

20.12.19

Advisory Committee on Chemicals Scheduling
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
Via email: chemicals.scheduling@health.gov.au

Dear Secretary,

**SUBMISSION ON AN APPLICATION TO AMEND SCHEDULE 7 OF THE POISONS STANDARD
(CHEMICALS) – Nicotine in Heated Tobacco Products**

It is my honour to write to you and humbly offer my views on the role of heated tobacco devices and consumables as substitutes for smoking, as an addition to the existing public health harm tobacco reduction measures addressing non-communicable diseases arising from smoking.

Background

I am a qualified addictions psychotherapist, dealing with smoking cessation and other addictions; and a lawyer admitted to the Law Societies of England & Wales and the Hong Kong SAR. I am qualified as a quit smoking counsellor certified by the Health Promotion Board of the Singapore Ministry of Health.

I work with addicts in recovery and their families at a large private mental health clinic in Singapore, Promises Healthcare Pte. Ltd.; and as the Chairman of the only non-denominational and non-government linked addictions recovery charity in Singapore, We Care Community Service Ltd.

I am also an advisor to the Singapore National Council of Social Services on mental health; and a director on the Board of the Singapore Anti-Narcotics Association.

Introduction – Public Health Trade-offs

It has recently come to my attention that while cigarettes are easily available in Australia, heated tobacco products/heat-not-burn-products (“HNB”), which are likely to be a far safer alternative to cigarettes for smokers, are not.

I respectfully submit that, smoking harm reduction measures in public health policy involve risk and reward trade-offs. Ultimately, public health rewards must outweigh public health risks. I hope that my submission assists you in exploring the trade-offs.

Making the right trade-offs could not be more crucial for your nation. It is a matter of premature morbidity and early death for millions of smokers in Australia and for their loved ones - who are exposed to side stream, second-hand and third-hand smoke.

The trade-offs include: the continuance of nicotine use and compulsive use vs safer nicotine delivery and less early morbidity and mortality; the early science of HNB and lack of long term studies vs the current strong, published, credible, peer-reviewed, scientific evidence; the possibility that non-smokers use HNB who would not otherwise have smoked vs the interests of millions of existing smokers and their loved ones, including children and youth; limiting the harm of extending smokeless

tobacco use vs breaking the cigarette monopoly and allowing smokers to transition to a product that is 90% or more less harmful than smoking.

Singapore and Australia and Smoking Prevalence after implementing the WHO MPOWER Measures

In Singapore, notwithstanding the Government's diligent implementation of the MPOWER Measures under the WHO's Framework Convention on Tobacco Control (FCTC) (<https://www.who.int/tobacco/mpower/publications/en/>), smoking prevalence has remained stagnant at about **14% since 2001**^{1,2}.

The WHO reports in the **Singapore** Country Profile that current smoking prevalence is **14.8%** and smoking among men is **28%** (WHO Report on Global Tobacco Epidemic 2019: https://www.who.int/tobacco/surveillance/policy/country_profile/sgp.pdf?ua=1).

Like Singapore, The **Australian** Government has also been a world leader in implementing the WHO's MPOWER Measures but the smoking prevalence rates remain stubbornly high; with current any tobacco smoking prevalence at **14.4%**, and at **16.4%** for males: (WHO Report on Global Tobacco Epidemic 2019 :https://www.who.int/tobacco/surveillance/policy/country_profile/aus.pdf)

Indeed, even in the country most applauded for thoroughly implementing the MPOWER Measures - **Brazil** - which has also received over USD1bn in donations from Bloomberg, and considerable tobacco control capacity building resources and advice over many years from the WHO - current smoking prevalence remains a stubborn **14.7%**, and **18.8%** among men. (WHO Report on Global Tobacco Epidemic 2019: https://www.who.int/tobacco/surveillance/policy/country_profile/bra.pdf).

Of course, conventional tobacco control measures (prevention education, quit smoking resources, smoking bans, media campaigns, advertising, packaging and promotion restrictions, education and age restrictions and taxes) remain vital, but it is humbly submitted that such measures have reached saturation point - and have ceased to affect smoking prevalence reductions.

There are also many unintended public health risks associated with the MPOWER Measures.

By way of an example, high taxes can temporarily reduce cigarettes sold, but, over time, as has been seen in Australia, this leads to many smokers migrating from conventional commercial cigarettes to roll-your-owns – but without filters, to avoid the tax. The young are particularly vulnerable to this.

It can also lead to burgeoning black markets in untaxed cigarettes. Higher taxes inevitably exacerbate poverty, the plight of single parent families and minorities, and stretch the incomes of those with mental illnesses – all of whom are heavier smokers than the general population. Placing the tax incidence more heavily on those most disadvantaged in society must be recognised as a problem - and weighed in the public health trade-off calculation.

¹ Health Fact Sheet (2015, May 25) World No Tobacco Day Information Paper. Health Promotion Board <https://www.nrdo.gov.sg/docs/librariesprovider3/default-document-library/nrdo-wntd-info-paper-2015.pdf?sfvrsn=0>

² MOH Singapore. Executive Summary on National Population Health Survey 2016/17 https://www.moh.gov.sg/docs/librariesprovider5/resources-statistics/reports/executive-summary-nphs-2016_17.pdf

Traditional Nicotine Replacement Therapy (“NRT”) and Medication has not solved the problem

In Singapore, using behavioural assistance, nicotine replacement therapy (“NRT”) and just going “cold turkey”, annual smoking cessation success rates are woefully low - and the National Health Survey in 2013 indicated cessation rates of below 3% of smokers per annum.

Typical quit rates vary between 1% and 4% globally, in countries that do not have e-cigarettes, heat-not-burn products (“HNB”) (devices that heat but do not combust, a specially prepared tobacco heat stick) or snus (a specially processed tobacco product placed under the upper lip). Those countries that have adopted e-cigarettes, HNB and/or snus have seen historic rates of decline in smoking prevalence rates, particularly among men and youth.

Alternative nicotine delivery products such as e-cigarettes, HNB, and snus are banned in Singapore.

In addition to NRT (nicotine patches, gums and lozenges) Singapore permits the use of the quit smoking medication: bupropion (an antidepressant); and Varenicline (a quit smoking drug). Both are intended to reduce cravings and urges, and Varenicline is also intended to reduce the pleasure derived from smoking – thus deterring relapses.

The randomised control trials of NRT, bupropion and Varenicline show hopeful cessation rates compared to no treatment (i.e. “cold turkey”), with studies showing that they are 3 to 4 times more effective than no treatment (The ASAM Principles of Addiction Medicine - 5th Ed (2014), Ch. 53, pp. 811-822) - but that does not tell the full story.

In studies, subjects are required to take NRT or the medication and are monitored and incentivised to stick to the NRT medication regime and stop smoking. In real life, smokers have to choose on their own initiative, to use NRT and medication and to purchase them in pharmacies. Their volition to do so is highly impaired by their addiction to smoking and the inadequacies of NRT and medication to meet their needs.

My clients suffering from addictions and (often) comorbid psychiatric illnesses are heavy life-long smokers and are not attracted to NRTs or medication. Those that have tried them, note that they do not sufficiently address cravings, and they do not replace the sensations, rituals and social aspects of smoking. The smoking habit - not just the nicotine - is simply not addressed by NRT and medication.

There are good pharmacological reasons for why cravings and urges are not well addressed with NRT. NRT does not deliver enough nicotine fast enough to the brain, and thus does not adequately emulate the psychoactive effects of smoke from burning tobacco, and cannot eliminate cravings. As NRTs do not satisfy smokers, they are not popular, and thus have had a muted effect on general smoking prevalence. Less than 3% of smokers use them for smoking cessation each year³.

In addition, NRTs are unattractively marketed; and delivered through pharmacies. They are thus considered medical products, necessitating a smoker to acknowledge that they are sick, which is not how smokers identify themselves.

Some of my clients have tried bupropion (an antidepressant) and Varenicline; but have not been able to tolerate the side effects such as nausea, headaches, nightmares, insomnia, loss of libido, dry mouth and so on; and report that they are not effective enough in reducing cravings.

³ Singapore National Health Survey, 2013.

It is hardly surprising that The WHO's MPOWER measures have reached a saturation point and are no longer materially reducing smoking prevalence in Singapore and Australia.

Inhaling tobacco smoke is a very powerful addiction; and has been likened to the addiction to substances such as heroin and methamphetamine. 75% to 80% of smokers each year wish to give it up; 20%-15% try; and 2% - 5% succeed for periods exceeding 12 months^{4,5,6}. 50% of smokers who are cancer patients continue to smoke^{7,8}. 40% of smokers who have amputations resulting from gangrene continue to smoke. 70%-80% of people who use cigarettes smoke every day.

This extreme addiction profile is not seen in any other legal substance addiction.

The addiction arises as a combination of factors. These factors include: (1) the reinforcing nature of the chemicals in smoke; (2) the wide array of the psychoactive benefit from smoking; (3) the sensations, rituals and the social nature of smoking; (4) the wide availability of cigarettes and low prices; (5) the absence of intoxication with smoking, making tasks possible and even improving performance; (6) common normalized use in the population; (7) social acceptance of smoking; (8) the 20 to 40 year delay of the negative effects of smoking versus the immediate gratification that smoker demands; and (9) the absence of desirable alternatives to smoking.

HNB can be another tool in the WHO MPOWER arsenal to fight smoking

In contrast to NRT and quit smoking medication, HNB provides a good substitute smoking. The faster and more effective delivery of nicotine to the sites of action in the brain, and the sensations, smells, visual and social stimuli and queues, meet the needs of smokers wanting to quit.

Using heated tobacco products is substantially safer than smoking because tobacco is heated not burned in the process of releasing the nicotine and flavours from tobacco. There is no combustion. The tobacco is electrically heated to below the temperature at which combustion begins (typically not above the range 300–350°C; combustion occurs at ~900°C). It is combustion that produces the majority of the harmful and potentially harmful constituents in smoke.

It is the tar particles and toxic gases in smoke that causes premature mortality and morbidity - not the nicotine. It has been established for over 45 years that people may smoke for the nicotine, but they die from the tar and carbon monoxide.

The first heated tobacco product has recently been classified as “appropriate for the protection of public health” by the U.S. Food and Drug Administration and is likely to be much less harmful

⁴ Le Houezec (2003). Role of nicotine pharmacokinetics in nicotine addiction and nicotine replacement therapy: a review. *Int. J. Tuberc. Lung Dis.* 7(9), pp. 811-819.

⁵ Dani et al. (2014). The Pharmacology of Nicotine and Tobacco in *ASAM Principles of Addiction Medicine*, 4th Ed (2014), Ch. 12 pp. 201-216

⁶ Hurt et al. (2014). Pharmacologic Interventions for Tobacco Dependence in *ASAM Principles of Addiction Medicine*, 4th Ed (2014), Ch. 53 pp. 811-822

⁷ Live Science (2006, December: After Lung Cancer Surgery nearly half of patients with lung cancer return to smoking. <https://www.livescience.com/9420-lung-cancer-surgery-patients-resume-smoking.html>

⁸ American Association of Cancer Research. (2014, August 6). Nearly 10% of cancer patients still smoke: <https://medicalxpress.com/news/2014-08-percent-patients-cancer.html> 30% of cancer deaths related to smoking. Smoking's Many Myths: <https://www.livescience.com/3093-smoking-myths-examined.html>, Cancer Research UK: Tobacco and Cancer: <https://www.cancerresearchuk.org/health-professional/cancer-statistics/risk/tobacco#heading-Zero>

Significant, credible, independent evidence that demonstrates that heated tobacco products are significantly less harmful alternatives to cigarettes – 90% or more less harmful based on toxicological evidence. Further, alternative products such as heated tobacco products have none of the shortcomings of NRTs, bupropion or Varenicline, as they provide adequate substitutes for the sensations, rituals and social aspects of smoking.

Their acceptability to smokers (in contrast to NRT and medication) is borne out in the historically unprecedented reductions in cigarette sales in South Korea, Japan and in Europe, where HNB has become commercially successful among smokers.

Heated tobacco products were first introduced in Japan towards the end of 2014; this introduction of heated tobacco products from tobacco manufacturer saw an unprecedented decline in the use of cigarettes. Cigarette volumes in Japan have fallen by 33 percent in three years, from 43.6 billion sticks in Jan-March 2016 to 29.1 billion sticks in Jan-March 2019⁹. Analysts at CitiGroup attribute the disruption of the cigarette market to heated tobacco products¹⁰. A one third decline in cigarette sales in three years is unprecedented and shows the potential of this technology to bring on the endgame for smoking.

Furthermore, a 4-year study that was published by the American Cancer Society found that the introduction of [REDACTED] was likely responsible for a significant reduction in the sales of cigarettes in Japan¹¹.

Data from Japan has shown that in fact new technologies can help to implement anti-cigarette measures by increasing public perception that cigarettes are obsolete, defective, outmoded, unacceptable products for which there are safer alternatives.

Some have expressed fears that adopting new technologies may delay or threaten the implementation of conventional measures. However, there is no practical reason why MPOWER and HNB cannot live side by side - just as NRT has been an integral part of the MPOWER Measures for 30 years. HNB is simply another form of nicotine replacement that is substantially safer than cigarettes.

Harm reduction strategies like NRT are enshrined in the preamble and definitions in the WHO Framework Convention on Tobacco Control 2004; tobacco harm reduction is recognised as part of the definition of tobacco control in the WHO Framework Convention on Tobacco Control: tobacco control means a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke.

Balancing the Interests of Children and Youth

Some are anxious that many youth may become smokers by picking up the new nicotine delivery technology.

However, the population evidence is that smoking prevalence rates have fallen dramatically in countries that allow these technologies. Japan, France, the UK, and the US have seen in recent years unprecedented drops in smoking rates. Thus, there is no evidence that large numbers of youth are transitioning from these technologies to smoking and displacing the youth who have quit.

⁹ Japan Tobacco, Japanese Domestic Cigarette Sales Results, Monthly reports 2016-19.

<https://bit.ly/2oKlzcJ>

¹⁰ A. Spielman, The new world of tobacco, Citi Group, page 20. 18 April 2018

¹¹ Stoklosa M, Cahn Z, Liber A, et al Effect of [REDACTED] introduction on cigarette sales: evidence of decline and replacement. Tobacco Control Published Online First: 17 June 2019. doi: 10.1136/tobaccocontrol-2019-054998

Qualitative evidence suggests that youth do not see smoking and using these technologies as fungible. Smoking is seen by many of them as aversive and dangerous - and further evidence of the folly of older generations.

The anxiety over youth using HNB must also be balanced against the interests of smokers, and the affected children and youth who smoke, or suffer from the smoke from siblings, parents and friends.

Proportionate Regulation is Needed

In light of recent events in the United States with cannabis vapour use, we must recognise that poorly designed and delayed regulation of smoke-free products will adversely impact public health.

There should therefore be: a. risk proportionate and rational regulation of the nicotine delivery technologies; b. robust product safety standards; c. marketing, promotions and advertising restrictions; d. minimum age of purchasing; and d. publically funded and encouraged technological improvements and scientific investigations into HNB vapour and devices.

These regulatory factors must be balanced, to ensure that: a. the technologies are as free availability to smokers as cigarettes; b. good information on them is widely available to consumers; and prices are at least as affordable as cigarettes; in order to encourage the complete switch over from smoking.

With smoking prevalence stubborn stuck at 15% since 2013¹², the regulatory system should not confer a monopoly to the most dangerous form of a consumer product (tobacco smoke) – to the exclusion of safe forms (HNB vapour).

Bans remove the ability of governments to: monitor and restrict use; support the introduction of technology that will make products safer; specify and control product quality and safety; and monitor and control the distribution channels. Black markets, poor and dangerous products and use by children and youth inevitably result from bans.

Conclusion

I humbly submit that the benefits of materially reducing smoking prevalence and striving for the goal of a smoke-free Australia, far outweighs the risks involving in perpetuating nicotine use. This very dilemma on nicotine use was debated before the global introduction of NRT many years ago - and the WHO and all nations resoundingly decided in favour of nicotine replacement for tobacco harm reduction.

I hope that the Committee will follow this global harm reduction policy by approving amendments to the Poisons Standard.

Respectfully,

Andrew da Roza

¹² Greenhalgh, EM, Bayly, M, & Winstanley, MH. 1.3 Prevalence of smoking—adults. In Scollo, MM and Winstanley, MH [editors]. Tobacco in Australia: Facts and issues. Melbourne: Cancer Council Victoria <https://www.tobaccoinaustralia.org.au/chapter-1-prevalence/1-3-prevalence-of-smoking-adults>

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