

Response to the scheduling delegates' interim decision on nicotine, dated 2 February 2017

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**The Delegates of the Secretary
Joint Advisory Committees on Medicines and Chemicals Scheduling
Therapeutic Goods Administration**

By e-mail: medicines.scheduling@health.gov.au

Dear Delegates,

We would like to submit a response to the interim decision on the Application for amendment of Schedule 7 entry for nicotine on the Poisons Standard (dated 2 February 2017).

We are Australian academics, researchers and clinicians who were co-authors of submissions to support the original application (1, 2) We believe there are two fundamental flaws in the TGA's reasons listed on page 84 of the report, 'Interim decisions & reasons for decisions by delegates of the Secretary to the Department of Health'.

1. The report focusses only on the potential risks of nicotine for ENDS use, but ignores the substantial potential benefits for adult Australian smokers.

Any risk assessment is meaningless unless it considers the benefits as well as the risks and this is required under subsection 52E (1) of the Therapeutic Goods Act 1989. Cigarettes are the most lethal consumer product ever invented and kill two out of three Australian smokers. (3) In the European Union alone it is estimated that over 6 million smokers had quit smoking using e-cigarettes by 2014. (4) On the evidence available, the risk-benefit analysis strongly favours the use of nicotine in ENDS for smokers who are unable to quit with other cessation methods. It is unethical and unscientific to exempt nicotine in tobacco products and to deny smokers access to a much safer alternative.

Assessments of the benefits include the following recent statements from comprehensive, reviews by independent public health organisations:

- 'E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.' (5)
- 'Recent studies support the Cochrane Review findings that EC can help people to quit smoking and reduce their cigarette consumption. There is also evidence that EC can encourage quitting or cigarette consumption reduction even among those not intending to quit or rejecting other support. More research is needed in this area.' (6)
- 'Taking the totality of evidence including controlled trials, observational studies, changes in population smoking and ENDS use, the experience of nicotine replacement therapy, and widely reported user experience, there is confidence that ENDS are helping many smokers to quit smoking.' (7)
- 'Overall, there is encouraging evidence that vapour devices can be at least as effective as other nicotine replacements as aids to help tobacco smokers quit.' (8)

Denying the exemption for nicotine for use in ENDS denies Australian smokers a harm reduction opportunity and thereby contributes to an increase in smoking-related disease and its cost to the individual and the community.

2. In the reasons for the interim decision, the risks attributed to nicotine are exaggerated and are not supported by the empirical evidence or the overseas experience

a. 'There is a risk of nicotine dependence'

ENDS are used almost exclusively by smokers or recent ex-smokers who are already dependent on nicotine. (5, 7, 9) Users are transferring their dependence to another delivery system which has the benefit of delivering 'clean nicotine' without all the products of combustion which cause almost all the harm from smoking. Some will continue to use nicotine long-term. Others will use it temporarily. However, the net effect is a significant improvement in health, even in dual users. (10, 11)

b. 'There is some evidence that ENDS use in never-smoking youth may increase the risk of subsequent initiation of cigarettes and other combustible products'

10 years of experience in the UK, US and Europe suggests that the opposite is true — that ENDS may be diverting adolescents away from smoking.

A recent comprehensive review from Canada concluded that 'fears of a gateway effect are unjustified and overblown' and that 'vaping is replacing—rather than encouraging—the smoking of tobacco cigarettes among young people.' (8) Independent reviews from the UK agree with this finding. (5) It is obviously better for young people not to use e-cigarettes, but vaping is preferable to smoking as it is at least 95 per cent safer. (5)

The clear evidence from international experience is that most e-cigarette use by young people is experimental and short-lived and regular use by non-smoking adolescents is rare. (7, 12-16) Many young smokers use e-cigarettes to help them quit (17, 18) and the great majority do not use nicotine. (19, 20) It is therefore no surprise that smoking rates in young people are falling rapidly in countries where e-cigarettes are available. In the US for example, the rate of decline in smoking over the last 4 years is the fastest on record. (19)

c. 'There is some dual use'

Dual use is in many cases a transition stage for vapers who are trying to quit and there is good evidence that many of them go on to complete cessation. (21, 22) Most dual users significantly reduce the number of cigarettes they smoke (9) and studies show substantially reduced biomarkers (23-25) although one study showed no change when cigarette reduction was minimal (26). Dual use is still associated with improvements in health, such as COPD (27), asthma (28) and hypertension (11). Dual use is recommended in NRT users and promotes cessation and it is likely the same effect will be seen with ENDS. (29)

Some dual users admit to using ENDS in places where they cannot smoke, but the proportion is small. Furthermore, there is no evidence that this prevents smoking cessation.

d. 'There is a risk that ENDS will have a negative impact on tobacco control and may re-normalise smoking'

Overseas evidence suggests the opposite. According to Public Health England, 'There is no evidence that e-cigarettes are undermining the long-term decline in cigarette smoking among adults and youth, and may in fact be contributing to it.' (6) The United Kingdom Centre for Tobacco & Alcohol Studies concluded 'there is confidence that ENDS are ... not having negative effects like renormalising smoking, reducing quit rates or creating gateway effects.' (7) The UK Royal College of Physicians reached a similar conclusion. (5)

e. ‘Exposure to nicotine in adolescents may have long-term consequences for brain development’

Almost all research in this area has been done on animals and often includes chronic, high dose exposure to nicotine. (30) It is unclear how animal research translates to normal doses used in humans. Nicotine replacement therapy is approved from the age of 12 years and there is no evidence of adverse cognitive effects after over 30 years of use. (31) An expert Australian panel convened by GlaxoSmithKline concluded that ‘NRT can be safely used by adolescent smokers to help them quit’. (32)

f. ‘There is little evidence regarding the safety of long term nicotine exposure from ENDS’

Although it is the main addictive chemical in tobacco, long-term use of nicotine is regarded as low risk (except in pregnancy), based on over 50 years of snus use (moist, oral tobacco used in Sweden) (33) and over 30 years of nicotine replacement therapy, such as nicotine patches. (31) Nicotine is not the harmful ingredient in tobacco. It does not cause cancer or lung disease and has only minor effects on the cardiovascular system. (34)

Most importantly, ENDS with nicotine are not delivering the products of combustion that cause most of the harm to health from smoking, so the overall benefit to health from switching from smoking to ENDS is substantial.

g. ‘Nicotine can cause nausea, vomiting, convulsions ...’

There is almost no risk to ENDS users from nicotine toxicity as vapers regulate their nicotine intake. (35) The blood nicotine levels from long-term ENDS users are the same as from long-term users of nicotine replacement therapy which is freely available. (26)

h. ‘The dosage, formulation, labelling, packaging and presentation of the nicotine as would occur if the scheduling was amended would allow nicotine to be too accessible as a liquid which has higher risks and requires appropriate control’

The risks from low-concentrations of liquid nicotine in childproof containers are similar to other potentially poisonous household chemicals. (6) Furthermore, the availability of legal nicotine liquids would reduce the risks of an unregulated black market and home mixing with very high concentrations of nicotine liquid. Risks are associated with many products from which society benefits. Instead of banning them, we advocate proportionate approaches to managing the risks.

i. ‘In the USA, accidental poisonings associated with e-cigarettes have increased’

Reports of accidental poisonings have increased with greater availability, but the absolute rate is still extremely low. In 2013, ENDS and e-liquids accounted for 0.06% of calls to US Poisons Centres. (36) The rate of poisonings has been declining in the US since its peak in 2014. (37)

Furthermore, the level of risk is extremely low. Most cases of accidental nicotine exposure result in prompt vomiting and rarely cause serious harm. (38, 39) Only 2 cases of death from poisoning with nicotine have been reported internationally. According to Public Health England, the risk of poisoning from ingestion of e-liquids is comparable to similar potentially poisonous household substances. (6)

Toxic substances are ubiquitous in the modern world and are managed by childproof containers, education, keeping out of the reach of children and information about managing poisoning, not by prohibition.

j. ‘Public health authorities have varying views about the benefits of ENDS to tobacco harm reduction and as an aid in smoking cessation’

This is correct. Some public health organisations in the US are driven by an abstinence-only approach which is opposed to all other approaches. Harm minimisation supporters takes a more pragmatic view and understand that some people are simply unable to quit smoking or nicotine and that the main goal is to reduce smoking-related death and disease. For many smokers, ENDS are the only

effective solution. The cessation benefits of ENDS are recognised by Public Health England (6), the UK Royal College of Physicians (5), The UK Centre for Tobacco & Alcohol Studies (7) and the University of Victoria, BC, Centre for Addictions Research of BC, Canada (8) and many other organisations.

k. 'Excepting nicotine from Schedule 7 would likely result in increased nicotine exposure via ENDS'

There is no evidence for this statement. The experience is that ENDS users titrate their nicotine intake to maintain levels at or below those of smoking. (35) Millions of smokers have quit with the aid of ENDS, thereby eliminating nicotine intake altogether. (4, 40) Uptake of nicotine-containing ENDS is almost exclusively confined to existing smokers and ex-smokers. (5-7)

l. 'The use of a label warning statement 'not to be sold to a person under the age of 18 years' is not likely to be effective unless there is enforcement of this requirement'

This rule has already been introduced in most states. Enforcement should be mandated, just as it is with tobacco products and alcohol.

m. 'There is a risk there will be inappropriate marketing and advertising of nicotine for use with ENDS'

A regulatory code for ENDS has been established in the UK. (41) This enforces socially responsible advertising that must not appeal to people under 18 year or show people who appear under 25 years, must not encourage non-smokers to use ENDS etc. These regulations could and should be incorporated into the existing framework under Australian consumer law.

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