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**CONSULTATION: PROPOSED AMENDMENTS TO THE POISONS STANDARD – ACMS
AND JOINT ACMS/ACCS MEETINGS, JUNE 2020 - NICOTINE**

INTRODUCTION

Imperial Brands Australasia (**Imperial**) welcomes the invitation from the Secretary of the Department of Health (**DOHA**) to make a public submission in relation to the scheduling proposal for nicotine referred to in the document 'Consultation: Proposed amendments to the Poisons Standard – ACMS and Joint ACMS/ACCS meetings, June 2020'.

Imperial participates in a range of government consultations that are relevant to our business. We do this on the basis that our views will be considered in an objective manner and that the evidence and views we provide will be properly evaluated, with due regard given to relevant legal and legislative requirements and the principles of best practice regulation.

We would like to take the opportunity to reiterate our belief that the sale and supply of less harmful nicotine containing Next Generation Products (**NGP**) such as nicotine e-cigarettes should be permitted, in light of the growing consensus among public health specialists that these products can contribute greatly to tobacco harm reduction and therefore offer significant potential public health benefits.

In line with this belief, Imperial does not support the proposed amendments to the scheduling of nicotine because the amendments:

1. do not meaningfully change the scheduling of nicotine;
2. are proposed without justifiable reasons in support;
3. fail to promote the Government's policy with banning illegal nicotine imports;
4. increase risk of unsafe nicotine use, potential abuse of nicotine, and inappropriate dosage, formulation, labelling, packaging and presentation of nicotine by failing to address the emerging domestic black market with nicotine;
5. ignore the benefits with appropriately regulated and safe use of nicotine NGPs; and

6. ignore the purposes for which consumers use nicotine in NGPs and the extent of that use.

Imperial recognises the role of Governments and Public Health Authorities in the regulation of nicotine and supports those measures that are reasonable, proportionate and evidence based.

Unfortunately, the proposed scheduling amendments for nicotine are seated in a fundamental opposition to vaping and a strict commitment to prevent any liberalisation on laws. This opposition remains despite Australia being the only western democracy to ban the sale of nicotine liquids for e-cigarettes. The position is at odds with many contemporary countries including New Zealand and exists despite the growing body of scientific evidence of the reduced harm of vaping products.

Imperial is concerned that rather than support adult smokers looking to transition away from combustible tobacco, the amendments will further frustrate the efforts of these adults to choose less harmful products.

BACKGROUND

Imperial is an Australian based wholly owned subsidiary of Imperial Brands PLC, an international fast-moving consumer goods company specialising in tobacco and non-tobacco products. Imperial entered the Australian market in September 1999 at the request of the ACCC to ensure that competition was maintained following the global merger between British American Tobacco (**BAT**) and Rothmans International. We are a company with a strong tobacco heritage. However, at Imperial we understand society's concerns about the health risks of smoking and as a result, we are increasingly focusing our attention on our portfolio of nicotine alternatives.

Our focus on researching, developing and commercialising products that reduce harm has created a strong track record investing in genuine science. In the 1950s Imperial opened its first scientific laboratory and played a leading role in developing new equipment and techniques for analysing tobacco and smoke. This paved the way for decades of research into tobacco and non-tobacco products.

Since establishing our first research and development laboratory in the early 1950s, we have invested substantial sums in tobacco research and will continue to do so in the future. In recent years we have increasingly focused our innovation and R&D work on NGPs.

OUR APPROACH – FROM SMOKING TOBACCO TO SOMETHING BETTER

We are currently witnessing the biggest consumer shift in our history, with millions of adult smokers around the world choosing to transition to potentially less harmful non-combustible nicotine NGPs. NGP – particularly vapour products, which do not contain tobacco – are seen as representing a less harmful alternative to cigarettes, thereby creating a huge global public health opportunity.

As a result, we are increasingly focusing our attention on developing and expanding our NGP portfolio. We want to reduce the health impact of smoking tobacco by encouraging smokers to transition to products with lower health risks.

PROPOSED AMENDMENTS TO NICOTINE SCHEDULING

The amendments do not meaningfully change the scheduling of nicotine

If the Secretary of DOHA adopts the proposed amendments, Imperial considers it follows that nicotine will receive the following treatment under the Poisons Standard:

- Nicotine in OTC medicines (i.e. smoking cessation treatments involving oromucosal or transdermal use) and in tobacco prepared and packed for smoking will remain exempt from scheduling.
- All nicotine in preparations for 'human use' will be a Schedule 4 prescription only medicine instead of nicotine that is in a preparation for 'human therapeutic use' as currently provided.
- Nicotine, when not exempted from scheduling or not classified as a Schedule 4 prescription only medicine, is a Schedule 7 dangerous poison.
- An amendment to Appendix D (additional controls on possession or supply of poisons included in Schedule 4) will confirm that nicotine is available only from, or on the prescription of, an authorised medical practitioner.
- Nicotine for the treatment of animals will no longer be scheduled but will not be exempted.

Imperial takes the view that these suggested amendments for human use nicotine do not meaningfully change the scheduling of nicotine. Save for the removal of animal treatment nicotine in Schedule 6, the amendments only change the language for nicotine in the Poisons Standard. The amendments, if made, will not in substance change the treatment of nicotine under the Poisons Standard.

In particular, the proposed changes do not alter the current situation where:

- nicotine in OTC medicines involving oromucosal or transdermal use and in tobacco prepared and packed for smoking will remain exempt from scheduling; and
- members of the public must possess a medical prescription to lawfully obtain nicotine that is not an OTC medicine or in tobacco prepared and packed for smoking.

The amendments do nothing to meaningfully change the scheduling of nicotine; consequently, Imperial takes the position that the amendments are wholly unnecessary.

The amendments are proposed without justifiable reasons in support

The stated reasons for the proposed changes include to:¹

- clarify the access controls for nicotine in Australia;
- clarify that nicotine for human use, other than tobacco for smoking, is only exempt from Schedule 4 when it is included in oromucosal and transdermal preparations for smoking cessation; and
- ensure that possession of Schedule 4 products containing nicotine must be in accordance with a legal prescription.

In Imperial's view, these reasons are insufficient and unjustified.

The Poisons Standard already makes it clear that nicotine is not in Schedule 7 only when it is for use in certain animal treatments, in tobacco prepared and packed for smoking, or in preparations for human therapeutic use. Outside these exceptional circumstances, nicotine always falls squarely under Schedule 7 and requires authorisation to import and possess.

The Poisons Standard also already provides that nicotine in preparations for human therapeutic use falls under Schedule 4 if not 'for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use.' Consequently, it is already the case that aside from oromucosal or transdermal use, all human therapeutic use nicotine belongs in Schedule 4 and is a prescription only medicine.

The amendments do not promote the Government's policy with banning illegal nicotine imports

Although the proposed amendments for nicotine scheduling were initiated by the Delegate of the Secretary of DOHA,² the amendments do not promote the Government's policy and motion to 'ban the importation of e-cigarette liquids containing nicotine.'³ This is despite the claims from the following media reports:

- a 'crackdown is coming on Australians who illegally import nicotine vaping products online';⁴
- 'the *Sydney Morning Herald* and *The Age* can reveal federal health minister Greg Hunt has directed the Therapeutic Goods Administration to work with the Department of Home Affairs to consider a new approach to policing and regulating e-cigarettes';⁵

¹ *Consultation: Proposed amendments to the Poisons Standard – ACMS and Joint ACMS/ACCS meetings, June 2020* (17 April 2020), 32.

² *Consultation: Proposed amendments to the Poisons Standard – ACMS and Joint ACMS/ACCS meetings, June 2020* (17 April 2020), 31.

³ Commonwealth, *Parliamentary Debates, Senate*, 27 February 2020, 35-36.

⁴ Dana McCauley, 'Government launches border crackdown on illegal vaping imports', *The Sydney Morning Herald* (online, 29 February 2020).

⁵ Dana McCauley, 'Government launches border crackdown on illegal vaping imports', *The Sydney Morning Herald* (online, 29 February 2020).

- that despite ‘laws prohibiting the importation of nicotine vape liquids – except under a little-used scheme that requires a prescription – there has until now been little obstacle to buying it online, with thousands of vapers – including those aged under 18 – importing it without obstruction’;⁶
- ‘the minister has written to the Home Affairs Department seeking a tightening of border control measures to prevent nicotine vaping liquids from entering the country’;⁷
- a spokesman saying that ‘Ministers are exploring options with the Therapeutic Goods Administration within the Department of Health and the Department of Home Affairs’.⁸

Having already identified that the amendments do not promote banning illegal nicotine imports, Imperial further submits that legislative amendments for this purpose are wholly unnecessary anyway. Instead, it would appear that the issue is more one of ensuring stronger law enforcement at the borders.

Schedule 4 nicotine personally imported for human therapeutic use in the treatment of the importer already requires a written authority issued by a medical practitioner (i.e. a prescription).⁹ There can be no confusion over when nicotine is imported for human therapeutic use. If a medical practitioner has issued a written authority to import the nicotine as a therapeutic good, then plainly the nicotine is for therapeutic use.

Outside human therapeutic use nicotine, the import and possession of Schedule 7 nicotine always requires an authority under the laws of the States and Territories.

Therefore, it is not difficult to detect illegally imported nicotine. If the nicotine is not in tobacco and the importer does not have an authority, it is an illegal import and open to seizure by appropriately resourced law enforcement agencies.

The amendments fail to address the emerging domestic black market with nicotine

There is evidence of a domestic nicotine black market emerging. For example, ABC News has previously reported that NSW health inspectors visited 227 retailers selling e-liquids from November 2015 to April 2018 and found that over 40 per cent of these retailers were selling products that contained nicotine.¹⁰ That same article also reported that vape users ‘agree it is possible to buy

⁶ Dana McCauley, ‘Government launches border crackdown on illegal vaping imports’, *The Sydney Morning Herald* (online, 29 February 2020).

⁷ Dana McCauley, ‘Government launches border crackdown on illegal vaping imports’, *The Sydney Morning Herald* (online, 29 February 2020).

⁸ Jade Gailberger, ‘Ban nicotine e-cigarettes, SA Senator Stirling Griff says’, *The Daily Telegraph* (online, 10 March 2020).

⁹ *Therapeutic Goods Act 1989* (Cth) s 18; *Therapeutic Goods Regulations 1990* (Cth) reg 12(1) sch 5 item 1.

¹⁰ Flint Duxfield, ‘NSW Health Department finds not all e-juices are as nicotine free as they claim’, *ABC News* (online, 12 June 2018) <<https://www.abc.net.au/news/2018-06-12/not-all-e-juices-are-as-nicotine-free-as-they-claim/9857540>>.

nicotine from retailers if you know who to ask' and quoted one vaper as having experienced shops who sold nicotine 'under the table'.¹¹

Another ABC News article quoted one tobacco control expert as saying 'it was an "open secret" that you could buy e-liquid containing nicotine' and that he had been told 'there's a fair amount of amateur, backyard lab production of e-juices which are being sold'.¹² The *Daily Telegraph* has also previously reported that liquid nicotine products 'remain widespread in Victoria due to under-the-counter sales and products purchased over the internet'.¹³

The nicotine black market wholly disregards fundamental safety matters surrounding the use of nicotine including its toxicity, potential for abuse, appropriate and lawful dosage, formulation, labelling, packaging and presentation. Indeed, it may be anticipated that the nicotine black market would operate much like the illicit tobacco black market in that it may be more easily accessible for underage users, bypass health information on packaging, and present nicotine products with vastly more dangerous health risks than those manufactured by reputable regulated industries.¹⁴

By not meaningfully changing the scheduling of nicotine, the amendments do nothing to combat the emerging nicotine domestic black market. Instead, the amendments leave the black market unchecked and permit it to flourish. This represents a missed opportunity.

The amendments ignore the benefits with using nicotine NGPs

Leading international public health bodies have drawn attention to the correlation between access to e-cigarettes and a reduction in the smoking incidence. In 2018, Public Health England published an independent expert e-cigarette evidence review which included in its main findings that; "e-cigarette use is associated with improved quit success rates over the last year and an accelerated drop in smoking rates across the country" and "e-cigarettes could be contributing to at least 20,000 successful new quits per year and possibly many more".¹⁵

England, Canada and a number of European countries, all of which provide adult consumers with access to e-cigarettes containing nicotine fluids, have experienced significant declines in smoking

¹¹ Flint Duxfield, 'NSW Health Department finds not all e-juices are as nicotine free as they claim', *ABC News* (online, 12 June 2018) <<https://www.abc.net.au/news/2018-06-12/not-all-e-juices-are-as-nicotine-free-as-they-claim/9857540>>

¹² Olivia Willis, 'Nicotine found in 'nicotine-free' e-cigarette liquids sold in Australia, study finds', *ABC News* (online, 14 January 2019) <<https://www.abc.net.au/news/health/2019-01-14/nicotine-found-in-nicotine-free-e-cigarette-liquids/10709786>>.

¹³ Grant McArthur, 'Retailers still pushing banned liquid nicotine products', *The Daily Telegraph* (online, 10 March 2020).

¹⁴ Black Economy Taskforce (Final Report, October 2017) 305.

¹⁵ <https://www.gov.uk/government/news/phe-publishes-independent-expert-e-cigarettes-evidence-review>

rates in recent years¹⁶. From 2013 to 2016 the UK witnessed a 3.2% decline in smoking rates¹⁷, while Australia, which has singled out tobacco for a plethora of regulation approximating illegality, experienced a decline of 0.5% over the same period¹⁸.

By failing to meaningfully change the scheduling for nicotine, the proposed amendments ignore the potential benefits with using e-cigarettes containing nicotine fluids in lieu of conventional tobacco products and the consequent public health issues.

The amendments ignore the purposes for which consumers use nicotine in NGPs and the extent of that use

The reality is that many people import nicotine into Australia to use in e-cigarettes for at least two reasons:

- they know that use is significantly less harmful to their health than using combustible tobacco products; and/or
- nicotine e-cigarettes are more appealing than the nicotine replacement products registered on the Australian Register of Therapeutic Goods.

Nicotine replacement products have limited appeal to smokers because they lack the sensorial and behavioural aspects of the smoking experience and therefore they have a poorer success rate at replacing smoking. For example, one recent study published in *The New England Journal of Medicine* found that, while perceived to be less satisfying than cigarettes, 'e-cigarettes provided greater satisfaction and were rated as more helpful to refrain from smoking than nicotine replacement products.'¹⁹ That study involved a clinical trial with 900 participants, found that the 1 year abstinence rate was 18% for the e-cigarette group compared to 9.9% for the NRT group, and concluded that e-cigarettes 'were more effective for smoking cessation than nicotine-replacement therapy'.²⁰

The amendments completely ignore the fact that many consumers probably import and use nicotine in e-cigarettes because they know doing so is significantly less harmful than smoking and it offers them a more satisfying experience than nicotine replacement products.

¹⁶ Source: Australian Tobacco Harm Reduction Association, <https://au.news.yahoo.com/australia-highest-priced-cigarettes-world-arent-people-quitting-012023457.html>

¹⁷ Office for National Statistics, <https://www.ons.gov.uk/>

¹⁸ The Department of Health, National Drug Strategy Household Survey 2016 Key Findings

¹⁹ Hajek et al., 'A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy' (14 February 2019) 380 *The New England Journal of Medicine* 629, 634.

²⁰ Hajek et al., 'A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy' (14 February 2019) 380 *The New England Journal of Medicine* 629, 636.

In summary, the amendments are unsatisfactory because they fail to recognise and facilitate this legitimate use of nicotine and they encourage smokers to continue resorting to significantly more harmful tobacco products.

CONCLUSION

Reducing the health impacts of tobacco requires that Governments, regulators and public health bodies play a positive role, which includes implementing a legislative framework that allows the NGP category to develop and giving consumers the confidence to trial, and ultimately transition, to these less harmful products.

Unfortunately the proposed nicotine scheduling amendments do not advance this cause. Instead they ignore the benefits of liberalising nicotine scheduling to assist smokers change from combustible tobacco products to significantly less harmful NGPs. They also ignore that nicotine e-cigarettes are more appealing than the nicotine replacement products registered on the Australian Register of Therapeutic Goods as a quit smoking aid.

Further, the amendments fail to address the emerging domestic black market in nicotine. That failure consequently increases risk of unsafe use, potential abuse, and inappropriate dosage, formulation, labelling, packaging and presentation of nicotine.

Ideological opposition and ingrained biases should not factor in an evidence based approach to policy and legislative development.

Imperial respectfully requests that DOHA rejects the proposed scheduling amendments for nicotine and considers the growing body of scientific evidence on the public health benefits with NGPs.

Imperial Brands Australasia

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