. Making low-risk products like e-cigarettes more difficult to access than combustible cigarettes, indisputably the most dangerous tobacco product on the market in Australia, works against fundamental tenets of public health.

For the foregoing reasons, INNCO does not support the interim decision with the exception of the call for child-resistant packaging. We respectfully request that the interim decision be amended to pursue a policy that is in step with countries that are moving towards harm reduction as an ethical and effective means of reducing smoking rates.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Julie Woessner".

Julie Woessner
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