

## Proposed amendments to the Poisons Standard - ACCS, ACMS and Joint ACMS/ACCS meetings, March 2020 – Nicotine (in relation to Heated Tobacco Products)

Thank you for this opportunity to comment on the proposed change to regulations to allow Heated Tobacco Products to be included under the exemption in the SUSMP for smoked tobacco products. I would welcome the opportunity to appear in person to provide clarification or expansion on any part of this submission.

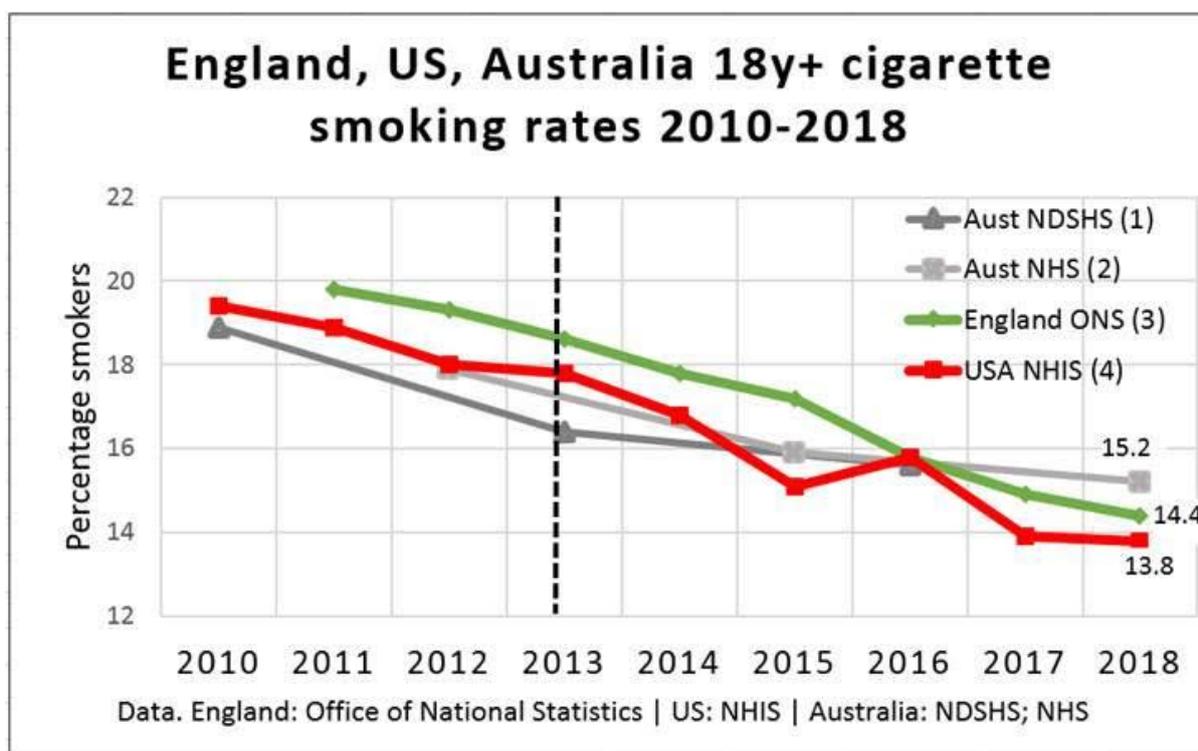
**I support this amendment to enable sale of reduced risk tobacco products (in the form of Heated Tobacco Products), within Australia.**

### Is smoking causing deaths of Australians?

*Tobacco **smoking** is one of the largest **preventable** causes of death and disease in Australia with smoking estimated to kill almost 19,000 Australians a year and responsible for 9.0% of the total burden of disease in Australia in 2011.*

*[Australian Bureau of Statistics: National Health Survey: First Results, 2017-1](#)*

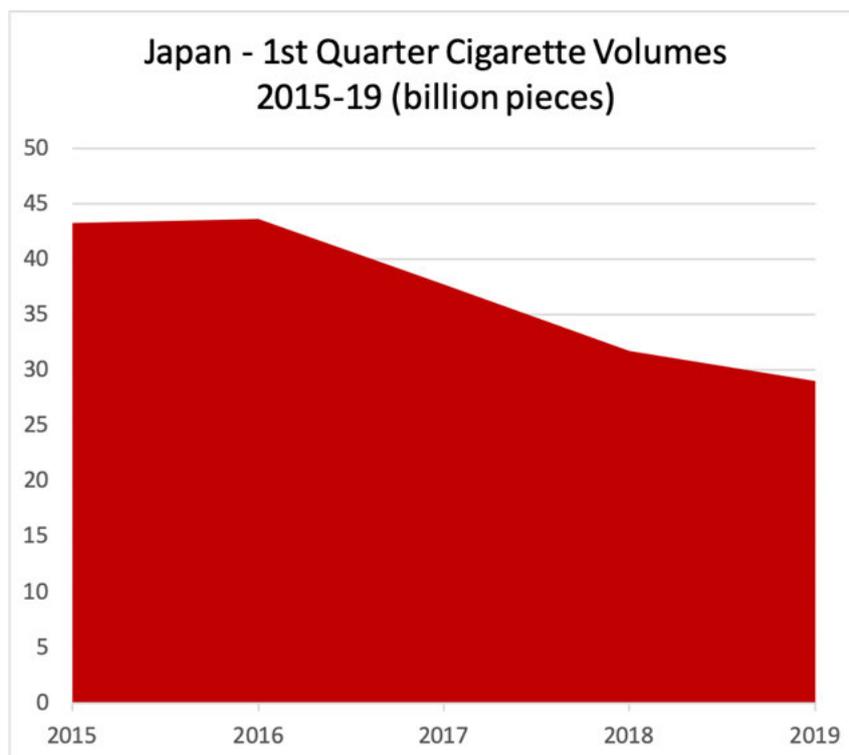
This suggests that, every half hour, an Australian dies from smoking related disease. The term preventable, though, highlights an important truth. What it would take to prevent smoking related death is to *stop people inhaling the smoke of burnt tobacco*. While tobacco control in Australia has historically been a world leader in getting people to stop smoking, recent (over the last 5-6 years) smoking rates, suggest those days are over.



## Can Heated Tobacco Products reduce the incidence of smoking cigarettes?

Both the UK (a Part to the Framework Convention on Tobacco Control, like Australia) and the US (which isn't a Party to the FCTC) have surpassed Australia's efforts to reduce the incidence of cigarette smoking. Notably, both Britain & America allow sale of HTP. The reduction in smoking rates in those countries though, is largely due to the legal sale of nicotine containing e-cigarettes.

To see the potential of HTP to reduce smoking rates, we can do no better than look at Japan. In Japan, vaping with nicotine is banned (largely by the same 'legacy laws' which sees nicotine restricted in Australia). Although there is a small, committed group in Japan who vape (illegally, like in Australia), the major shift in the country has been largely due to HTPs.



In just 4 years since the beginning of sales of HTP in Japan, cigarette sales have **dropped by approximately 30%**. No innovation or measure enacted by conventional tobacco control has resulted in such stunning reductions in the legacy (& dangerous) product of cigarettes.

This plummeting or 'free fall' of cigarette smoking incidence has been due to the disruptive technology (HTP).

## Are Heated Tobacco Products less harmful than smoking cigarettes?

Theophrastus von Hohenheim (AKA Paracelsus) posited almost 500 years ago, that "All things are poisonous and nothing is without poison; only the dose makes a thing not poisonous". This principle has been paraphrased as "the dose makes the poison" and has become one of the founding principles of modern toxicology.

*FDA recognizes that tobacco products exist on a **continuum of risk**, with combustible cigarettes being the deadliest.*

[FDA Authorizes Modified Risk Tobacco Products](#)

The [REDACTED] Tobacco Heating System from Phillip Morris International recently passed a Pre-Market Tobacco Application (overseen by the FDA) which requires that the sale of this new product serve the health of the population of Americans (smokers and non-smokers alike). A Modified Risk Tobacco Product application is currently under consideration (the MRTTP for Swedish Snus has recently been approved).

### **What does the science say about HTP in general?**

*This review found that the potential for harm to humans is reduced when using HNB [Heat Not Burn] devices compared to CC [Conventional Cigarettes] as indicated by significant reductions in BoE [Biomarkers of Exposure] levels. ...*

### **Implications**

*This study supports claims made by tobacco manufacturers on the improved safety of HNB tobacco devices in comparison to CC. These novel devices lead to reduced exposure to key biomarkers, which are linked to the health consequences attributed to tobacco use. This has strong implications for international public health as well as further research and policy development relating to the safety aspects and legalities of novel tobacco products.*

[Human Biomarker Exposure From Cigarettes Versus Novel Heat-Not-Burn Devices: A Systematic Review and Meta-Analysis](#)

*The use of [REDACTED] or [REDACTED] reduced the exposure to smoke toxicants in a manner comparable to quitting tobacco use [74,75]. After switching from conventional cigarettes to HTPs ([REDACTED] or [REDACTED]) a significant reduction in the levels of biomarkers of exposure to harmful and potentially harmful constituents was observed [76–78].*

[NEW IDEAS, OLD PROBLEMS? HEATED TOBACCO PRODUCTS – A SYSTEMATIC REVIEW](#)

### **WHO FCTC support for tobacco harm reduction**

While the section “Australian regulations for HTPs” mentions the Framework Convention on Tobacco Control’s Article 5.3 (in a nutshell - don’t let decisions be swayed by tobacco industry involvement) in all 4 points, it fails to mention Article 1d of the same convention. Vis.

*“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;*

[WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL](#)

The World Health Organisation further expounds the meaning of harm reduction thus:

*For the purpose of this advisory note, TobReg concluded that the objective of reducing harm due to tobacco use is to **decrease morbidity and mortality among persons who continue to use tobacco and nicotine** and are unwilling or unable to quit, with due consideration of the effects at population level.*

[The Scientific Basis for Tobacco Product Regulation](#)

## Protecting non-smokers from taking up HnB products

Authorities are concerned with the possibility of people who would not otherwise smoke, taking up use of HnB products because they are of lower risk. My surveillance suggests that PMI is being very cautious about how and to whom the [REDACTED] product is sold. They only sell the devices through their own stores, strictly enforce age limits, and will refuse sale to anyone who is not currently a smoker.

I feel this is less than optimal, mainly for the lack of 'points of sale'. It might be suitable for people living in major cities, but would be less optimal for people living in country towns. HnB products should be available most places where cigarettes are sold. The usual points of sale of cigarettes are generally considered to be complying with age restrictions. If not, their licence to sell should be revoked, and a stiff fine imposed.

Advertising of the HnB products would most likely be disallowed, as has been the case with cigarettes. So how do smokers even find out about the existence of these reduced risk products?

Australia's legalisation of HnB products should include the requirement of suitable (as specified by the government) [Tobacco Harm Reduction Messages Targeted to Smokers](#). An insert inside, or on, packs of combustible tobacco products would be a 'laser focused' way to inform smokers, and *only smokers*, of the advantages of switching to HnB products.

## Conclusion

Making Heated Tobacco Products available for retail sale in Australia, would:

- Serve the public health by providing smokers with pleasurable alternatives which have a significantly reduced risk & health burden.
- Go a way toward fulfilling our obligations under Article 1d of the FCTC.

**Please do the right thing by the people of Australia who smoke (and those around them), and allow HTP products to be sold in Australia.**