



PHILIP MORRIS

AUSTRALIA NEW ZEALAND PACIFIC ISLANDS

NOVEMBER 2019

Application to amend the Australian Commonwealth Poisons Standard to legalise all Heated Tobacco Products (HTPs)

WHAT IS PHILIP MORRIS DOING?

We have announced a [smoke-free transformation](#), our vision to change society and deliver a better, smoke-free future. Although we have made significant progress around the world, this commitment has been unachievable in Australia due to the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard), a law which effectively bans the sale of [less harmful alternatives to cigarettes](#), such as HTPs. Nicotine in "tobacco prepared and packed for smoking" is already exempted from this ban, making cigarettes available.

On 1 November 2019, Philip Morris filed a science-based application for an amendment to the Poisons Standard that would allow nicotine in 'tobacco prepared and packed for heating' to be treated in the same way as 'tobacco prepared and packed for smoking'.

This application will be considered by the Advisory Committee on Chemicals Scheduling (ACCS), a statutory committee of the Therapeutic Goods Administration (TGA). The ACCS will make recommendations to the Secretary of the Department of Health, who will then decide (based on ACCS recommendations and public submissions received) on whether the Poisons Standard should be amended to exempt nicotine in HTPs. If the decision of the Secretary is to support the application, all products in the HTP category would be legalised subject to existing tobacco control laws.

PROPOSED AMENDMENT TO SCHEDULE 7 - DANGEROUS POISONS:

NICOTINE except:

- a) when included in Schedule 6;
- b) in preparations for human therapeutic use; **or**
- c) in tobacco prepared and packed for smoking; **or**
- d) **in tobacco prepared and packed for heating.**

WHY MAKE THIS APPLICATION?

Despite the scientific evidence and positive experience around the world, this process is by no means certain. The most recent consideration of the scheduling of nicotine was in 2017, based on [an application to exempt nicotine in liquid solutions intended for use in e-cigarettes](#). The final decision determined the current scheduling of nicotine remained appropriate and the application was unsuccessful. Since then, progress towards tobacco harm reduction has stalled in Australia, along with smoking rates.

It makes no sense that only the most harmful form of nicotine consumption is available as a consumer product, in the form of cigarettes, while it is illegal to sell or consume both liquid nicotine e-cigarette vaping products and HTPs. Without this amendment to the Poisons Standard, it will leave smokers with no other choice than continuing to smoke combustible cigarettes or quit, but data shows that many will not choose the latter even if it is the best choice they have.

Australia's nearly 3 million smokers deserve to have access to better products backed by solid science. Nicotine is addictive and not risk-free. However, it is the burning of tobacco, not nicotine, which produces the toxic chemicals that are primarily associated with smoking related diseases.

PHILIP MORRIS LIMITED

L6, 30 CONVENTION CENTRE PLACE, SOUTH WHARF, VIC 3006, AUSTRALIA

T +61 3 8531 1000 ABN 65 004 694 428

Earlier this year after a thorough, two-year scientific review of all the available evidence, the United States Food and Drug Administration (FDA), the world's toughest and most respected health regulator, authorised our HTP (referred to by its commercial name, IQOS), for sale as "[appropriate for the protection of public health](#)". Announcing their findings, the FDA also said:

"Additionally, IQOS delivers nicotine in levels close to combustible cigarettes suggesting a likelihood that IQOS users may be able to completely transition away from combustible cigarettes and use IQOS exclusively. Available data, while limited, also indicate that few non-tobacco users would be likely to choose to start using IQOS, including youth."

Our scientifically substantiated HTP is sold in 51 markets and it is estimated that there are approximately 12.4 million users, of which 71 percent have stopped smoking and switched, with the balance in various stages of conversion/transition.

WHAT IS THE SCIENTIFIC REVIEW PROCESS FOR THIS APPLICATION?

Detailed [guidance on the process for amending the Poisons Standard](#) is provided by the TGA. Their website notes that the Poisons Standard is a Legislative Instrument for the purposes of the *Legislative Instruments Act 2003*. The Poisons Standard consists of decisions regarding the classification of medicines and poisons into Schedules that controls how medicines and chemicals are made accessible to consumers based on the substances contained within them. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons.

Nicotine is currently classified in Schedule 7 as a dangerous poison, though as noted above, nicotine in "tobacco prepared and packed for smoking" is already exempt from the Poisons Standard.

The [Advisory Committee on Chemicals Scheduling](#) (ACCS) was established to advise and make recommendations to the Secretary of the Department of Health (or their delegate), who is the ultimate decision maker on the level of access required for chemicals and, in some instances, medicines. The Committee comprises nine members nominated by Federal, State and Territory Governments and eight appointed members who are professionals with specific scientific, medical or clinical expertise, as well as appropriate experience with consumer health issues relating to chemicals.

WHEN WILL THE APPLICATION BE REVIEWED?

All ACCS meeting dates and decision timeframes are available from the [TGA website](#), but are summarised below:



WHAT DOES THIS MEAN FOR...?

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| 1. SMOKERS: Access to scientifically proven less harmful alternatives to cigarettes for those who would otherwise continue to smoke. |
| 2. VAPERS: A scientific evidence-based policy debate about tobacco harm reduction and momentum for appropriate regulatory reform to ensure product safety standards are implemented for smoke-free products. |
| 3. HEALTHCARE PROFESSIONALS & SCIENTISTS: Review and evaluate the science behind HTPs and contribute to both the ACCS evaluation process and future expansion of the knowledge base around such products. |
| 4. GOVERNMENT: Reduction of both smoking rates and the burden of disease caused by smoking, while offering an opportunity to improve the lives of nearly three million Australian smokers. |

This application will impact several public policy areas in addition to health policy.
For further information, please contact Philip Morris External Affairs (caa@pmi.com or +61 3 8531 1000).
For media inquiries, please contact the Media Unit on +61 447 407 454.