

**Supplementary Submission to the ACMS**  
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**PROPOSED AMENDMENT TO EXEMPT 'TOBACCO PREPARED AND  
PACKED FOR HEATING' FROM SCHEDULE 7 OF THE POISONS STANDARD  
following an interim decision announced by the Therapeutic Goods  
Administration June 2020**

submitted by

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## **Supplementary Submission to: Therapeutic Goods Administration (TGA) Joint Advisory Committee on Medicines Scheduling (ACMS) / Advisory Committee on Chemicals Scheduling (AACS)**

The following comments are respectfully submitted on behalf of the International Network of Nicotine Consumer Organizations (INNCO) **in support** of an amendment to the current Poisons Standard (Nicotine) for heated tobacco products to be added to the list of exemptions contained in Schedule 7.

INNCO, a global non-profit of more than 30 member consumer groups, makes this submission in support of the millions of Australians who will continue to smoke if denied access to reduced-risk products.<sup>1</sup> We are a consumer organization, representing the interests of consumers, not the industry. INNCO unites the voices of consumer groups across six continents in our call for rights-based, risk-relative and balanced tobacco harm reduction 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.

### **The Concept Of Harm Reduction**

‘Safer does not mean safe’ is a term often used by tobacco control and medical health regulators to justify their opposition in authorising approval for the sale of reduced-risk nicotine products. While at first glance this might appear a valid argument, when viewed within the wider context of drug harm reduction, it loses its potency. Denying people who smoke access to reduced-risk nicotine products not only undermines general harm reduction principles otherwise embraced by Australia, but deprives people who smoke of the opportunity to reduce their harm by using low-risk alternatives that are accessible, available, acceptable and of good quality in accordance with international human rights obligations.<sup>2</sup>

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<sup>1</sup> We note that while this submission specifically addresses an amendment to exempt “tobacco prepared and packed for heating” from Schedule 7 of the Poisons Standard, the arguments in favor of such an amendment apply equally, if not more forcefully, to e-cigarettes (also known as vapour products) and low-risk forms of smokeless tobacco (such as snus).

<sup>2</sup> UN system coordination Task Team on the Implementation of the UN System Common Position on drug-related matters, What we have learned over the last ten years: A summary of knowledge acquired and produced by the UN system on drug-related matters (March 2019), E/C.12/CAN/CO/6, E/C.12/ESP/CO/5, E/C.12/PHL/CO/5-6, E/C.12/GRC/CO/2, E/C.12/MKD/CO/2-4 and E/C.12/SWE/CO/6  
[https://www.unodc.org/documents/commissions/CND/2019/Contributions/UN\\_Entities/What\\_we\\_have\\_learned\\_over\\_the\\_last\\_ten\\_years\\_-\\_14\\_March\\_2019\\_-\\_w\\_signature.pdf](https://www.unodc.org/documents/commissions/CND/2019/Contributions/UN_Entities/What_we_have_learned_over_the_last_ten_years_-_14_March_2019_-_w_signature.pdf)

Drug Harm Reduction has now become an integral part of public health policy, recognised globally by international health agencies including the WHO<sup>3</sup>, the UN<sup>4</sup>, and Harm Reduction International<sup>5</sup> (an approved member of the United Nations Global Framework for Noncommunicable Diseases). Indeed, Australia officially adopted “harm minimisation” as its official national drug policy on 2 April 1985.

Harm reduction refers to policies and practices that try to reduce the harm that people do to themselves or others from their drug use. It is grounded in the recognition that many people throughout the world are unable or unwilling to stop using illicit or licit drugs—in the context of this submission, stop smoking cigarettes--to reduce the death and disease drug use/smoking imparts upon its users.

Harm reduction can be contrasted with primary prevention which tries to prevent people from using drugs in the first place, or to stop them using it once they have started. Obviously, the requirement for harm reduction would ultimately become redundant if it were possible to prevent everyone from starting to use any harmful drug in the first place. However, anthropological evidence reaching back over thousands of years strongly suggests that completely eliminating harmful drug use is neither realistic nor achievable.

Tobacco harm reduction offers a safer alternative to people who smoke which, if properly controlled and regulated,<sup>6</sup> has the potential to significantly improve the health and wellbeing of millions of Australians who would otherwise smoke, and dramatically reduce premature death caused by smoking. Simply stated, tobacco harm reduction saves lives.

The legislative requirements of the Therapeutic Goods Act and the Poisons Standard (currently under review) suggest that in order for a tobacco harm reduction product to be legally accessible by adults who smoke, it must pass the requirements as a therapeutic product (designed and proven to be a [medical] smoking cessation aid), defined as a poison and prohibited from sale, or be granted an exemption (requiring an amendment to the Act).

Australia is rightfully proud of its record in tobacco control innovations; however, the reduction of adult smoking rates in percentage terms has slowed perceptively over the last six years. For the first time, smoking rates in the United Kingdom and the United States are now lower than in Australia. It is hard not to believe that the much higher prevalence of vaping in these countries is at least partly responsible for this difference in smoking rate trajectories.

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<sup>3</sup>World Health Organization, see a list of publications on management of substance abuse  
[https://www.who.int/substance\\_abuse/publications/drugs/en/](https://www.who.int/substance_abuse/publications/drugs/en/)

<sup>4</sup> UN system coordination Task Team on the Implementation of the UN System Common Position on drug-related matters, What we have learned over the last ten years: A summary of knowledge acquired and produced by the UN system on drug-related matters (March 2019),  
[https://www.unodc.org/documents/commissions/CND/2019/Contributions/UN\\_Entities/What\\_we\\_have\\_learned\\_over\\_the\\_last\\_ten\\_years\\_-\\_14\\_March\\_2019\\_-\\_w\\_signature.pdf](https://www.unodc.org/documents/commissions/CND/2019/Contributions/UN_Entities/What_we_have_learned_over_the_last_ten_years_-_14_March_2019_-_w_signature.pdf)

<sup>5</sup>Harm Reduction International, The Global State of Harm Reduction (2018),  
<https://www.hri.global/files/2019/02/05/global-state-harm-reduction-2018.pdf>

<sup>6</sup> Public Health England, Evidence Review of e-cigarettes and heated tobacco products 2018: A report commissioned by Public Health England,  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/684963/Evidence\\_review\\_of\\_e-cigarettes\\_and\\_heated\\_tobacco\\_products\\_2018.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/684963/Evidence_review_of_e-cigarettes_and_heated_tobacco_products_2018.pdf)

While traditional tobacco control strategies have resulted in reduced smoking rates over the years, there is little left in the arsenal. For example, Australia already imposes one of the highest tax rates on tobacco in the world, and as the tax rate increases, the use of black market tobacco likewise increases. In order to continue to reduce the rate of smoking, governments must be willing to embrace new tools and strategies. Tobacco harm reduction provides an additional, pragmatic strategy consistent with Australia's progressive views on harm reduction in the drug use arena.

## Heated Tobacco Products are a Low-Risk Alternative to Smoking

INNCO recognises that the responsibility placed upon those charged with evaluating and authorizing a new nicotine-containing product for public consumption is enormous. However, while the Therapeutic Goods Administration (TGA) focuses on concerns about introducing a new tobacco product, they summarily dismiss the evidence of the public health benefit of allowing new, **lower-risk** tobacco products. In its interim decision, TGA notes, "I consider that maintaining the current scheduling for HTPs is necessary to protect public health from the risks associated with introducing a new nicotine product for non-therapeutic use." TGA fails to acknowledge that the existing non-therapeutic nicotine products on the market are all incredibly high risk. The net result of this type of analysis is that consumers who continue using nicotine have no other alternative but to continue to use high-risk combustible tobacco.

This unwillingness to allow lower-risk tobacco products onto the market to compete with the high-risk products and to allow consumers to affirmatively improve their health and wellbeing is out of step with what is occurring elsewhere in the developed world. For example, the World Health Organization (WHO) Regional Office for Europe recently issued a report noting "there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in traditional cigarettes"<sup>7</sup> (emphasis supplied).

In truth, there is little doubt that a person who replaces his or her smoking habit with a heated tobacco product (HTP) will reduce their exposure to harmful chemicals. The United States Food and Drug Administration (US FDA) granted a premarket tobacco product application (PMTA) submitted by Philip Morris International (PMI) for IQOS (a HTP), and in doing so found that marketing IQOS is "appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes."<sup>8</sup>

On 7 July 2020, the US FDA authorized the marketing of IQOS as a modified risk tobacco product (MRTP), allowing IQOS to be marketed with the following information:

### AVAILABLE EVIDENCE TO DATE:

- The IQOS system heats tobacco but does not burn it.
- This significantly reduces the production of harmful and potentially harmful chemicals.

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<sup>7</sup> Regional Office for Europe of the World Health Organization, "Electronic Nicotine and Non-Nicotine Delivery Systems: A Brief," 2020, <https://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/electronic-nicotine-and-non-nicotine-delivery-systems-a-brief-2020>

<sup>8</sup> "FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway," Food and Drug Administration News Release, April 30, 2019, <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.

- Scientific studies have shown that switching completely from conventional cigarettes to the IQOS system significantly reduces your body's exposure to harmful or potentially harmful chemicals.

Over two million pages of scientific data and research were submitted by PMI to the US FDA over a period of three years to substantiate their claim that the use of IQOS presents significantly less risk to smokers' health in comparison to the deadly effects of combustible tobacco. Their application underwent a rigorous scientific evaluation process and IQOS was finally granted approval as a retail tobacco product in 2019, with MRTTP authorization granted in 2020. IQOS is on sale in 50 countries and has significantly reduced the Japanese combustible cigarette market.<sup>9</sup>

Dr Konstantinos Farsalinos, a globally respected scientific expert on the toxicology of tobacco and nicotine products whose papers received the highest number of positive citations in the Greek academic community in 2019, compared the toxicity of e-cigarettes to heated tobacco products and found both products to be significantly less toxic than combustible cigarettes.<sup>10</sup>

In light of the foregoing, it is difficult to understand the claim of the TGA that "there is insufficient scientific evidence to support their reduced risk status". Their concern that HTPs may attract young people to start using a tobacco product is extremely unlikely given that these would be regulated high-end products marketed to adult smokers at a retail price point which would undoubtedly deter the majority of young people.

## CONCLUSION

*Tobacco smoking remains the leading preventable cause of death and disease in Australia. Smoking leads to a wide range of diseases including many types of cancer, heart disease and stroke, chest and lung illnesses and stomach ulcers. It claims the lives of 15,500 Australians every year.*

AUSTRALIAN CANCER COUNCIL 2019<sup>11</sup>

The Australian government has adopted an endgame approach to tobacco control which aims to eliminate, or reduce to a negligible percentage, all tobacco and nicotine use within a signified timescale. However laudable this intent, the opposition to tobacco harm reduction displayed by Australian medical groups is as inexplicable as it is tragic. While the Australian government continues to ignore the ever-increasing evidence of the overall public health benefit of regulated safer nicotine products, there remains a lethal product freely available for purchase by adult consumers.

The most harmful delivery method of nicotine, combustible tobacco, the leading cause of premature death worldwide, guaranteed to claim the lives of over 6 million people every year, remains legally

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<sup>9</sup> Stoklosa M, Cahn Z, Liber A, et al Effect of IQOS introduction on cigarette sales: evidence of decline and replacement Tobacco Control 2020;29:381-387, <https://tobaccocontrol.bmj.com/content/29/4/381>.

<sup>10</sup> Konstantinos Farsalinos, "Toxicant exposure Heated tobacco products vs. e-cigarettes," presentation at Global Forum on Nicotine in Warsaw, Poland, June 16, 2017, at [https://gfn.net.co/downloads/Presentations\\_2017\\_/Dr%20Konstantinos%20Farsalinos.pdf](https://gfn.net.co/downloads/Presentations_2017_/Dr%20Konstantinos%20Farsalinos.pdf) See also <https://www.youtube.com/watch?v=7rHfiochhOg>

<sup>11</sup> Australian Cancer Council (2019) <https://www.cancer.org.au/policy-and-advocacy/position-statements/smoking-and-tobacco-control/>

protected and freely accessible to every Australian citizen on the high street. In fact, the only non-therapeutic nicotine products available to Australian citizens are the most lethal tobacco products. People who smoke and who are unable or unwilling to quit, are left with no easy or accessible option to reduce risk. People who smoke are expected to “quit or die,” and for those who are unable or unwilling to quit, they will continue to smoke if they do not have access to an affordable and acceptable low-risk alternative that allows them to replace their smoking habit. “Quit or die” in this context is a coercive policy that ignores genuine public health and general harm reduction principles and violates human rights.

HTPs and other lower-risk non-therapeutic nicotine products provide a valuable tool to help reduce the smoking rate. Regulation of such products must be reasonable and proportionate, and relegating these products to a medical-only model will result in a de facto ban on low-risk products that could otherwise help millions make the switch away from smoking and improve their health. People who smoke need more options, not fewer. Denying access to low-risk products or making them more difficult to access than cigarettes, indisputably the most dangerous tobacco product on the market in Australia, works against fundamental tenets of public health.

For the foregoing reasons, we strongly urge the TGA to reconsider its interim decision and allow Australian smokers safer alternatives to cigarettes and in so doing, allow them to significantly reduce their health risk and extend their lives.

We appreciate the opportunity to present this submission and thank you in advance for your serious consideration of the issues we have raised.

Respectfully submitted,



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