February 10th, 2020

Advisory Committee on Medicines Scheduling
Advisory Committee on Chemicals Scheduling
Therapeutic Goods Administration
Woden ACT 2606,
Australia

Re: Proposed amendments referred for scheduling advice to the Joint ACMS-ACCS In relation to Nicotine

Thank you for the opportunity to make a submission on this matter. I do not support the proposed change to the Poisons' Standard.

Before making comments specific to matters that should exercise the mind of the Secretary, under subsection 52D(2), I wish to make some initial remarks before specific remarks covering points (a) to (f). I recognise that these product are sometimes referred to as Heated Tobaco Products(HTP) and on other occasions as Heat not Burn Products(HnB). I have tried to standardise on HnB.

Background of nicotine and the Poisons' Standard

Nicotine is scheduled as a poison and appropriately so. It is potentially lethal in small volumes at standard concentrations. Probably the only recent death from nicotine as a lethal poison is the tragic death in Victoria, during 2018, of Baby J. who consumed after a moment's inattention his mother's nicotine liquid that was being prepared for use in an e-cigarette device. This eventuality is practically impossible with Heat not Burn(HnB) delivery systems but the TGA must keep in mind that precedent-setting altered approval status for HnB systems will almost certainly be followed by applications to change status for a range of other novel nicotine delivery systems.

There are two exceptions as noted.

1. Nicotine replacement therapies (NRT) are approved Therapeutic Goods under the Act. This in each case has required a clearly specified, consistent product with demonstrated satisfactory balance between effectiveness and known or potential harms. There is an overwhelming consensus that NRT does not create a state of addiction.
2. Nicotine in tobacco is permitted; in essence as a historical anomaly. There is no regulation of nicotine concentration, form of presentation or co-constituents. There is complete certainty that, if combustible tobacco was presented now as a new application, it would be rejected on any number of grounds. Whilst tobacco advertising and promotion is current greatly limited, there is an ongoing challenge to control this in new media and the era of social influencers etc.

Notwithstanding that it is a poison, the great bulk of nicotine harms are related to:

1. The establishment and maintenance of addiction that is sated by ongoing use of a product that, whilst delivering nicotine, has a wide range of companion toxins. The specific elements of tobacco smoke that cause one or more of the recognised smoking-related harms is not known for any disease. What is clear is that there is a non-linear relationship between exposure and harms.
2. Neuropsychological consequences of avoidable nicotine exposure that is an issue at any age but particularly in young people
3. The addictive nature of nicotine/tobacco removes choice based on free will from smokers or users who wish to cease use for health, financial or any other concern that they may have

In reality, there is no such unitary substance as tobacco

Despite all romantic notions, tobacco such as presented in a cigarette is not just tobacco leaves wrapped in paper. It is based on remanufactured leaf – cured tobacco with a range of expanders and additives. It is simply a quirk of history that we allow this to be called tobacco on a continuing basis.

The reality is that all major tobacco manufacturers have modified their remanufactured leaf to create a product that is as tolerable and as addictive as possible. This has been by their own research[1] and reverse engineering of competitors' products with improving commercial performance[2]. No smoker can be assured from day to day, that the product is the same as at the time of previous or recent purchase. Over time with this evolution of remanufactured leaf, tobacco products have become more addictive.

In this case, the process of product refinement is may be augmented by the [redacted] Connect App. Various tobacco companies have a well-documented history of experimenting with novel products in specific communities with major or minor product variations. These are difficult to perform forcing a reliance on panel testing and slow product evolution with the only outcome measure being sales. Technology such as the [redacted] Connect App changes all that. The capacity exists for a HnB product manufacturer to subtly alter their product and study the effect of patterns of use and discontinuation. No matter the accompanying legal platitudes about respecting each individual's privacy, consolidated data could make HnB product users non-consenting participants in a commercial experiment. In evidence to the US Congress this week, [redacted] representatives avoided direct questions about the use of such data in refining [redacted] where they now have 35% ownership.

The effect for TGA is that, if it were to endorse a HnB tobacco product under similar loose terms, it could not have and would not have any certainty about the composition of the product that it is approving now nor any control over subsequent product refinement and manipulation.

I will now proceed to comment on the following matters that the Secretary must take into account when exercising a power under subsection 52D(2), (where relevant):

The risks and benefits of the use of a substance;

PMI admit that the product is not risk-free. There are no benefits intrinsic to the product. The application is not for a smoking cessation product.

The FDA in 2018 noted, that the public health impact of HnB products, such as [redacted] depends not only on whether they are less harmful than conventional cigarettes, but whether they help to increase or decrease the prevalence of smoking.[3] Pertaining to this, in a recent statement, the US Surgeon-General concluded that *"there is presently inadequate evidence to conclude that e-cigarettes, in general, increase smoking cessation."* [4] There are no data that support the contention that *in vivo* switching from combustible tobacco use to use of [redacted] confers reduction in any or all short-term or long-term harms. The matter of whether less harm may accrue is therefore speculation in an information void. In a further statement the US Surgeon General concludes *"The emergence of a wide array of new tobacco products and the increasing use of those products, combined with continued use of other conventional tobacco products, such as menthol cigarettes and smokeless tobacco, could complicate cessation efforts aimed at cigarette smoking. These products include hookahs (water pipes), little cigars and cigarillos, e-cigarettes, and heated tobacco products"*.[4]

The purposes for which a substance is to be used and the extent of use of a substance;

Common sense leads to the only conclusion that this is intended to market/promote as an enduring use product in the context of rapid declines in combustible tobacco use. Based on behaviour in markets where it is approved, there is an emphasis on promotion to youth via a range of channels. PMI is back to sponsoring [redacted] in Formula 1 as part of so-called "Mission Winnow". Another non-HnB nicotine delivery system, Vype, is promoted via another Formula 1 team.

Based on an analysis of the International Tobacco Control Policy Evaluation Project Youth Tobacco and E-cigarette Survey, conducted in Canada, England and the USA, Czoli et al conclude that youth awareness of HTPs is emerging in Western countries. Interest in trying these products is very high among smokers, but also present among non-smokers. They state that "The findings are directly relevant to policy, given that youth appeal of HTPs represents a fundamental component of evaluating their public health impact."[5]

The toxicity of a substance;

The US FDA, while approving [redacted] in the fashion that it has based on its own regulatory act, has not classified [redacted] as a Modified risk tobacco product(MRTP). The FDA's Tobacco Products Scientific Advisory Committee (TPSAC) reviewed the MRTP application in January 2018. Whilst the TPSAC committee agreed, in an 8 to 1 vote, that scientific studies have shown that switching completely from cigarettes to the [redacted] system significantly reduces your body's exposure to harmful or potentially harmful chemicals[HPHCs]. Of the

eight committee members who agreed, five of eight voted that PMI has not 'demonstrated that the reductions in exposure are reasonably likely to translate to a measurable and substantial reduction in morbidity and/or mortality'.[3]

In a recent publication in the journal Tobacco Control, Neal Benowitz and his group reported that the so called PMI-58 substances that are claimed by PMI to be in lower levels than in smoke from reference cigarettes are only part of the story. Separately there is a large number of substances that are present in greater concentrations in [redacted] output. This should be no surprise as pyrolytic degradation of volatile products must generate different output from those generated by combustion at a much greater temperature.[6]

The UK Committees on Toxicology, Carcinogenicity and Mutagenicity of chemicals in food, consumer products and the Environment in a report, from late 2017, firstly noted that there is limited information on these products from independent sources. Their final summary conclusion is as follows "Overall, the Committees conclude there are toxicological risks from novel heat-not-burn tobacco products though data on impacts to human health is very limited. Compared with the known risks from conventional cigarettes, they are probably less harmful. Even so, smokers would do better to quit entirely." [7]

The dosage, formulation, labelling, packaging and presentation of a substance;

This application establishes no limits on future product manipulation. [redacted] is not heated tobacco *per se* but a nicotine delivery system. Based on the information presented, it is completely unclear what specifications would need to be met for a so-called HnB Tobacco Product to be considered as such rather than another alternate means of nicotine delivery. This is not unimportant. In a scenario where HnB products were permitted but *status quo* restrictions applied to vaping-like products such as [redacted], what barrier exists for the development and sale of a hybrid system where solutions and tobacco are co-heated?

Research has shown that cigarette marketing techniques, such as heavy price promotions and using attractive models in advertisements, increase the risk of smoking initiation, especially among adolescents and young adults. PMI with [redacted] has used both techniques in the short time since their launch in the US[8]

The potential for abuse of a substance;

It is not so much the potential for abuse but the certainty if the product becomes available and widely used. This is clearly its intended purpose. PMI will, based on past practices, implement every endeavour to make this product as addictive as possible. Alongside products such as [redacted], PMI has an implemented sales strategy that appears, whether by intent, indifference or accident, to most effectively target young users including under 18s at a time when combustible tobacco use in that group in Australia is at a record low and still declining

Any other matters that the Secretary considers necessary to protect public health.

Australia is doing well in reducing smoking rates but we should want to do better and there are current efforts by the States and the Federal Government to achieve lower smoking rates through updates to National Tobacco Policy, re-consideration of key elements of the Preventative Health Strategy and review of Tobacco Pack Warnings amongst other activities. These are all consistent with implementation of Article 14 of the Framework Convention on Tobacco Control. For certain actions of government to be engaged in reducing smoking rates to a value as low as can be achieved, as quickly as this is possible, while another action may risk this by endorsing a new nicotine delivery product with unquantified harms is an absurdist proposition.

Fundamentally, the question here is about the application and not the applicant but this applicant has earned no right for favoured treatment or trust. In the current model, the tobacco industry has a corporate mission of selling unhealthy products so as to profit its shareholders. Its aims and purposes are intrinsically misaligned with the public good and will ever remain so. No matter that an aggressive dog wags its tail and licks your hand in a friendly fashion, you would not leave it unattended with a child.

Acknowledgement

I wish to thank [redacted] for suggestions and provision of some references

References

1 Stevenson T, Proctor RN. The Secret and Soul of Marlboro. Am J Pub Health 2008; 98: 1184-1194.

2 Velicer C, Lempert LK, Glantz S. Cigarette company trade secrets are not secret: an analysis of reverse engineering reports in internal tobacco industry documents released as a result of litigation. Tob Control 2015; 24:469–480

3 Food and Drug Administration Center for Tobacco Products Tobacco Products. Scientific Advisory Committee. 2018. Summary meeting minutes (January 24-25,2018). 2018

4 U.S. Department of Health and Human Services. *Smoking Cessation. A Report of the Surgeon General*. Atlanta, Georgia: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2020.

5 Czoli CD, White CM, Reid JL, et al. Tob Control 2019;29:89–95.

6 St Helen G, Peyton J, Nardone N, Benowitz N. [redacted] examination of Philip Morris International's clain of reduced exposure. Tob Control 2018; 2018: s30-36.

7 UK Committees on toxicity, carcinogenicity and mutagenicity of chemicals in food, consumer products and the environment (COT, COC and COM), Dec 2017. https://cot.food.gov.uk/sites/default/files/heat_not_burn_tobacco_summary.pdf Accessed Feb 2020.

8 Churchill V, Weaver SR, Spears CA, et al. Tob Control 2020; Epub ahead of print: doi:10.1136/tobaccocontrol-2019-055488