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15 February 2017

Medicines Scheduling Secretariat

Therapeutic Goods Administration

PO Box 100

WODEN ACT 2606

RE: Proposed Amendments to the Poisons Standard Further comments on a proposal to amend the Poisons Standard Schedule 7 entry for substances including nicotine – critique of the delegates' interim decision
Joint Submission of the Australian Taxpayers' Alliance & MyChoice Australia

Executive Summary

1. The ATA and MyChoice Australia are disappointed by the (Therapeutic Goods Administration (TGA)'s interim decision to maintain the current scheduling of nicotine, thereby depriving Australian smokers of life-saving vaping technology.

2. The ATA and MyChoice believe that the TGA has not met its statutory obligation to uphold the welfare of Australians in that it has inadequately taken note of overwhelming scientific consensus on the effectiveness of nicotine-loaded vaping liquids as a smoking cessation aid or the substantial body of evidence attesting to the lack of risks associated with nicotine vaping.

3. The ATA and MyChoice further note that the interim decision contains no sincere attempt to address the points raised by the abovementioned scientific evidence and is rife with qualifications such as 'may' and 'might' which further attest that such concerns are devoid of substance.

4. The ATA and MyChoice note the absurdity and counter-intuitiveness of the decision to keep non-prescription nicotine illegal - unless delivered through the carcinogenic combustion of smoking tobacco which continues to be sold over the counter.

5. The ATA and MyChoice respectfully submit that the TGA re-acquaint themselves with Section 52E of *The Act* which requires them to objectively assess the benefits of rescheduling or harms arising from retaining the status quo. The ATA and MyChoice request that a credible attempt be made to address the harmful unintended consequences of the current scheduling policy whereby fewer smokers would switch from tobacco and more would rely on unregulated black/grey markets to access nicotine liquids.

6. The ATA and MyChoice will comprehensively outline our response to the TGA's unsubstantiated interim decision below. We hope that the TGA will sincerely consider and lend appropriate weight to the overwhelming scientific evidence and reverse its interim decision before further harm is done to our smokers as a result of the TGA's pro-Cancer interim decision to maintain the status quo.

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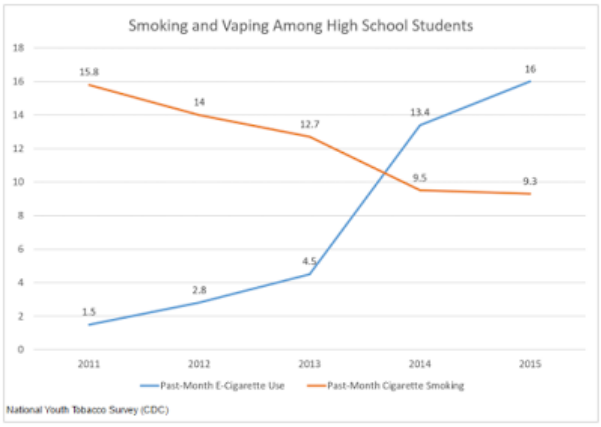
Response to the TGA Interim Decision

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

7. The ATA and MyChoice firstly note that the claim about nicotine vaping by never-smoking youth has been comprehensively refuted by recent studies from the UK which demonstrate that vaping by never-smoking youth in that country occurs at very low levels and virtually always on an 'experimental' basis.[1]

8. It is further submitted that there is no evidence that e-cigarettes or vaping is causing adolescents to take up smoking as they enter adulthood.[2] The "public health concerns" speculated by the TGA are not substantiated by evidence, whereby policymaking ought to be substantiated by evidence and not mere conjecture or speculation.

9. Evidence from the US, courtesy of the United States government CDC (Centre for Disease Control) National Youth Tobacco Survey, indicates that in that country, cigarette smoking rates amongst youth smokers had dropped significantly in direct tandem with the uptake rate for nicotine vaping:



[1] 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. https://academic.oup.com/ntr/article-abstract/18/1/102/2583946/E-Cigarette-Uptake-Amongst-UK-Youth

[2] O'Leary R, MacDonald M, Stockwell T, Reist D. Clearing the Air: A systematic review on the harms and benefits of ecigarettes and vapour devices. University of Victoria, BC: Centre for Addictions Research of BC.; 2017 http://www.uvic.ca/home/about/campus-news/media-releases-tips/2017+e-cigarettes-carbc-macdonald-stockwell+media-release

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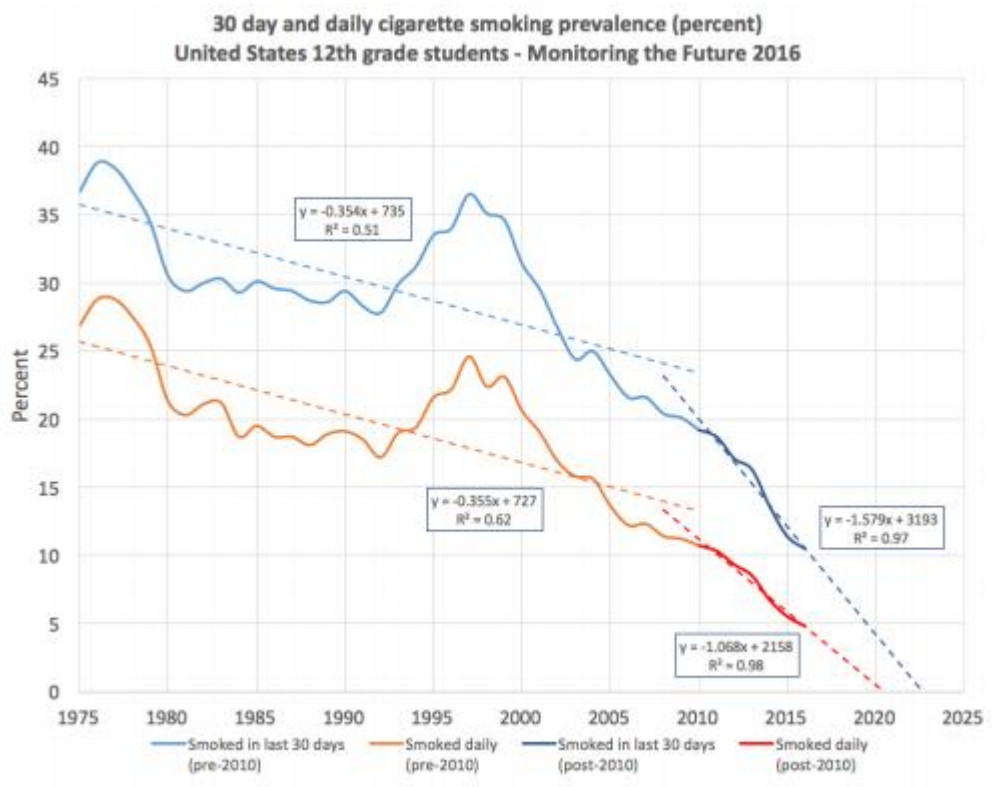
The following chart illustrates that the post-2010 decline rate in smoking is three times the decline rate in previous years.[3] This confirms that contrary to the unfounded fears of the TGA, nicotine vaping has not created a 'gateway' to smoking uptake by adolescents.



10. The ATA and MyChoice take note of the TGA's deep concern for "some evidence" that non-smokers "may" "increase (their) risk" of taking up vaping and that vaping "may" "re-normalise" smoking despite a failure to consider readily available US government data about the effectiveness of vaping in addressing the US teenage smoking problem.

11. The claim that vaping "re-normalises" smoking has been refuted by concrete evidence that a vast majority of those who vape are former non-smokers seeking an effective a smoking cessation tool has been confirmed by a comprehensive, recent long-term study in a leading medical journal.[4]

[3] 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.

[4] 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: A Cross-sectional Study. Ann Intern Med. [Epub ahead of print 7 February 2017] doi: 10.7326/M16-1107 http://annals.org/aim/article/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement

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12. The ATA and MyChoice are concerned by the TGA's insinuation that "there is some dual use of tobacco and ENDS by smokers" is somehow negative as this statement ignores the very mechanism by which individuals quit smoking. Evidence confirms that dual use eventually leads to a complete switch to vaping.[5] Evidence also confirms a complete depletion in the build-up of toxic chemicals in the bodies of smokers who switch to vaping as reliance on tobacco smoking reduces in favour of vaping uptake.[6] Dual use is also common during the transition process between smoking and currently available nicotine gum anti-smoking aids.[7] Even smokers who seek to quit the habit "cold turkey" often relapse multiple times.

13. Dual users may be continuing to smoke because they are ill-informed about relative risk and benefits of exclusive vaping. Some health agencies and activists have been responsible for such misinformation and the blame for the individual choice to engage in dual smoking-vaping can be attributed in large part to such misinformation.

> "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."

14. The ATA notes the frequent usage of low modality language such as 'may' and 'potentially' as well as 'unknown' and 'uncertain'. We note that the TGA has conceded that there is in fact no concrete evidence supporting the fears which have supported this interim decision.

15. Long-term studies of Nicotine Replacement Therapy (NRT) which includes legal nicotine gums have found no significant correlation or causation to any disease.[8] The only evidence linking

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[5] 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. http://www.mdpi.com/1660-4601/11/4/4356/htm;
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. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5099206/

[6] 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: A Cross-sectional Study. Ann Intern Med. [Epub ahead of print 7 February 2017] doi: 10.7326/M16-1107 http://annals.org/aim/article/2599869/nicotine-carcinogen-toxin-exposure-long-term-e-cigarette-nicotine-replacement

[7] Kornitzer, M., Boutsen, M., Dramaix, M., Thijs, J., & Gustavsson, G. (1995). Combined use of nicotine patch and gum in smoking cessation: a placebo-controlled clinical trial. Preventive medicine, 24(1), 41-47. Chicago http://www.sciencedirect.com/science/article/pii/S0091743585710067

[8] 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.

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nicotine to brain development issues are animal studies,[9] with no evidence linking the two in humans despite large populations which have been exposed to years of nicotine use.

16. The Royal College of Physicians (UK) has deemed that nicotine is 95% safer than tobacco smoking,[10] and Public Health England not only recommends the legalisation of nicotine vaping, but suggests that doctors recommend it as a smoking cessation tool.[11]

17. The TGA's assertion that there is 'no evidence' about the long-term effects of nicotine and that the risks are simply 'unknown' or 'uncertain' is intellectually dishonest as (despite the non-availability of long-term studies about specific newly introduced nicotine products), there is significant academic and scientific evidence about the chemistry and physics of nicotine vapours which indicate that those who inhale these vapours are not exposed to toxic agents.[12]

18. The TGA's reliance on mere speculation upon which to base its decision is akin to anti-vaccination activists who call for a ban on vaccinations premised upon an asserted (yet baseless) link to autism. The ATA and MyChoice Australia would hope that the level of intellectual rigour at the TGA would rise at least slightly above this.

> "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."

19. This statement assumes extreme levels of nicotine which far exceed even a frequent user's exposure to the product. Vapers are likely to cease vaping due to the natural inclination that they have vaped too much well before the overdose level required for most of these risks eventuates.[13]

20. The ATA notes that a majority of the symptoms listed can be caused by an excessive dosage of virtually any consumable product. An overdose of bananas can lead to potassium poisoning which causes nausea and vomiting and can even induce death in individuals with

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[9] Naiura R. Re-thinking nicotine and its effects, Schroeder Institute, Truth Initiative, United States. 2 December 2016.
[10] Royal College of Physicians (London), Nicotine without smoke: tobacco harm reduction. 28 April 2016.
[11] Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [link] Ecigarettes: an evidence update 19 August 2015.
[12] 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; 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;14:1; 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; 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 3.
[13] 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;

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some kidney conditions.[14] Similarly, caffeine in high doses may cause similar results, and indeed, reading the TGA interim decision on this matter also led to confusion, high blood pressure, headaches, and agitation. It is therefore the typical dosage range that the TGA should consider in making its decision as well as any natural reaction from the body which could proactively prevent a 'fatal' nicotine overdose.

21. Rescheduling provided by standard regulations would ensure the best outcomes in mitigating any risks associated with the product. The ATA and MyChoice note that the TGA's failure to reschedule the product despite consumer demand is likely to result in a black/grey market which would expose the consumers to far greater risk. This is especially pertinent given the prevalence of near 99% concentrated nicotine solutions available for import from China and legalized non-prescription nicotine solutions available in New Zealand.

"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."

22. Legalised trade of nicotine liquids without a prescription would be under proposed concentrations of less than 3.2% which represent no significant risk warranting exceptional or unusual precaution.

23. The ATA and MyChoice note that distilled alcoholic spirits are widely available, sold without prescription for personal use and do not include warning labels. The ATA and MyChoice further note that special variants of these spirits such as cinnamon-flavoured whiskey are sold in bottles which, if consumed whole, could induce alcohol poisoning. The ATA and MyChoice note that public health authorities place trust in reasonable adults to exercise the basic cognitive function required to ascertain that such behavior might not be advisable. The ATA and MyChoice Australia request that the same standard of expected consumer behavior be applied to nicotine liquids which are less dangerous when irresponsibly consumed than most alcoholic beverages.

"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."

24. There is no precedent for the management of dangerous household substances including bleach as well as medications such as Panadol, paracetamol and anti-depressants or even alcohol by reducing container sizes.

[14] http://www.ironmanmagazine.com/special-k/

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25. Possible means of mitigating the risk, as applied to far more lethal household chemicals, include warning labels, child-resistant packaging and a guide on what to do in the event of an emergency ingestion.

26. This approach is taken with children's toys which include small parts that are potentially fatal choking hazards. These toys are sold under the explicit premise that they will be placed near and will be actively used by young children unlike nicotine liquids which are likely to be kept separate from children and to come into contact with children only by accident and almost always in exceptional or rare circumstances.

27. Given the immense precedent in this regard pertaining to household hazards, the ATA and MyChoice note that this line of reasoning by the TGA is without substance.

"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."

28. The ATA and MyChoice note that this particular finding from the TGA, inserted without context, is misleading and deceptive given that e-cigarettes were barely used in 2010 and the introduction of any new product is likely to result in some increase in accidental use above the 0 starting point whereby the rapid uptake of e-cigarettes between 2010 and 2014 is a materially important contextual circumstance which the TGA has failed to consider in its appraisal of the increased rate of accidental use.

29. The TGA's cited data,[15] contrary to its inference, does not actually attest to the abovementioned accidental poisoning rate. Rather the figure cited refers to the incidence of 'exposures' to the product which includes people coming into contact with it in some different way to its usual intended use such as ingested, inhalation, absorption through the skin or eyes etc. Many many of these are likely to have been minor or trivial exposures which do not qualify as 'poisonings'.

30. The ATA and MyChoice are deeply concerned that the TGA has ignored the explicit qualification in its own source that the death in question was the result of deliberate intravenous injection of nicotine and was hence not accidental.

31. The ATA and MyChoice respectfully submit that the TGA as a policymaking organisation ought to fully appraise the context and surrounding circumstances of the figures it cites when justifying its interim decisions. This is especially important in reviews such as the present where life-saving vape technology has the potential to enable millions of Australians to quit cancer-causing tobacco smoking, an outcome that it has successfully achieved in the European Union.[16]

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[15] 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

[16] Vardavas, C. I., Filippidis, F. T., & Agaku, I. T. (2015). Determinants and prevalence of e-cigarette use throughout the European Union: a secondary analysis of 26 566 youth and adults from 27 Countries. Tobacco control,24(5), 442-448.

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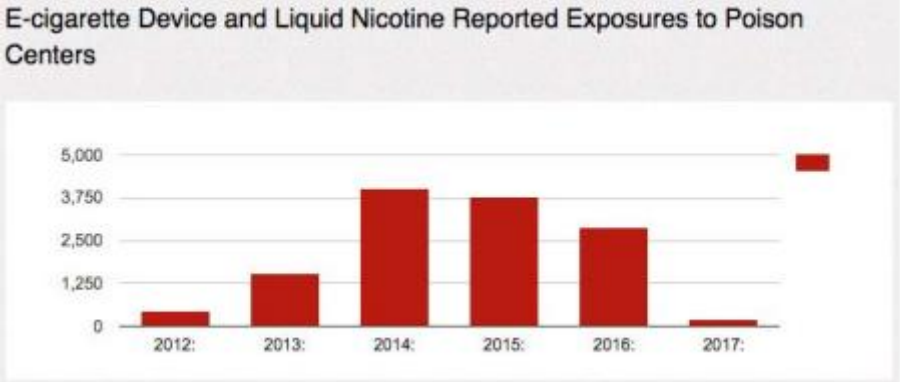
32. The ATA and MyChoice further note that the stated finding of 215 reported exposures in 2014 is a small fraction of the 4000+ exposure calls, most of them dealing with common household items, to US poison centres.[17]

33. The TGA has also failed to acknowledge that the exposure call rate for nicotine has reduced significantly between 2014 and the present year.[18] The ATA and MyChoice believe that this figure, taken in tandem with rapidly increasing uptake of the product, attests to the benefits of its legalisation and the dissemination of knowledge about safety and precautions which is possible with wide availability of the product.



34. The ATA and MyChoice further note that given the likelihood of consumers obtaining the product in Australia through black markets such as New Zealand and China (where black market dealers sell highly concentrated 99% nicotine solutions online, easily available to Australians)[19] if it is not rescheduled, that the TGA interim decision is effectively putting these individuals' lives at risk and ought to be reversed.

"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. Excepting 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."

35. The ATA and MyChoice are perplexed that the TGA would firstly acknowledge the primary aim of delivering nicotine through legalized e-liquids in order to aid smoking cessation and as a harm reduction strategy for tobacco smoking and then subsequently assert that the

[17] 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.
[18] Ibid.
[19] Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, Counterfactual 4 May 2016.

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increased uptake of nicotine resulting from e-cigarette use is a 'negative' effect which could justify the maintenance of its current scheduling. The ATA and MyChoice note that the uptake of ENDS by smokers of carcinogenic combustible tobacco is the precise aim of its legalization and is essential to its value as a harm-reduction strategy.

36. Nicotine is a non-carcinogenic product devoid of toxic agents associated with combustible tobacco. There is no evidence that it has any long-term ill effects.[20] Its intended effect is to satiate the cravings experienced by those who wish to cease tobacco smoking. Increased exposure to nicotine through ENDS is a good sign of tobacco harm reduction at work whereby the TGA has completely failed to acknowledge the drastic reduction in user exposure to toxic tobacco-related contaminants seen in the long-term studies of those who have switched from tobacco to vaping.[21]

37. The ATA and MyChoice respectfully submit that the TGA ought to lend this evidence the reasonable weighting it deserves when reconsidering its pro-Cancer 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."

38. The ATA and MyChoice note that any law which is not enforced is likely to be ineffective. The same understanding is applied to regular cigarettes which are sold over the counter with labels precluding their sale to minors whereby enforcement is conducted through inspectors enlisted by government agencies for that task. The ATA and MyChoice submit that the same inspectors can take on the role of enforcing the requirement for nicotine e-liquids sold at licensed shops in a manner that does not require any significant additional training.

39. The ATA and MyChoice further submit that one of the key, proven benefits of nicotine vaping, as attested by multiple studies from other jurisdictions such as USA,[22] is that it addresses the problem of teenage tobacco smoking by providing an alternative low-risk path that assists teenage smokers in quitting.

40. Studies further indicate that age-related restrictions on vaping actually increase the rates of teenage smoking.[23] Other measures which aim to restrict or inhibit vaping are hence also likely to have the same effect.

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[20] Lion Shahab, L., Goniewicz, M, L., PhD; Blount, B, C., Brown, J., McNeill, A., Alwis, K, U., Feng, J., Wang, L., & West, R. Nicotine, carcinogen, and toxin exposure in long-term e-cigarette and nicotine replacement therapy users: a cross-sectional study. Annals of Internal Medicine. doi:10.7326/M16-1107.

[21] Ibid.

[22] 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.

[23] 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 [

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41. The ATA and MyChoice note that where there are concerns about adolescent or teenager uptake of a product, the most common and effective strategy for addressing the problem is through marketing guidelines and regulations. For example, the UK's guidelines on the marketing of e-cigarettes have been welcomed by public health authorities and could easily be adopted in Australia.[24]

42. The ATA and MyChoice further note however, that care must be taken to ensure that advertising and marketing regulations are not too restrictive as the aim of life-saving vaping technology is to reduce the harm caused to existing tobacco smokers, including teenage smokers, by fostering a switch from tobacco smoking to vaping.

TGA Redaction Policy

43. The ATA and MyChoice are disappointed and concerned by the TGA's decision to withhold the names of specific contributors to the interim decision. The ATA and MyChoice believe in the importance of transparency, especially in matters of public policy concerning scientific assertions and notions of public safety. Confidentiality should be afforded albeit only where there is a reasonable justification for it.

44. Transparency is important in order to critique and address any flaws or counter-arguments in debates of public importance, including a critical examination of asserted evidence for the inferences provided given any potential conflicts of interest.

45. The and MyChoice selected the following option upon tender of our submission:

    "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."

46. We are concerned that the TGA's editorial decision to redact contributor's names could be motivated by a desire to stifle the extent of public awareness and debate possible around the present issue and to limit the exposure of the findings raised by the TGA's review to the Australian and International expert community. We therefore recommend that this policy be reversed prior to the undertaking of the final decision of the TGA.

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

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