The Secretary
Therapeutic Goods Administration (TGA)
Department of Health
Government of Australia
By email: chemicals.scheduling@health.gov.au

8 July 2020

Dear sir or madam

Amendments to the Poisons Standard (Chemicals): Interim decision on nicotine for heated tobacco products – comment by David Abrams, Clive Bates Ray Niaura and David Sweanor

We write as independent experts in tobacco and nicotine policy (see about the authors) to raise concerns about the negative interim decision in relation to nicotine and heated tobacco products. The TGA is considering a proposal to amend Schedule 7 of the Poison Standard to exempt nicotine in the form of "tobacco prepared and packed for heating". The proposal was referred to the Advisory Committee on Medicines and Chemicals Scheduling in joint session (Joint ACMS-ACCS #24, March 2020). The interim decision is not to amend Schedule 7 to allow heated tobacco products to be sold lawfully in Australia.[1] Nicotine in the form of "tobacco prepared and packed for smoking" is, however, permitted under the Poison Standard. We believe the interim decision is flawed, asymmetric and based on inadequate reasoning. It should be reversed in the final decision.

The overriding interest of smokers has been ignored. The analysis presented does not adequately recognise the pervasive availability of much more harmful nicotine products. "Tobacco prepared and packed for smoking", typically cigarettes, is permitted in the Poison Standard Schedule 7, whereas far safer consumer nicotine products are not. For those using the drug nicotine, only smoking products, the most dangerous delivery system, are readily available in Australia. It is comparable to the TGA licensing an intravenous drug but insisting it can only be administered through the dirtiest needles. There are 2.9 million adult smokers (15.2% adults, 2017-18) in Australia concentrated in the poorest socioeconomic groups.[2] There is no ethical, scientific or public health reason to deliberately deny these users access to a product that is, beyond any reasonable doubt, far safer than cigarettes. The arguments have been set out by leading Australian and international experts for nicotine in e-liquid form[3] and these are no less applicable for heated tobacco products.

Policy coherence requires the availability of low risk alternatives. The underlying policy of the Australian government is to stigmatise smoking[4] (sometimes referred to as 'denormalisation') and to

1 Therapeutic Goods Administration (Australia), Notice of interim decisions on proposed amendments to the Poisons Standard - ACMS/ACCS/Joint ACMS-ACCS meetings, March 2020. 3.2 Nicotine (Heated Tobacco Products) [link]

2 Australian Bureau of Statistics, National Health Survey: First Results, 2017-18 (latest version): Smoking, February 2019 [link]

3 Abrams D et al. 40 Australian and international experts: Proposed Amendments to the Poisons Standard Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine, September 2016 [link]. Further comments on the interim decision, February 2017 [link]

4 Hefler M, Carter SM. Smoking to fit a stigmatised identity? A qualitative study of marginalised young people in Australia. Heal (United Kingdom). *Health*. 2019 May 1;23(3):306–24. [link]

raise taxation on cigarettes to high levels at a rapid rate to incentivise smoking cessation.[5] The price of 20 premium cigarettes has now reached A$32 (US$22).[6] The effect of the excise policy combined with nicotine poisons scheduling policy is to impose a sharply regressive tax on dependent nicotine users while preventing access to far safer alternatives, by excluding the options to quit smoking by switching to heated tobacco products, e-cigarettes, smokeless tobacco and novel nicotine patches.

The government's policy amounts to menacing its own citizens with an implicit threat that can be paraphrased as follows: *quit smoking or we will stigmatise you and make you pay with your money and eventually your life.* Despite such strong and deliberately painful incentives to quit smoking, we do not see any reflection in the interim decision of the imperative to help Australians access better options to respond to these incentives, or any consideration the ethics or collateral harms arising from raising the price of dependence-forming products while limiting the options to stop using them.

In the sections below, we address several of the findings in the interim decision with short responses:

Interim decision: toxicity

> *The available data indicate that HTPs contain toxic compounds including carcinogens and that HTPs aerosol can be cytotoxic and mutagenic and, can potentially produce pathophysiological changes in human tissues comparable to those produced by cigarette smoke*

Response. The interim decision continues the TGA's avoidance of the implications of relative risk by referring to studies that show some plausible risk, without recognition that this is likely to be negligible or one to two orders of magnitude lower than cigarettes. Judgements about these products must be based on the public health impact of substitution and how they function as alternatives. Biomarkers of exposure show dramatic reductions in toxic exposure (see next section) and many smokers would welcome that, even if it takes longer to show that reduced exposure translates to reduced harm.

Interim decision: biomarkers of potential harm

> *Independent researchers analysing data that Philip Morris provided to the US FDA in support of marketing of their IQOS HTP product found no statistically detectable difference between IQOS and conventional cigarettes for 23 of the 24 non-cancer biomarkers of potential harm measured in Americans, and 10 of 13 measured in Japanese.*

Response. In making the use of relatively short term data on *biomarkers of harm*, the TGA is uncritically adopting a narrowly pedantic approach to risk used to create an activist talking-point.[7] That analysis ignores the compelling evidence from *biomarkers of exposure*, which show toxic

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5 Department of Health (Aus), Tobacco Excise [link]. Australian Taxation Office, Tobacco Excise [link] accessed 7 July 2020

6 Numbeo, Price Rankings by Country of Cigarettes 20 Pack (Marlboro) (Markets) [link]

7 Glantz SA. PMI's own in vivo clinical data on biomarkers of potential harm in Americans show that IQOS is not detectably different from conventional cigarettes. Tob Control. 2018 Nov 1;27(Suppl 1):s9–12. [link]

exposures are reduced to levels comparable to smoking cessation.[8] Some biomarkers of harm change slowly or merely stop deteriorating after smoking cessation and it is not surprising that there were only limited changes in biomarkers of harm in the timescale of the trial.[9] It makes no sense to refuse to draw public health conclusions from biomarkers showing greatly reduced exposure. Further to its earlier decision that the iQOS heated tobacco product is "appropriate for the protection of public health", the US FDA has just announced that is granting a modified-risk order for the iQOS heated tobacco product, and will allow the following claims:[10]

> *"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.*
> - *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."*

Why would the TGA maintain an approach to poison scheduling that prevents smokers significantly reducing their exposure to harmful or potentially harmful chemicals? This option is available to Europeans, it has proven highly successful in Japan, and it can now be actively promoted to American smokers: why not Australians?

Interim decision: regulation

> *In this regard, I note that the application, if agreed, would exempt nicotine when in tobacco when prepared and packed for heating from all regulation as a poison.*

Response. It is a straightforward matter to impose conditions or to delay the rescheduling date until a regulatory framework can be put in place. Heated tobacco products can be regulated as a reduced risk tobacco product, with regulation proportionate to risk. Removing a barrier is not the same as defining the appropriate regulatory regime and this is not a reason to reject the proposal.

Interim decision: poison risk

> *I note that the [New South Wales Poison Information Centre] reported that over 82% of calls relating to tobacco exposures were accidental paediatric exposures. I agree with the concerns raised by NSW PIC that HTPs may increase the risk of exposure to greater quantities of tobacco in accidental paediatric exposures.*

Response. This statistic does not address the *absolute* number of calls or the health impact. The most recent data available from the NSW PIC website (2013) does not show tobacco to be in the top

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8 Food and Drug Administration (FDA) Office of Science, Center For Tobacco Products. Briefing Document January 24-25, 2018 Meeting of the Tobacco Products Scientific Advisory Committee (TPSAC) Modified Risk Tobacco Product Applications(MRTPAs) MR0000059-MR0000061 Philip Morris Products S.A. [link] See figure 2 on page 11 and figures 6 and 7 on pages 25 and 26.

9 Rodu B. Smoke But No Fire: IQOS Opponent Misrepresents 3-Month Studies to FDA, Tobacco Truth, 17 November 2017 [link] and Bates C. PubPeer review of Glantz SA *op cit,* August 2018 [link]

10 Food and Drug Administration (United States) Modified Risk Orders [link]. Philip Morris SA IQOS System Holder and Charger, Decision summary and Technical Project Lead Review, 7 July 2020 [link]

ten list of exposures, which was headed by common TGA-approved drugs.[11] US data shows tobacco and e-cigarette exposure calls were just 0.5% of the total.[12] There is no reason why rescheduling would increase exposures as most heated tobacco use would be as an alternative to smoking. Furthermore, a more comprehensive assessment of risks would include risk of death, injury or other harms arising from accidental domestic fires or bushfires started by discarded smoking materials. These risks would be reduced by displacement of smoking by heated tobacco products. The TGA analysis and presentation of risk is thus incomplete and selective.

Interim decision: equivalence to NRT and medicines licensing pathway

> *Harm reduction has been cited by the Applicant and in public submissions advocating for the scheduling proposal, with these submissions also claiming that HTPs are another harm reduction tool, similar to nicotine replacement therapy products.*
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> *I note that the current pathway to supply Schedule 4 nicotine products for smoking cessation is available for HTPs. An application for registration on the ARTG could be made, which would involve assessment of the safety, efficacy and quality by the TGA, consistent with the requirements for existing nicotine replacement products.*

Response. This framing reflects a misunderstanding of the positioning of heated tobacco products as perceived by smokers and as marketed by the companies involved. Nicotine replacement therapies are medications designed for temporary use to assist in smoking cessation, albeit with weak evidence of real-world effectiveness outside the contrived environment of clinical trials.[13] Heated tobacco products are *alternative consumer products*, designed to replace smoking behaviour with a much lower risk alternative way of consuming nicotine and experiencing some of the effects of smoking. It works by its appeal to smokers as a rival product, not as a medication. It is possible for a consumer product to provide a reduced exposure without it being classed as a medication: diet cola, for example, is not an obesity medicine. Exempting heated tobacco products from poison scheduling would not make them medication like NRT. Heated tobacco products are a consumer alternative to far more risky smoking products, and the need to be regulated as what they are, not misclassified.

Interim decision: public health benefit

> *I am not satisfied that there is a net public health benefit from wider availability of nicotine in the form of HTPs. I do not consider that HTPs would make a significant contribution to population harm reduction if I agreed to amend the Poisons Standard as proposed in the application.*

Response. It is unclear what would convince the delegate of the public health benefit. The US Food and Drug Administration (FDA) undertook and exhaustive analysis of the science supporting the iQOS heated tobacco product and concluded its release onto the US market would be "*appropriate*

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[11] New South Wales Poison Information Centre. Annual Report 2013. The top ten exposures were: Paracetamol, Ibuprofen Ethanol, Quetiapine, Paracetamol + narcotic combination analgesic, Diazepam, Spiders, Bleach (hypochlorite-based), Desiccant (silica gel), Cleaners. [link]

[12] David D. Gummin, et al.) 2018 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 36th Annual Report, Clinical Toxicology, 57:12, 1220-1413, DOI: 10.1080/15563650.2019.1677022

[13] Brown J, Beard E, Kotz D, Michie S, West R. Real-world effectiveness of e-cigarettes when used to aid smoking cessation: a cross-sectional population study. Addiction. 2014 Sep 1;109(9):1531–40. [link] Press release [link]

for the protection of public health".[14] In Japan, the introduction of heated tobacco products in 2016 coincided with a one-third decline in cigarette consumption by 2019.[15] It remains unclear why introducing this much-safer product as an alternative to smoking would not be appropriate for the protection of public health in Australia. It takes highly contrived reasoning to claim that the introduction of a safer product would somehow increase harm overall.[16]

Interim decision: views of Australian health organisations

> *Of the thirty-six (36) submissions received in total, twenty-three (23) submission were opposed the scheduling proposal […] I note the strong concerns raised in these submissions; that the wide availability of HTPs would carry significant public health risks and that claims of relative safety have not been substantiated.*

Response. The government should look beyond the defensive abstinence-only posture of many Australian health organisations. These disruptive developments challenge the coercive, punitive and state-led working model for tobacco control worldwide and it is not surprising, though disappointing, that some groups are resisting change. The most important stakeholders are the at-risk populations, notably middle-aged adult smokers experiencing some form of disadvantage. The TGA appears to be giving little weight to the welfare of the 2.9 million adult smokers in Australia.

For the reasons set out above, we hope the interim decision is reversed when made final and that "tobacco prepared and packed for heating" is exempted from Schedule 7 of the Poison Standard.

Please contact us if we can provide on any specific points.

Yours faithfully,

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[14] Food and Drug Administration (United States) Premarket Tobacco Product Marketing Orders [link]. Philip Morris SA IQOS System Holder and Charger, Decision summary and Technical Project Lead Review, 30 April 2019 [link]

[15] Cummings KM, Nahhas GJ, Sweanor DT. What Is Accounting for the Rapid Decline in Cigarette Sales in Japan? Int J Environ Res Public Health. 2020 May 20;17(10):3570.

[16] Bates C. Ten perverse intellectual contortions: a guide to the sophistry of anti-vaping activists, The Counterfactual, 6 April 2018 [link]

About the authors

Dr. David B. Abrams is Professor, Department of Social and Behavioral Science NYU College of Global Public Health New York University. USA. He directed the Office of Behavioral and Social Sciences Research (OBSSR), National Institutes of Health. He has published over 280 peer-reviewed articles, is Principal Investigator on numerous NIH grants and served on the Board of Scientific Advisors of the National Cancer Institute. Dr. Abrams was President of the Society for Behavioral Medicine and recipient of their Distinguished Scientist, Research Mentorship and Service Awards; received the Cullen Memorial Award, American Society for Preventive Oncology for lifetime contributions to tobacco control; Research Laureate Award, American Academy of Health Behavior; and the Distinguished Alumni Award, Rutgers University. He authored the award-winning: *The Tobacco Dependence Treatment Handbook: A Guide to Best Practices.* His current focus is health promotion in populations and nicotine use from basic science to prevention, treatment, public health and health care practice, to policy.

Clive D. Bates is Director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainability and public health. He has had a diverse career in the public, private and not-for-profit sectors. He started out with the IT company, IBM, then switched career to work in the environment movement. From 1997-2003 he was Director of Action on Smoking and Health (UK), campaigning to reduce the harms caused by tobacco. From 2000, he was closely involved in the development of the Framework Convention on Tobacco Control as head of a leading non-profit tobacco control organisation and was instrumental in the establishment of the Framework Convention Alliance of supportive NGOs. In 2003, he joined Prime Minister Blair's Strategy Unit as a senior UK civil servant and worked in senior roles in government and regulators, and for the United Nations in Sudan. He started Counterfactual in 2013.

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David T. Sweanor JD is Adjunct Professor of Law and Chair of the Advisory Board of the Centre for Health Law, Policy and Ethics at the University of Ottawa. He has worked on global tobacco and health issues for more than 30 years, helping set many global precedents in Canada. He has also worked globally on tobacco issues with the WHO, PAHO, World Bank and numerous other bodies and spoken and published widely. His interests extend to a wide range of topics, and in addition to his personal work he funds numerous initiatives. He was the recipient of the Outstanding Individual Philanthropist award for Ottawa in 2016.