

Proposed Amendments to the Poisons Standard

Further comments on the interim decision on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine

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Proposed Amendments to the Poisons Standard

Further comments on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine – critique of the delegates’ interim decision

1. Overview comments on the interim decision

We note the advice of the joint ACCS-ACMS and the delegates’ interim decision not to allow the proposed rescheduling of nicotine. The rescheduling would have made it lawful to manufacture, import and sell nicotine e-liquids and e-cigarettes¹. We welcome the opportunity to follow up the submissions that we contributed in support of the proposed rescheduling².

In section 2, we provide a line-by-line critique of the reasoning presented to support the interim decision. We do not find any elements of the reasoning sufficient, individually or taken together, to justify the interim decision. In our view, the case has not been made and the ACCS-ACMS and delegates should reconsider. In outline, our critique of the reasoning presented is as follows:

- There is no credible case for exempting nicotine from schedule 7 *only when it is delivered via a tobacco product for smoking* – by far the most harmful way of taking nicotine. The reasoning does not confront the absurdity of granting exclusive access to the lawful consumer nicotine market to only the most harmful products. Why grant this protection to the cigarette trade?
- The evidence concerning youth use of e-cigarettes is misrepresented throughout the reasoning. Youth vaping is highly concentrated in smokers or adolescents who would otherwise smoke, and is mostly experimental and without nicotine. There is no evidence anywhere of harmful gateway effects. In the U.S., youth smoking is falling at a much greater rate than the long-run trend.
- The safety risks of nicotine liquids at the strengths envisaged in the rescheduling have been misrepresented and do not amount to a justification for the interim decision. These liquids are widely available in Europe and the United States and are not presenting any serious problems at any significant scale. Any risks are minor, manageable and comparable to other routine hazards.
- The reasoning fails to acknowledge the radical reduction in risk arising from switching from smoking to e-cigarettes arising from the completely different chemical and physical processes involved. To actively prevent Australians accessing substitute products with greatly reduced risk would require a strong technical, ethical and legal justification, but none is provided.
- The reasoning does not address the harmful unintended consequences of the current scheduling policy: fewer smokers switching and more use of unregulated black or grey markets to access nicotine liquids. No credible attempt has been made, as required under Section 52E of the Act, to objectively assess the benefits of rescheduling or harms arising from retaining the status quo.

¹ Therapeutic Goods Administration. Scheduling delegates’ interim decisions and invitation for further comment: ACCS/ACMS, November 2016. Joint meeting of the Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #14) 2.1 Nicotine , 2 February 2017 [\[link\]](#)

² Including Mendelsohn C. et al. Proposed Amendments to the Poisons Standard Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine, 30 August 2016 [\[link\]](#) and others.

2. Line-by-line critique of the reasoning supporting the interim decision

We provide comments on each element of the reasoning (reproduced in full in grey boxes) supporting the interim decision. We do not find that any elements of the reasoning, taken separately or together, provide an adequate justification for the interim decision.

Summary of Joint ACCS-ACMS advice to the delegates

The committee advised that the current scheduling of nicotine remains appropriate.

Delegates' interim decision

The delegates' interim decision is the current scheduling of nicotine remains appropriate. The delegates acknowledge and agree with the ACCS-ACMS advice.

Comment. We disagree with this advice and with interim decision that is based on it. We hope the decision is reversed before further damage is done. Under current scheduling, the only form of consumer nicotine exempt from the Poisons Schedule 7 is:

"tobacco prepared and packed for smoking"

It is perplexing and disturbing that health-orientated organisations and regulators should grant exclusive access to the consumer nicotine market – comprising 2.84 million Australian citizens or 16 percent of the adult population – *to only the most harmful products*, namely cigarettes and other products that involve combustion of dried tobacco leaf and inhalation of the resulting tar-laden toxic smoke. No explanation for this inexplicable preferential treatment for the cigarette supply chain is offered, and, in our view, no justification is possible.

The advice provided to the delegates does not engage with or acknowledge the concept of harm reduction – that Australian smokers deserve the same opportunities to reduce their health risks as Europeans or Americans and that they should not have to resort to international black or grey market trade to do this. Millions of Europeans report that they have used e-cigarettes to quit smoking^{3 4}. Why do authorities in Australia wish to deny that option to Australians? The interim decision is indefensible and inconsistent with the principles of fundamental justice.

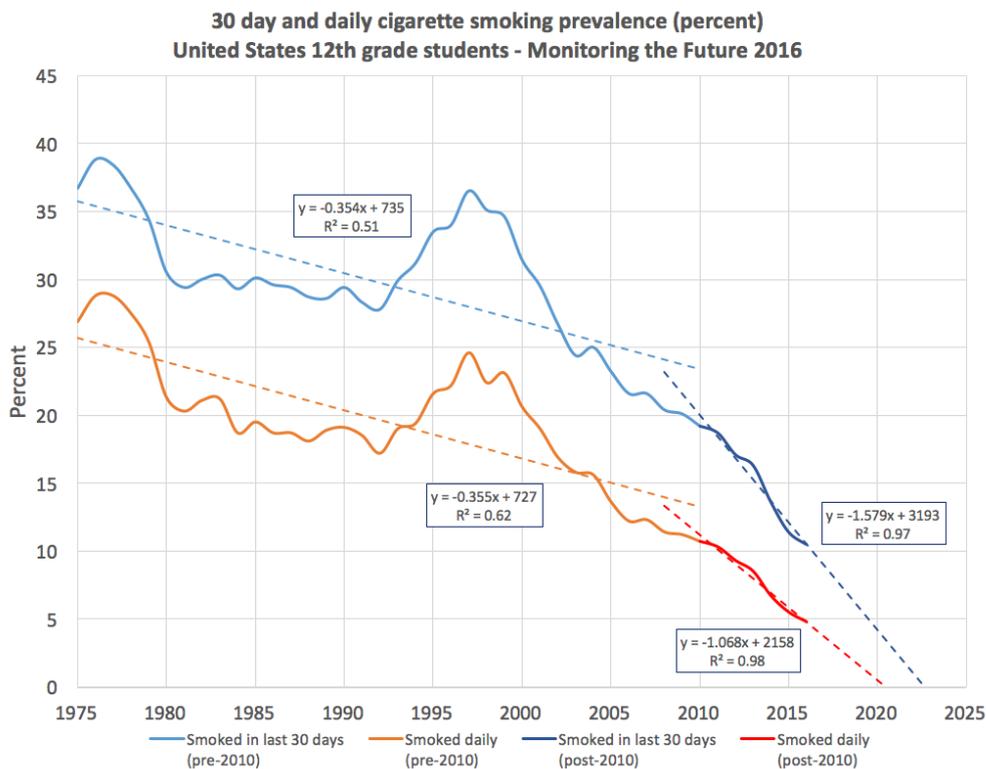
- There is a risk of nicotine dependence associated with use of Electronic Nicotine Delivery System (ENDS). The potential for nicotine dependence is much higher with third generation ENDS and is greater than with the nicotine replacement therapy products marketed in Australia. In countries such as the USA where there has been more ready access to ENDS there is some evidence that ENDS use in never-smoking youth may increase the risk of subsequent initiation of cigarettes and other combustible products during the transition to adulthood when the purchase of tobacco products becomes legal.

³ Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. *Addiction*. 2016 Jun 24; [\[link\]](#)

⁴ Farsalinos KE, Poulas K, Voudris V, Le Houezec J. E-cigarette use in the European Union: millions of smokers claim e-cigarettes helped them quit. *Addiction*. 2017 Mar;112(3):545–6. [\[link\]](#)

Comment. This advice offers a poor characterisation of the pattern of ENDS use anywhere and a poor basis for decision-making in Australia. It ignores the most obvious feature of ENDS use – that it is highly concentrated in adult smokers trying to quit smoking or cut down – i.e. people who are already nicotine dependent but wish to improve their health and wellbeing. Use in never-smoking youth is at a very low level and mostly experimental⁵, and it is possible that such adolescents would have gone on to smoke in the absence of ENDS.

There is no evidence that e-cigarettes are causing adolescents to become smokers as they enter adulthood⁶. In the United States, the rate of teenage and adult smoking has been declining rapidly since the introduction of e-cigarettes. For example, the Monitoring the Future dataset tracks the long-term trend in cigarette smoking in American 12th grade (age 17-18) students⁷. The chart below plots this data, and shows a post-2010 rate of decline *three times* the long run average prior to 2010.



While the nature of the available data cannot show that the accelerated decline is *caused by* the rise of e-cigarettes after 2010, they do provide some reassurance that e-cigarettes are not creating a surge of new adolescent smokers emerging from the other side of a gateway. Far more likely is that they are providing an alternative to smoking and so opening an ‘exit’ gateway or diversion from smoking.

⁵ Bauld L, MacKintosh AM, Ford A, McNeill A. E-Cigarette Uptake Amongst UK Youth: Experimentation, but Little or No Regular Use in Nonsmokers. *Nicotine Tob Res. England*; 2015 Aug 6;18(1):102–3. [\[link\]](#)

⁶ O'Leary R, MacDonald M, Stockwell T, Reist D. *Clearing the Air: A systematic review on the harms and benefits of e-cigarettes and vapour devices.* University of Victoria, BC: Centre for Addictions Research of BC.; 2017 [\[link\]](#)

⁷ Miech RA, Johnston LD, O'Malley PM, Bachman JG, Schulenberg JE. *Monitoring the Future national survey results on drug use, 1975-2016: Data tables. Table 2 - Trends in Prevalence of Use of Cigarettes in Grades 8, 10, and 12.* University of Michigan; Ann Arbor: 2016. [\[Tables\]](#)[\[Dataset\]](#). Chart created Clive Bate [\[on-line\]](#)

There are also more proportionate means to protect young people than to deprive millions of adult nicotine users of the means to access much lower risk products. Young people also have an interest in the health of adults: their older relatives, and themselves, family and friends as they grow up. Overreaction to unproven and unlikely theoretical risks is not in their interests. The data on youth uptake of e-cigarettes and effects on youth smoking are misrepresented in the reasoning as presented, and provide no support for the interim decision.

- There is some dual use of conventional cigarettes and ENDS in smokers.

Comment. Dual use is mentioned here as if it is a problem. However, dual use is often part of a pathway to exclusive vaping^{8 9} and so to greatly reduced risk. It is likely to have health benefits for anyone who makes a substantial cut in smoking or obtains a significant share of their nicotine from vaping – several studies have found improvements in relevant biomarkers in dual users^{10 11 12}.

It is important to understand that almost all smoking cessation attempts involve ‘dual use’ – though often sequentially rather than in parallel. Because of the low success rate of all quitting methods, including ‘cold turkey’, most smokers will make serial attempts to quit with multiple relapses, and so will continue to smoke intermittently throughout their journey to from smoker to complete smoking cessation. Very few smokers quit completely and permanently on the first attempt.

As far as dual use is concerned, some health agencies and activists may be guilty of contributory negligence. Dual users may be continuing to smoke because they are misinformed about relative risk and benefits of exclusive vaping. It is a fundamental failure of policy to misinform the public about relative risks of different nicotine products and then hold them responsible for making ill-informed personal choices such as continued smoking. Claims about dual use do not support the interim decision.

- There are several published studies showing that youth who initiate smoking with e-cigarettes are about three times more likely to be smoking conventional cigarettes a year later. There is a risk that ENDS will have a negative impact on tobacco control and may re-normalise smoking. If exempt from Schedule 7, availability of ENDS in children may cause an increase in smoking as they transition to adulthood, which raises public health concerns.

⁸ Farsalinos KE, Romagna G, Tsiapras D, Kyrzopoulos S, Voudris V. Characteristics, perceived side effects and benefits of electronic cigarette use: A worldwide survey of more than 19,000 consumers. *Int J Environ Res Public Health*. Switzerland: Multidisciplinary Digital Publishing Institute; 2014 Apr 22;11(4):4356–73. [\[link\]](#)

⁹ Zhuang Y-L, Cummins SE, Y Sun J, Zhu S-H. Long-term e-cigarette use and smoking cessation: a longitudinal study with U.S. population. *Tob Control*. BMJ Publishing Group Ltd; 2016;25(Suppl 1):i90–5. [\[link\]](#)

¹⁰ D’Ruiz CD, Graff DW, Robinson E. Reductions in biomarkers of exposure, impacts on smoking urge and assessment of product use and tolerability in adult smokers following partial or complete substitution of cigarettes with electronic cigarettes. *BMC Public Health*. 2016 Jul 12;16(1):543. [\[link\]](#)

¹¹ McRobbie H, Phillips A, Goniewicz ML, Smith KM, Knight-West O, Przulj D, et al. Effects of Switching to Electronic Cigarettes with and without Concurrent Smoking on Exposure to Nicotine, Carbon Monoxide, and Acrolein. *Cancer Prev Res*. 2015;8(9). [\[link\]](#)

¹² Goniewicz ML, Gawron M, Smith DM, Peng M, Jacob P, Benowitz NL. Exposure to Nicotine and Selected Toxicants in Cigarette Smokers Who Switched to Electronic Cigarettes: A Longitudinal Within-Subjects Observational Study. *Nicotine Tob Res*. Oxford University Press; 2017 Feb;19(2):160–7. [\[link\]](#)

Comment. To raise these observations as a concern is to misunderstand the data on which the claim is based. The observation described is an *association*. A possible explanation is that one behaviour (vaping) causes another (smoking). The data do not establish this relationship. Far more likely is that a third factor is a common cause of both smoking and vaping, an effect known as shared liability or more generally “confounding”. Candidates for this factor include parental smoking, rebellious nature, delinquency, poor educational attainment or poor mental health. In other words, whatever inclines young people to smoke also inclines them to vape. That should not be a surprising finding given that these behaviours (vaping and smoking) are similar and are substitutes. The order in which they initiate these is of little consequence. The important difference is the radical reduction in risk if they vape instead of smoke.

Deeper analysis of the U.S. data provides a better orientation for decision-making. Two papers characterise the U.S. situation more clearly. For example, Warner shows that vaping is highly concentrated in young smokers, with non-smokers making only light, experimental use:

Non-smoking high school students are highly unlikely to use e-cigarettes; among those who do, most used them only on 1-2 of the past 30 days. By contrast, current smokers are likely to use e-cigarettes and on many more days. (Warner KE, 2016)¹³

Villanti and colleagues show that the number of teenagers making more intense use of e-cigarette is vanishingly small.

In the 9.3% of youth reporting any past 30-day e-cigarette use, 63% also reported using a tobacco product; among the 3.3% past 30-day exclusive e-cigarette users, about two-thirds (2.1%) had ever used combustible or non-combustible tobacco products and one-third (1.2%) had not. Few never tobacco users had used e-cigarettes on 10 or more days in the past month (absolute percent < 0.1%). (Villanti AC et al 2016)¹⁴

- There is little evidence regarding the safety of long term nicotine exposure via ENDS. Exposure to nicotine in adolescents may have long-term consequences for brain development, potentially leading to learning and anxiety disorders. The toxicity of long term exposure to nicotine delivered by ENDS is unknown. Long-term exposure to excipients via the ENDS route of exposure is uncertain.

Comment. The long term safety of nicotine has been extensively studied through the use of NRT¹⁵ and snus¹⁶ and not been found to be a cause of significant disease. The influence of nicotine on

¹³ Warner KE. Frequency of E-Cigarette Use and Cigarette Smoking by American Students in 2014. *Am J Prev Med.* 2016 Aug;51(2):179–84. [\[link\]](#)

¹⁴ Villanti AC, Pearson JL, Glasser AM, Johnson AL, Collins LK, Niaura RS, et al. Frequency of youth e-cigarette and tobacco use patterns in the U.S.: Measurement precision is critical to inform public health. *Nicotine Tob Res.* 2016 Dec 24;ntw388. [\[link\]](#)

¹⁵ Lee PN, Fariss MW. A systematic review of possible serious adverse health effects of nicotine replacement therapy. *Arch Toxicol.* Springer Berlin Heidelberg; 2016 Oct 3;1–30. [\[link\]](#)

¹⁶ Lee PN. Epidemiological evidence relating snus to health - an updated review based on recent publications. *Harm Reduct J.* England; 2013;10(1):36. [\[link\]](#)

adolescent brain development remains speculative and based largely on animal studies¹⁷, with little supporting evidence in humans – for example observations of adverse effects in the large population of nicotine users who have smoked over many decades.

This advice fails to take account of *what is known* about nicotine exposure via ENDS and what is known about exposure to cigarette smoke. There is extensive knowledge available in systematic reviews – for example, Glasser and colleagues recently reviewed 687 articles¹⁸ to conclude:

Studies indicate that ENDS are increasing in use, particularly among current smokers, pose substantially less harm to smokers than cigarettes, are being used to reduce/quit smoking, and are widely available.

It is a scientific banality to note that we do not have multi-decadal longitudinal studies for recently introduced products. However, it is wrong to imply that we have no insights into the likely long term risk arising from these products. There is extensive evidence characterising the physics and chemistry of e-cigarette aerosol and cigarette smoke. E-cigarettes create *much* lower exposures to toxic agents^{19 20 21 22 23 24}. Taking account of the toxicology evidence, Public Health England²⁵ and the Royal College of Physicians (London)²⁶ provided a guideline assessment that e-cigarettes are likely to be at least 95 percent lower risk than smoking. RCP summarised its guidance as follows:

Although it is not possible to precisely quantify the long-term health risks associated with e-cigarettes, the available data suggest that they are unlikely to exceed 5% of those associated with smoked tobacco products, and may well be substantially lower than this figure".
(Section 5.5 page 87)

The ACCS-ACMS advice does not provide any basis for disputing this cautious expert assessment or present any theory to suggest why very much lower toxic exposures would not translate into greatly reduced disease burdens. Further, the much simpler chemistry of e-cigarette aerosol would allow

¹⁷ Naiura R. Re-thinking nicotine and its effects, Schroeder Institute, Truth Initiative, United States. 2 December 2016 [[link](#)][[PDF](#)]

¹⁸ Glasser AM, Collins L, Pearson JL, Abudayyeh H, Niaura RS, Abrams DB, et al. Overview of Electronic Nicotine Delivery Systems: A Systematic Review. *Am J Prev Med*. 2016 Nov;0(0):1469–71. [[link](#)]

¹⁹ Goniewicz ML, Knysak J, Gawron M, Kosmider L, Sobczak A, Kurek J, et al. Levels of selected carcinogens and toxicants in vapour from electronic cigarettes. *Tob Control*. 2014 Mar;23(2):133–9. [[link](#)]

²⁰ Burstyn I. Peering through the mist: systematic review of what the chemistry of contaminants in electronic cigarettes tells us about health risks, *BMC Public Health* 2014;**14**:18. [[link](#)]

²¹ Farsalinos KE, Polosa R. Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Therapeutic Advances in Drug Safety* 2014;**5**:67–86. [[link](#)]

²² Hajek P, Etter J-F, Benowitz N, Eissenberg T, McRobbie H. Electronic cigarettes: review of use, content, safety, effects on smokers and potential for harm and benefit. *Addiction* [Internet]. 2014 Aug 31 [[link](#)]

²³ Margham J, McAdam K, Forster M, Liu C, Wright C, Mariner D, et al. Chemical Composition of Aerosol from an E-Cigarette: A Quantitative Comparison with Cigarette Smoke. *Chem Res Toxicol*. American Chemical Society; 2016 Oct 17;29(10):1662–78. [[link](#)]

²⁴ Shahab L, Goniewicz ML, Blount BC, Brown J, McNeill A, Alwis KU, et al. Nicotine, Carcinogen, and Toxin Exposure in Long-Term E-Cigarette and Nicotine Replacement Therapy Users. *Ann Intern Med*. 2017 Feb 7;24:442–8. [[link](#)]

²⁵ Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [[link](#)] E-cigarettes: an evidence update 19 August 2015. [[link](#)]

²⁶ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [[link](#)]

for easier modification if evidence emerged that particular constituents were problematic. This part of the reasoning fails to recognise the profound difference in risk that e-cigarettes offer to current smokers, which is the main reason to accept the rescheduling. Because it misses the point, this part of the reasoning does not provide support for the interim decision.

- Nicotine can cause nausea, vomiting, convulsions, bronchorrhoea, high blood pressure, ataxia, tachycardia, headache, dizziness, confusion, agitation, restlessness, neuromuscular blockade, respiratory failure and death in overdose.

Comment. These symptoms are only relevant at very high exposures, far above normal use. Users of nicotine liquids control their exposure by the straightforward approach of not vaping whenever they sense they have had enough nicotine²⁷. There are no reports of overdoses among regular users. Accidental exposures do happen but they represent a manageable and minor detriment compared to the risks associated with smoking. Extreme exposure to many everyday substances can be harmful, but it does not justify banning them. This argument does not support the interim decision.

- 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 controls.

Comment. Experience from Europe and the United States suggests these issues are not a material problem, and the reasoning cannot point to any harms that are arising from the widespread availability of these products. However, there are important risks that rescheduling would mitigate:

- The very significant harms that arise from smoking: these arise from exposure to smoke of both users and bystanders, and from fire risks.
- The risks arising from an unregulated black or grey market in e-liquids.

The advantage of making nicotine-containing liquids widely accessible is that they would be used instead of smoking. At the same time, the hazards arising from nicotine liquids at the dilutions proposed (3.6 percent or less) do not produce risks that would be exceptional or require unusual levels of precaution. This part of the reasoning does not support the interim decision.

- The proposed maximum amount of 900 mg of nicotine per pack is within the estimated lower limit causing fatal outcome (500 mg to 1g). There have been reports of unintentional ingestion of ENDS liquid by children with severe outcomes in some cases. The proposed maximum concentration of 36 mg of nicotine per mL is high (the EU Tobacco Product Directive specifies a maximum concentration of 20 mg/mL). The amount of nicotine in 5 mL of a 3.6% solution in ENDS is 180 mg, which would likely cause significant toxicity in a young child (5 mL would be one swallow for a toddler). Child-resistant packaging would reduce the risk of unintentional exposure to the solution in children.

²⁷ Dawkins LE, Kimber CF, Doig M, Feyerabend C, Corcoran O. Self-titration by experienced e-cigarette users: blood nicotine delivery and subjective effects. *Psychopharmacology (Berl)*. 2016 May; [\[link\]](#)

Comment. It is unclear why the ACCS-ACMS advice believes this is the appropriate way to regulate this potential hazard. It is difficult to find examples where the risk to health from substance exposure is controlled by *limiting container size* as in the discussion above. The advice does not provide any precedent for managing hazards in this way. This is not the case for common medicines such as paracetamol, sedatives or anti-depressants. It is not the case for alcohol and it would be wholly impractical for many household substances such as bleach. However, there is a well-established approach to address this risk:

- Use of child-resistant packaging
- Warning of the hazard
- Providing advice on what to do if exposed

Given that Australia's *de facto* ban on e-liquids forces many users to purchase from unauthorised sources, some of which may not be adopting these standards, it is more likely that the current scheduling is *increasing* this risk. Furthermore, international trade may be in highly concentrated and much more hazardous nicotine liquids than proposed for rescheduling. It is possible to purchase near pure nicotine concentrate from vendors in China²⁸. The TGA should try to avoid the regulators' 'compliance fallacy' and be aware of the adverse real-world consequences of its restrictions, given that people do in reality seek work-arounds to regulations that threaten their health.

The European Union Tobacco Products Directive (14/40/EU) does not provide any sort of model for Australia, Europe or anywhere else. The limits on strengths and container sizes have been repeatedly challenged as counter-productive by experts²⁹. This part of the reasoning ignores the usual approach to managing exposure hazards and does not, therefore, support the interim decision.

- In the USA, accidental poisonings associated with e-cigarettes have increased from one per month in 2010 to 215 per month in 2014 including one death.

Comment. It is not surprising that there should be an increase in *anything* associated with e-cigarettes over the period 2010-2014 as this coincides with the period over which they were introduced – and they were barely in use in 2010. The cited data³⁰ refer to 'exposure' calls, not 'poisonings'. The term 'exposure' means someone has had contact with the substance in some way; for example, ingested, inhaled, absorbed by the skin or eyes, etc. Not all exposures are poisonings or overdoses and many will be trivial. The cited source makes it clear that the death in question was a suicide by intravenous admission of nicotine, *and so it was not an accidental*.

This statement provides little insight into scale of the hazard. For reference, the number of exposure calls to U.S. poison centers in 2014 was 4,024³¹. This is a minute fraction of calls associated with

²⁸ Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, Counterfactual 4 May 2016. [\[link\]](#)

²⁹ Farsalinos KF et al, Scientific Errors in the Tobacco Products Directive A letter sent by scientists to the European Union, 16 January 2017 [\[link\]](#)

³⁰ CDC MMWR. *Notes from the Field: Calls to Poison Centers for Exposures to Electronic Cigarettes — United States, September 2010–February 2014* April 4, 2014 / 63(13);292-293 [\[link\]](#)

³¹ American Association of Poison Control Centers, E-Cigarettes and Liquid Nicotine, accessed 11 Feb 2017. [\[link\]](#)

common household items such as medicines, cosmetics, alcohol and cleaning fluids. The table below shows the breakdown of exposure calls for the top 25 substances³².

Table 17A. Substance Categories Most Frequently Involved in Human Exposures (Top 25).

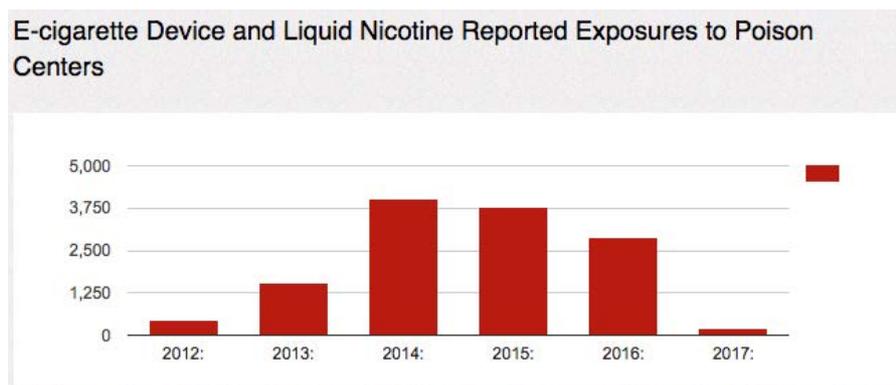
Substance (Major Generic Category)	All substances	% ^a	Single substance exposures	% ^b
Analgesics	291,062	11.29	187,329	9.73
Cosmetics/Personal Care Products	199,291	7.73	192,552	10.00
Cleaning Substances (Household)	198,018	7.68	178,973	9.29
Sedative/Hypnotics/Antipsychotics	150,715	5.85	55,653	2.89
Antidepressants	112,412	4.36	46,517	2.42
Antihistamines	103,327	4.01	72,989	3.79
Cardiovascular Drugs	102,170	3.96	45,466	2.36
Foreign Bodies/Toys/Miscellaneous	99,835	3.87	96,748	5.02
Pesticides	83,005	3.22	77,480	4.02
Topical Preparations	82,819	3.21	80,746	4.19
Alcohols	68,648	2.66	22,277	1.16
Vitamins	66,058	2.56	56,938	2.96
Cold and Cough Preparations	61,288	2.38	43,645	2.27
Stimulants and Street Drugs	59,869	2.32	34,660	1.80
Anticonvulsants	56,832	2.20	23,314	1.21
Hormones and Hormone Antagonists	56,775	2.20	38,651	2.01
Antimicrobials	56,726	2.20	46,358	2.41
Bites and Envenomations	55,017	2.13	54,298	2.82
Gastrointestinal Preparations	48,501	1.88	36,440	1.89
Plants	44,731	1.74	42,351	2.20
Dietary Supplements/Herbals/Homeopathic	42,535	1.65	34,569	1.80
Chemicals	38,975	1.51	33,138	1.72
Fumes/Gases/Vapors	33,944	1.32	31,238	1.62
Other/Unknown Nondrug Substances	32,001	1.24	28,688	1.49
Hydrocarbons	31,903	1.24	29,907	1.55

^aPercentages are based on the total number of substances reported in all exposures (N = 2,577,557)

^bPercentages are based on the total number of single substance exposures (N = 1,925,657)

The 4,024 e-cigarette exposure calls amounted to 0.15 percent of the total in 2014. The number of exposure calls related to analgesics was over seventy-times greater than for e-cigarettes.

Given the data is readily available, it is surprising that the advice to delegates did not cite the decline in exposure calls to U.S. Poison Centers since 2014.



The data cited in this part of reasoning is provided without context and is deeply misleading. Once placed in context, the hazard is clearly both minor and manageable. This part of the reasoning does not, therefore, support the interim decision.

³² James B. Mowry PharmD, Daniel A. Spyker PhD, MD, Daniel E. Brooks MD, Naya McMillan DrPH, MS & Jay L. Schauben PharmD (2015) 2014 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 32nd Annual Report, Clinical Toxicology, 53:10, 962-1147, [\[link\]](#)

- ENDS is used for Tobacco Harm Reduction, assistance with cessation of smoking and for recreational use. Public health authorities have varying views about the benefits of ENDS to tobacco harm reduction and as an aid in smoking cessation. Currently about 9% of current smokers and recent quitters in Australia use ENDS. Exempting nicotine from Schedule 7 would likely result in increased nicotine exposure via ENDS (based on countries such as the UK and USA where these products are more widely available, and the increase in Australia in recent years). In the UK 19% of smokers and 8% of ex-smokers currently use ENDS.

Comment. Increased population nicotine exposure via ENDS (rather than via smoking) is the intention of harm reduction strategies for continuing nicotine users. The idea is to let users switch from highly hazardous combustible nicotine delivery systems to ENDS to reduce the risk to the user by two orders of magnitude. This would be a *benefit* of rescheduling, not a reason to decide against it. The advice and reasoning for the interim decisions starts with the following in the box above:

ENDS is used for Tobacco Harm Reduction, assistance with cessation of smoking and for recreational use.

It is hard to see why regulators would oppose reducing harm, supporting smoking cessation and allowing recreational use with far lower risk. The corollary is that by *not* rescheduling, the regulators would increase harm, maintain smoking and require more harmful forms of recreational use – all in order to ensure that nicotine use does not increase in a much safer delivery system than smoking. This part of the reasoning is confused and self-contradicting and so does not support the interim decision.

- 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. There is a risk there will be inappropriate marketing and advertising of nicotine for use with ENDS if nicotine for use with ENDS is exempted from Schedule 7.

Comment. It is trivial that any law that that is not enforced is unlikely to be effective and the solution is to enforce it. However, it is not even obvious that strict enforcement of such age-restriction laws would be beneficial to health, though there is near universal support for such restrictions among consumers, the industry and health organisations. If the effect of e-cigarettes is to *replace* smoking among teenagers it is possible that such restrictions will have the unintended consequence of increasing smoking by obstructing this lower-risk pathway. In fact, there is now tentative evidence suggesting that this is happening. Research from the United States suggests that age restrictions placed on vaping have the effect of *increasing* teenage smoking^{33 34 35}. Note that if this effect is true for age restrictions, it is likely also to be true for any broader prohibitions (such as

³³ Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [\[link\]](#)

³⁴ Pesko MF, Hughes JM, Faisal FS. The influence of electronic cigarette age purchasing restrictions on adolescent tobacco and marijuana use. *Prev Med (Baltim)*, February 2016 [\[link\]](#)

³⁵ Pesko M, Currie J. The Effect of E-Cigarette Minimum Legal Sale Age Laws on Traditional Cigarette Use and Birth Outcomes among Pregnant Teenagers. Cambridge, MA; 2016 Nov. [\[link\]](#)

that favoured by the ACCS-ACMS) that blocks teenagers' access to safer alternatives to smoking. This evidence should be taken as indicative of potential harmful unintended consequences arising from Australia's prohibition of e-cigarettes embodied in the current schedule.

If marketing is a concern, then it is possible to place constraints on marketing – a practice used for many adult products including alcohol or gambling in many jurisdictions. The UK Committee on Advertising Practice has set out guidelines for U.K. advertising of e-cigarettes that were widely welcomed³⁶ and could be adapted for use in Australia. These are similar to the restrictions placed on alcohol advertising in the UK. However, there is again scope for unintended consequences arising from excessive restriction of the advertising of low risk alternatives to smoking – namely that there will be more smoking and less use of low risk alternatives. Basic economic analysis would support that expectation and some care is needed to avoid unintended consequences³⁷.

The concerns raised in this part of the reasoning are easily managed and it is even possible that effort to manage them would be beset by unintended consequences. This part of the reasoning, therefore, does not support the interim decision.

3. Unacceptable redaction policy

We were surprised and dismayed that the submissions had the names of the contributors redacted when published with the interim decision³⁸. This was the case for all submissions as far as we could see. We did not ask for and do not want our submissions and identities to be redacted. We favour transparency as a default with the right to confidentiality where there is legitimate reason for it. On the coversheet required for submission, we checked the following option:

Publish my entire submission in full, including my name and work title as it appears on the submission, on the TGA website. Note: Australian Privacy Principle 8.1 will not apply if you consent to this.

Given that we asked for our entire submission including names to be published, we are concerned that the redaction is a defensive editorial action by TGA, perhaps because to avoid giving visibility to the extent of support in the Australian and international expert community for the proposed rescheduling. If there is an alternative explanation, we would be grateful to have it.

We request removal of the redaction from earlier submissions. For the avoidance of doubt, we do not consider any information or names in this submission to be confidential or justifying redaction.

16 February 2017

³⁶ Committee on Advertising Practice (UK), U.K. Code of Broadcast Advertising: 33. E-cigarettes Broadcast [\[link\]](#); UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (CAP Code): 22. E-cigarettes [\[link\]](#)

³⁷ Tuchman A. Advertising and Demand for Addictive Goods: The Effects of E-Cigarette Advertising, Stanford University, (working paper) September 2015 [\[link\]](#)

³⁸ Redacted submission [\[link\]](#). Original submission [\[link\]](#)