

Parliament of Australia Senate Standing Committees on Community Affairs
Vaporised Nicotine Products Bill 2017
Comments on the draft Bill
Clive Bates, London, United Kingdom
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Parliament of Australia Senate Standing Committees on Community Affairs Vaporised Nicotine Products Bill 2017

1 The case for change

The value of the proposed Bill. We welcome this legislative initiative and believe it will be of value to the health and wellbeing of Australian citizens, to health professionals, to customs and law enforcement, and to the economy. We believe it supports informed consumer choice and provides the means for many people at risk from smoking-related disease to take control of their own risks in a way that appeals to them and without burdens on the taxpayer.

The urgency of addressing a harmful inconsistency. The Bill will eliminate a glaring and harmful inconsistency in Australia's health protection legislation. Australia's legislation only permits nicotine products to be placed on the market as a medicine or as "*tobacco prepared and packed for smoking*", primarily cigarettes. Australian legislation currently grants a monopoly to smoking products in that market place, and establishes insurmountable regulatory barriers-to-entry for e-cigarettes, heated tobacco products and smokeless tobacco. In doing so, it gives privileged market access to the most dangerous products, cigarettes, for which there is unambiguous evidence of great harm arising from sustained use. At the same time, current legislation it is blocking market access for products that are, beyond any reasonable doubt, very much lower in risk. This makes no sense from a scientific, ethical or compassionate perspective. This inconsistency has emerged into sharper focus following the rise of vapour technologies and heated tobacco products, and the emergence of evidence of highly positive public health impacts of smokeless tobacco in, for example, Sweden.

Low-risk tobacco and nicotine products are not medicines. These products could be regulated as medicines if the manufacturer makes a therapeutic claim, which they generally do not. It makes little commercial sense to seek a medicines marketing authorisation in a rapidly evolving and innovating consumer market. The products do not function as medicines or claim therapeutic effect, the consumers do not define themselves as sick, the manufacturers do not seek to treat a disease, and the products are not sold in a clinical or medicalised format. The products are not medicines by design or by use, and it is inappropriate to regulate them as if they are medicines.

The need for regulation that is fit for consumer products These products are consumer nicotine products that compete with cigarettes in a market for recreational use of the drug nicotine, with an important feature that they cause less harm. The value of the Bill is that it recognises this reality and attempts to provide a sound legal basis for the availability of these products in Australia.

Our comments for the Committee will focus on the draft Vaporised Nicotine Products Bill. However, we wish to annex substantive reasoned arguments for the changes that the Bill seeks to introduce.

- [Annex 1](#): Submission to the House Inquiry into e-cigarettes and personal vaporisers – July 2017
- [Annex 2](#): Submission of 40 experts to the Therapeutic Goods Administration arguing for proposal to reschedule nicotine to lift the *de facto* prohibition – September 2016
- [Annex 3](#): Response of 21 experts to Therapeutic Goods Administration – a detailed critique of TGA reasoning for rejection of the proposal – February 2017.

2 Broaden the scope of the Bill and amend the title

2.1 Policy intent

We recommend that the Bill is amended to provide a legal foundation for the lawful availability of *all* products that function as low-risk alternatives to smoking. This includes smokeless tobacco products and unheated nicotine products, as well as vapour products based both on nicotine and on tobacco. In this way, the Bill will provide a more complete and rational reform of the legislative and regulatory landscape for all tobacco and nicotine products. The following figure provides a segmentation of the low-risk consumer alternatives to smoking.



Figure 1: alternative low-risk nicotine products

2.2 Proposed changes to the Bill

To implement a more comprehensive approach to reduced risk nicotine products, the title and purpose of the Bill should reflect the broader purpose.

Draft Bill text	Proposed text amendment
Vaporised Nicotine Products Bill 2017	Low-Risk Nicotine Products Bill 2017
A Bill for an Act to make provision in relation to vaporised nicotine products and to distinguish vaping from smoking, and for related purposes	A Bill for an Act to make provision in relation to low-risk nicotine products and to distinguish such products from smoking, and for related purposes

Figure 2: proposed language to extend the scope and purpose of the Bill

3 Insert a definition of low-risk nicotine products

3.1 Policy intent

It will be helpful to have a single definition of ‘low-risk nicotine products’ that reflects the segmentation above and can be used in other parts of the Bill and any regulations.

3.2 Proposed changes to the Bill

Draft Bill text	Proposed text insertion
None	Inset after Section 2 of the Bill Definition Low-risk nicotine products means products that provide for the human consumption of nicotine, but without involving combustion processes or are not classified as therapeutic products. Such products include: (a) nicotine in tobacco prepared and packed for heating; (b) nicotine in smokeless tobacco prepared and packed for oral or nasal use; (c) nicotine without tobacco in solid or liquid preparations that have less than 7.5% nicotine by weight.

Figure 3: proposed language to provide a definition of low-risk nicotine products

Note: please see section 5.3 below for a discussion of the appropriate permissible strength for nicotine not included in tobacco.

4 Smoke-free legislation should not apply to low-risk nicotine products

4.1 Policy intent

Legislation should seek to prevent ‘scope creep’ of existing legislation that controls “smoking” to apply uncritically to “vaping” and without further democratic assent. Most smoke-free legislation was passed before these products were known to legislators. The processes and emissions of vapour or heated tobacco products are completely different to smoking in terms of their physics, chemistry and toxicity. There is no evidence of any material risk to bystanders arising from these products and much to suggest it is negligible. It would be wrong therefore simply to define *vaping* as *smoking* and apply legislation that was justified on the basis of completely different science and risks.

The policy intent therefore should be three fold:

1. To prevent unchallenged scope-creep by preventing the definition of smoking applying to use of low-risk nicotine products. This is essentially a clarification.
2. To place the default responsibility for vaping policy under the control of the property owner or operator, and to make this is a matter for house rules or the contract between the user and operator.
3. Where the legislature wishes to impose mandatory vaping policy, it should do this explicitly by properly amending legislation or regulations to make specific references to vaping.

4.2 Vaping in public places - Airports Act 1996

The owner or operator of an airport should be able to decide the policy for vaping in the airport. The policy for vaping should not be mandated by law (i.e. in regulations) unless there is evidence of material harm to bystanders or workers, which there is not. The proposed Bill clarifies that the scope of power to make regulations is limited to *smoking* – and this means products involving combustion.

This should not be seen as an unqualified right to vape anywhere on airport premises. The airport operator should be able to set a vaping policy that balances the commercial interests of the airport's businesses, the needs of vaping travellers and the preferences of those who do not vape or smoke – but this is a job for the *airport operator*, not the legislature.

The proposed amendment to the Airports Act is correct and confines *legislative* action to the control of *smoking* and prevents uncritical conflation of smoking and vaping, and therefore provides an important clarification about the scope of the law.

4.3 Vaping in public places – aircraft and buses

The same clarification should be provided in other Commonwealth legislation that controls smoking in the transportation system. There are two further examples.

Buses. Smoking on board buses registered under the *Interstate Road Transport Act 1985* is banned at all times while passengers are on board, pursuant to regulation 51B of the *Interstate Road Transport Regulations 1986*¹. There is no reference to vaping or equivalent in these regulations.

Aircraft. Regulations made under the *Air Navigation Act 1920* have prohibited smoking on all domestic flights since 1987. The current regulations, *Air Navigation Regulations 2016*². There is no reference to vaping or equivalent in these regulations.

Amendments to these regulations would make it clear that the word “smoking” is limited to “smoking a tobacco product using a combustion process”, as with airports and provide consistency. In this case, smoking policy would remain mandated by law, but the responsibility for vaping policy would revert to the owner and operator, and form part of the *contract* between the transportation user and operator. It does not mean that vaping should be automatically permitted on aircraft or buses, but just that the decision is not made by overstressing legislations that was

¹ Interstate Road Transport Regulations 1986 (as amended), section 51B [\[link\]](#)

² Air Navigation Regulation 2016, section 37 [\[link\]](#)

made for a different purpose, control of the exposure to tobacco smoke. Alternatively, legislation or regulations specific to vaping could be written – we argue there is no case to use force of law based on risks.

4.4 Smoking and vaping in other public places

Legislation controlling smoking in public places is almost all within the jurisdiction of states and territories. We are insufficiently versed in the framework for federalism in Australia to make a solid recommendation in this area. However, to pursue the policy intent, it would be necessary to pre-empt inappropriate extension of the definition of the word “smoking” to also mean “vaping” in legislation at the states and territories level. We do not think the Commonwealth has jurisdiction to do this, but systematic clarification of the terms ‘smoking’ and ‘vaping’ in Commonwealth legislation may facilitate clarification in of poorly-specified legislation by legislatures or the courts in the states and territories.

4.5 Proposed changes to the Bill

Draft Bill text	Proposed text insertion
None	<p>Interstate Road Transport Regulations 1986</p> <p>At the end of regulation 51B add:</p> <p>For the purposes of section, smoking means smoking a tobacco product using a combustion process.</p>
None	<p>Air Navigation Regulations</p> <p>At the end of regulation 37 add:</p> <p>For the purposes of section, smoking means smoking a tobacco product using a combustion process.</p>

Figure 4: proposed language to provide consistent distinction between smoking and vaping in Commonwealth legislation

5 Lifting the ban on low-risk nicotine products

5.1 Policy intent

This section of the Bill, currently section 3 of the Schedule of amendments, should meet two purposes:

1. Provide the basis for legalising vapor technologies and other non-combustible tobacco or nicotine products that are not medicines and not “tobacco prepared an packed for smoking”
2. Provide a basis for regulating these products (see Section 6 of this document).

Combustible tobacco products are permitted in Australia by virtue of an exemption provided in the Poison Schedule 7³. This schedule is amended via powers in section 52D and to meet purposes defined in 52E of the Therapeutic Goods Act. The right approach is to adjust the purposes of the Secretary (as in 52E of the Act) so that becomes ministers' responsibility to amend the schedules.

The Bill's proposed amendment to the Therapeutic Goods Act (section 3 of schedule 1 of the draft Bill) should be adjusted in the following ways:

1. To broaden the scope of the products liberalised to include smokeless tobacco and unheated nicotine products
2. To raise the maximum strength of the e-liquids permitted to 75mg/ml – a level that would be consistent with treating nicotine as a poison, which is the purpose of the Poisons Standard.
3. To provide a basis for regulating these products (see Section 6 of this document)

5.2 Raising the maximum permitted strength to a level commensurate with poison classification

There is no case for setting the threshold of nicotine concentration at 20mg/ml or limiting this at all other than at much higher levels than used in commercial devices. 20mg/ml is the same limit that was arbitrarily set in the European Union Tobacco Products Directive Article 20(3)b⁴ in 2014.

However, it has no basis in science or risk management and attracted criticism from the scientific expert community⁵ based on widespread misunderstanding of the risk posed by nicotine⁶.

There are essentially six reasons not to cap the strength at 20mg/ml.

1. The limit achieves absolutely nothing, so there are no benefits of the threshold to offset against risks. There is a well-established three-pronged approach to managing potentially hazardous substances in the home (bleach, medicines etc): use child resistant packaging; place a warning on the packaging; explain what to do if exposed.
2. Some vapers use products that have higher concentrations than 20mg/ml, and removing this option may risk relapse to smoking – but for no benefit. In Britain, six percent of vapers use liquids above 20mg/ml⁷. While this may not sound much, it equates to 170,000 users in the UK.
3. Though a small number continue to use higher strength liquids, many vapers use higher strength liquids during a transition from smoking to vaping and while they learn the techniques of vaping. Thus high strength liquids form a temporary bridge from smoking to vaping. Any measure of

³ Government of Australia, Therapeutic Goods Administration, The Poisons Standard July 2017. Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) [\[link\]](#) made under 52D(2)(b) of the *Therapeutic Goods Act 1989* [\[link\]](#)

⁴ European Union Tobacco Products Directive, 2014/40/EU Article 20 [\[link\]](#)

⁵ Etter JF et al, Scientific Errors in the Tobacco Products Directive A letter sent by scientists to the European Union, E-cigarette Research. (Letter from 15 experts to European Commission) 16 January 2014 [\[link\]](#)

⁶ Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014;**88**:5–7. doi:10.1007/s00204-013-1127-0 [\[link\]](#)

⁷ Action on Smoking and Health, Fact sheet: Use of electronic cigarettes (vapourisers) among adults in Great Britain, May 2017 [\[link\]](#)

current use therefore understate the importance of higher strength liquids in the process of switching. On study found that 20 percent of vaper had started on products higher than 20mg/ml⁸

4. Higher strength liquids may be more important to more highly dependent smokers, and therefore provide benefits to those at greater risk of smoking related disease. One of the most important concerns in designing a regulation is the approach to those who continue to smoke. Smokers frequently report that vaping is unsatisfying⁹:

However, since most current smokers who have tried ENDS reject them as a satisfying alternative to regular cigarettes, the potential of ENDS becoming a disruptive technology replacing regular cigarettes remains uncertain. ENDS need to improve as a satisfying alternative or the attractiveness and appeal of the regular cigarette must be degraded to increase the potential of ENDS replacing regular cigarettes.

Limiting nicotine strength adds to this problem rather than addressing it.

5. Limiting higher strength liquids may be a barrier to innovation and prevent the development of new products that are more convenient to use, less intrusive, created fewer emissions, provide stronger competition to cigarettes, better suited to starters or .
6. Limiting strength makes no sense from a health perspective. Vapers and smokers generally 'titrate' nicotine to achieve a desired level of consumption or exposure. Weaker liquids will mean inhaling a larger volume of aerolised liquid. To the extent there are toxins in the liquids, then weaker liquids will mean *higher* exposures – though still very low compared to cigarettes.

The scheduling of nicotine in the Poisons Standard should be to reflect its characteristics *as a poison*, not as an ingredient in a consumer product. In the United Kingdom, for example, nicotine is exempted from the Poisons Act 1972 in concentrations below 7.5% (75mg/ml or 75mg/g)¹⁰. There is no justification for setting an arbitrary nicotine limit for products useful and wanted by consumers. This is a flaw in the EU legislation.

There is no reason to repeat the policy error of the European Union in Australian regulation. Also, there is no reason to suggest in the wording of the Bill that these products should be treated the same way as tobacco prepared and packed for smoking. In every respect other than lifting the de facto prohibition created by the Therapeutic Goods Act and Poisons Standard, these products should be treated completely differently.

The following text would lift the prohibition on all low-risk nicotine products, and allow stronger liquids to be sold in consumer products.

⁸ Farsalinos KE, Romagna G, Tsiapras D, et al. 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* 2014;**11**:4356–73. [\[link\]](#)

⁹ Pechacek TF, Nayak P, Gregory KR, et al. The Potential That Electronic Nicotine Delivery Systems Can be a Disruptive Technology: Results From a National Survey. *Nicotine Tob Res* Published Online First: 3 May 2016. [\[link\]](#)

¹⁰ The UK exemption from poisons regulation for nicotine liquids under 7.5% concentration is implemented in The Poison Rules 1982, SI 82/218 Schedule 4 [\[link\]](#)

5.3 Proposed changes to the Bill

Draft Bill text	Proposed text amendment
<p><i>Therapeutic Goods Act 1989</i></p> <p>3 After section 52E</p> <p>Insert:</p> <p>52EAAA Certain products to be treated in the same way as tobacco</p> <p>(1) The Secretary must ensure that the current Poisons Standard applies in relation to:</p> <p>(a) nicotine in electronic nicotine delivery systems in concentrations no greater than 20 mg/mL; and</p> <p>(b) nicotine in tobacco prepared and packed for heating;</p> <p>in the same way as it applies in relation to nicotine in tobacco prepared and packed for smoking.</p>	<p><i>Therapeutic Goods Act 1989</i></p> <p>3 After section 52E</p> <p>Insert:</p> <p>52EAAA Certain products to be exempted from the Poisons Standard Schedule 7</p> <p>(1) The Secretary must ensure that the current Poisons Standard exempts the following forms of nicotine from Schedule 7 of the standard and achieves the equivalent in future:</p> <p>(a) nicotine in tobacco prepared and packed for smoking;</p> <p>(b) nicotine in tobacco prepared and packed for heating;</p> <p>(c) nicotine in smokeless tobacco prepared and packed for sucking or chewing;</p> <p>(d) nicotine in solid or liquid preparations for human use with less than 7.5% nicotine by weight, except in preparations for human therapeutic use or where a manufacturer, importer or vendor wishes to make a therapeutic claim</p>

Figure 5: Proposed language to allow reduced risk nicotine product on to the market

6 Provide a basis for regulating reduced risk nicotine products

6.1 Policy intent

As specified in the Bill and with the text proposed in Figure 5, the amendment to the Therapeutic Goods Act proposed in the Bill performs the function of removing the *de facto* pan on low-risk products. But it does not perform the function of providing regulatory safeguards that many would expect to see and would be probably be a pre-condition to achieve consent to the legislation. Though the Poison Standard exempts smoking products, these products are subject to other regulations that cover product characteristics, packaging, labelling and marketing. These include:

- Tobacco Advertising Prohibition Act 1992
- Tobacco Plain Packaging Act 2011
- The Competition and Consumer (Tobacco) Information Standard 2011 establishes the health warnings that must appear on tobacco product packaging.

The need to have regulatory safeguards was recognised in the citizen proposal for amendment of the Poison Schedule made in 2016. This proposal would have inserted some regulatory control into Schedule 7 of the Poison Standard¹¹ (see red text below and points i-vii under d).

Schedule 7 - Proposed amendment

NICOTINE **except:**

- a. when included in Schedule 6 [an exception for nicotine used to treat animals];
- b. in preparations for human therapeutic use; or
- c. in tobacco prepared and packed for smoking; **or**
- d. in preparations for use as a substitute for tobacco when packed and labelled:**
 - i. for use in an electronic nicotine delivery system (ENDS)**
 - ii. nicotine concentration up to 3.6%**
 - iii. maximum nicotine per container: 900 mg**
 - iv. in a child resistant container**
 - v. labelled with the concentration of nicotine and other ingredients**
 - vi. labelled with the statement 'Keep out of reach of children'**
 - vii. labelled with the statement 'Not to be sold to a person under the age of 18 years'.**

Figure 6: 2016 proposal to amending the Poison Standard Schedule 7

6.2 Approaches to regulating low-risk nicotine products

There are three approaches to addressing the need for some regulatory framework for these products once the de facto prohibition under the Therapeutic Goods Act and Poison Standard is lifted.

1. Reject this requirement and argue it is unnecessary, given the applicability of general consumer regulation to reduced risk nicotine products. There is in fact a reasonable case for this, as it has been the norm in the United States and most of the European Union until mid-2016, and there has been very little grounds for concern. That does not however mean it is the optimum approach.
2. Specify particular measures on the face of the Bill and use this to amend the Therapeutic Goods Act to include such measures, for example those specified in the 2016 amendment in Figure 6.
3. Amend the Therapeutic Goods Act and/or invoke the Competition and Consumer Act 2010 and Australian Consumer Law¹² to give The Secretary powers and duties to make consumer protection regulations regarding reduced-risk nicotine products

The third option provides flexibility, and comes with an existing institutional and governance framework. The available powers in the Competition and Consumer Act 2010 include the following.

¹¹ Therapeutic Goods Administration, Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #14) Final decisions on matters referred to an expert advisory committee: 2.1 Nicotine. 23 March 2017 [\[link\]](#)

¹² The Australian Consumer Law is embedded at Schedule 2 of the Competition and Consumer Act 2010 [\[link\]](#)

- *Industry codes*¹³. Ministers can make regulations to establish voluntary or mandatory codes regulating the conduct of participants in an industry towards consumers or other industry participants.
- *Safety of consumer goods and product related services*¹⁴. Ministers can regulate consumer goods and product-related services by implementing mandatory safety standards, banning products temporarily or permanently, issuing safety warning notices or issuing a compulsory recall notice to suppliers. This could be used to specify chemical, electrical, thermal and mechanical safety standards for reduced risk nicotine products.
- *Information Standards*¹⁵ This could cover covering labelling requirements, warnings etc. This section of the Act is used to specify warnings on tobacco products.

6.3 Proposed changes to the Bill

This proposal inserts a requirement to develop a consumer-based proportionate regulatory framework in consumer protection legislation, and specifies a harm reduction purpose for it.

Draft Bill text	Proposed text
None	<p>After section 2 of the draft Bill insert a new section:</p> <p>3. (1) The Secretary shall develop as appropriate a proportionate regulatory framework for low-risk nicotine products using the powers provided in the Competition and Consumer Act 2010.</p> <p>(2) The regulations for low-risk nicotine products referred to in sub-section (1) shall be appropriate for the protection of public health and have the aim of reducing the harms caused by smoking.</p>

Figure 7: Proposed language to establish a regulatory regime for low-risk nicotine products

7 Low-risk nicotine products require advertising and marketing

7.1 Policy intent

The aim should be to achieve ‘proportionality’ in the control of advertising of nicotine products. That would mean only extending full prohibitions to only the most dangerous products – i.e. those

¹³ Competition and Consumer Protection Act 2010, Part IVB – Industry Codes. [\[link\]](#)

¹⁴ Competition and Consumer Protection Act 2010. Schedule 2 Part 3-3—*Safety of consumer goods and product related services* [\[link\]](#).

¹⁵ Competition and Consumer Protection Act 2010. Schedule 2 Part 3-4—*Information Standards* [\[link\]](#).

involving combustion. For low-risk nicotine products (including low-risk *tobacco* products), there are significant advantages in permitting advertising. Some are listed below:

- Advertising of low-risk nicotine products functions as a form of anti-smoking advertising which aims to persuade smokers
- Advertising allows alternative products to build market share at the expense of cigarettes
- Advertising allows the development trusted brands that can carry and convey the appeal of low-risk alternatives to smoking
- Advertising allows the communication of innovations that are important to consumers – for example, safety, convenience, ease of use, comparative strengths relative to cigarettes

7.2 Clarification of intent regarding low-risk tobacco products

The Tobacco Advertising Prohibition Act 1992¹⁶ provides for a complete ban on *tobacco* advertising. There is also legislation that implements ‘plain packaging’¹⁷ for tobacco products. These Acts do not only apply to *smoking* products, but also cover advertising and packaging for non-combustion low-risk tobacco products such as smokeless and heated tobacco products. If the policy intent is to restrict complete prohibition to only smoking products, an approach I would support, then the proposed amendment (Schedule 1, section 4 of the Bill) to the Tobacco Advertising Prohibition Act is insufficient to do this, and the Act would require more extensive amendment. I have not included the necessary amendments to restrict the advertising prohibition and plain packaging legislation to

7.3 Regulating the advertising and marketing of low-risk non-tobacco nicotine products

The Competition and Consumer Act 2010 provides a framework for the control of advertising of products and this could apply to non-tobacco nicotine products. For example the provisions covering *Unfair practices: false or misleading representations*¹⁸. This places general constraints on advertising and promotion. The Australian Competition and Consumer Commission provides an Advertising and Selling Guide to explain the law¹⁹. The system also functions with industry-specific codes. The ABAC Responsible Alcohol Marketing Code²⁰ may provide a model for marketing age-restricted products. Tobacco advertising is prohibited, but that is valuable to adults. Note that alcohol is far more harmful than low-risk nicotine products.

7.4 Proposed changes to the Bill

The Bill would require substantial additions if the policy intent was to limit the advertising prohibition and plain packaging legislation only to *smoking* tobacco products, an approach I would support. The proposed text in Section 6 is sufficient to direct ministers to provide an appropriate regulatory framework that also includes advertising and packaging for non-tobacco products.

¹⁶ Tobacco Advertising Prohibition Act 1992 [\[link\]](#)

¹⁷ Tobacco Plain Packaging Act 2011 [\[link\]](#)

¹⁸ Competition and Consumer Protection Act 2010, Schedule 2 Part 3-1—*Unfair practices: false or misleading representations etc* [\[link\]](#).

¹⁹ Australian Competition and Consumer Commission, Advertising and Selling Guide , accessed 27 July 2017 [\[link\]](#)

²⁰ ABAC Responsible Alcohol Marketing Code, accessed 27 July 2017 [\[link\]](#)

8 A minimalist option

I believe that there is a strong case to refashion the body of Commonwealth legislation covering tobacco and nicotine to create clear distinctions between combustible and non-combustible products. This could be world-leading proportionate risk based regulation if done systematically, and I have discussed some of the elements of this in this submission. However, that should be the primary responsibility of government and government-backed legislation, and I hope this legislative initiative promotes a constructive government response.

8.1 Policy intent

If the parliament wishes to make a simple legislative intervention that eases and regularises the position of the thousands of Australian citizens who use e-cigarettes it could simply implement a variation on the amendment to the Poisons Standard proposed in 2016 but rejected by the TGA without any credible justification. See Figure 6 above. This proposal attracted widespread support, as well as predictable opposition.

8.2 Proposed language for a minimal Bill

This would be delivered by the Bill amending the Therapeutic Goods Act.

Proposed minimal text – replacement for Schedule 1

Therapeutic Goods Act 1989

After section 52E

52EAAA Certain products to be exempted from the Poisons Standard Schedule 7

- (1) The Secretary must ensure that the Poisons Standard schedule 7 applies to nicotine as defined in subsection 2:
- (2) NICOTINE except:
 - a. when included in Schedule 6;
 - b. in preparations for human therapeutic use; or
 - c. in tobacco prepared and packed for smoking, heating or oral use; or
 - d. in preparations for use as a substitute for tobacco when packed and labelled:
 - i. for use in an electronic nicotine delivery system (ENDS)
 - ii. in nicotine concentration up to 3.6%
 - iii. maximum nicotine per container: 900 mg
 - iv. in a child resistant container
 - v. labelled with the concentration of nicotine and other ingredients
 - vi. labelled with the statement 'Keep out of reach of children'
 - vii. labelled with the statement 'Not to be sold to a person under the age of 18 years'.

About the author

Clive Bates is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. He has had a diverse career in the public, private and non-profit sectors. After securing a degree in engineering from Cambridge University, he worked in information technology for IBM before moving on to work as an energy specialist with several environmental non-profits. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, campaigning to reduce the harms caused by tobacco. In 2003, he joined Prime Minister Tony Blair's Strategy Unit as a civil servant and worked in several roles in the public sector in the United Kingdom and for the United Nations in Sudan.

This report was written as part of Counterfactual's advocacy program without additional funding. Clive Bates and Counterfactual have no competing interests with respect to e-cigarette, tobacco or pharmaceutical industries.

Annex 1: Submission to the House Inquiry into e-cigarettes and personal vaporisers

July 2017

**Standing Committee on Health, Aged Care and Sport
Inquiry into the Use and Marketing of Electronic Cigarettes and Personal
Vaporisers in Australia**

Clive Bates, London, United Kingdom

5 July 2017

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Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia

Executive summary

- I am pleased to provide this evidence to assist the Committee's important work. This submission follows the format of the five questions set in the terms of reference for the inquiry¹.
- E-cigarettes and personal vaporisers function as consumer products and alternatives to smoking. Their positive impact for public health arises from their attractiveness as alternatives to smoking. These products are not medicines and not poisons in the way they used by consumers and medicines and poison regulation are inappropriate and ill-fitting regulatory frameworks.
- The experience from the United Kingdom and United States has been highly positive. In both cases, smoking has fallen rapidly among both adults and youth as vaping has risen, consistent with vaping products being used to quit smoking and displace cigarettes in the marketplace.
- Declines in smoking in the UK have proceeded at three times the rate of Australia since 2013, despite Australia's punitive tobacco policy. The United Kingdom now has achieved parity in adult smoking prevalence with Australia on a like-for-like basis – the first time since records began.
- E-cigarettes and personal vapourisers do not involve the combustion of tobacco leaf and inhalation of thousands of toxic products of combustion. They are, beyond any reasonable doubt, much less harmful than smoking. Though we cannot have decades of data, nor are we entirely ignorant. Based on what is known, a working estimate endorsed by UK experts is that e-cigarettes are at least 95% lower risk than smoking, and may be substantially lower than that.
- There is no scientific, ethical or compassionate case for Australia's *de facto* ban on e-cigarettes and personal vaporisers. There is no credible case to justify why Australians exposed to the health risks, stigma and punitive cost of smoking should be denied options widely available, welcomed by consumers and successful elsewhere. The burden of proof remains with the prohibitionists.
- There are many regulatory options available, but the primary concern should be with the unintended consequences of overzealous regulation. This can have the effect of protecting the cigarette trade and sustaining smoking by degrading the appeal of the lower-risk alternative.
- The proposal made to amend the Poison Schedule should have been accepted by the TGA – it makes no sense on to permit the most dangerous forms of nicotine ("tobacco prepared and packed for smoking") and to impose a *de facto* ban all the lower-risk alternatives.
- The best regulatory approach will be to provide a light-touch framework of standards and only deviate from a market-based approach where there is a clear consumer benefit. This will minimise the risk of unintended consequences. No additional tax on these products is justified.
- The prohibition on other low-risk tobacco and nicotine products, for example smokeless tobacco and heated tobacco products, should also be lifted to widen the options for smokers to quit.

¹ Parliament of Australia, House of Representatives. Standing Committee on Health, Aged Care and Sport, Inquiry into the Use and Marketing of Electronic Cigarettes and Personal Vaporisers in Australia, referred 25 May 2017 [\[link\]](#)

1 The use and marketing of e-cigarettes and personal vaporisers to assist people to quit smoking

1.1 Positioning of e-cigarettes are a consumer alternative to cigarettes

E-cigarettes are used as alternatives to smoking, as recreational nicotine products for which their appeal relative to smoking is a crucial factor in their success. An apt comparison would be with diet soda – diet soda is rarely described as an anti-obesity treatment or a medication, but more often as a different way of enjoying soda with fewer calories that may have an effect on obesity and appeals to those who are fitness and weight-conscious. The Royal College of Physicians recognises equivalent positioning in its extensive 2016 report on e-cigarettes for tobacco harm reduction²:

E-cigarettes are marketed as consumer products and are proving much more popular than NRT as a substitute and competitor for tobacco cigarettes. E-cigarettes appear to be effective when used by smokers as an aid to quitting smoking.

Reasons for using e-cigarettes show harm-reduction motivation. A survey published by UK Office for National Statistics³ give the following reasons for e-cigarette use:

Main reason for using e-cigarettes Great Britain, 2016	Percentage e- cigarette users age 16 and over
Perception that they are less harmful than cigarettes	26.6
Can be used indoors	4.4
Cheaper than tobacco products	8.1
Novelty	3.3
Aid to stop smoking	46.6
Range of different flavours available	5.1
Other reasons	5.9

Figure 1: main reasons for using e-cigarettes

The dominant stated purpose is reducing harm to health (26.6%) through quitting smoking (46.6%) and cutting the economic burden of smoking (8.1%) – meaning over 80% of the reasons given suggest a harm-reduction motivation. This is positive and should be encouraged.

In the tobacco and nicotine field, e-cigarettes and personal vaporisers function more like a product like ‘snus’ than a smoking cessation medication. Snus is a form of smokeless tobacco (and certainly not a medicine) that has largely displaced smoking in Sweden (smoking prevalence has fallen to 7.0%⁴) and this represents a ‘proof-of-concept’ for achieving deep cuts in smoking through the availability of low-risk alternative nicotine products with significant benefits to population health⁵.

² Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016 [\[link\]](#)

³ Office for National Statistics (UK). E-cigarette use in Great Britain. 2016, 15 June 2017. Table 3a Main reason for using e-cigarettes [\[link\]](#)

⁴ European Commission. Eurobarometer Special Survey 458: Attitudes of Europeans towards Tobacco and Electronic Cigarettes. 2017. Fieldwork March 2017. Published May 2017 [\[link\]](#) [\[PDF\]](#)

⁵ Ramström L, Borland R, Wikmans T. Patterns of Smoking and Snus Use in Sweden: Implications for Public Health. *Int J Environ Res Public Health*. Multidisciplinary Digital Publishing Institute (MDPI); 2016 Nov 9;13(11). [\[link\]](#)

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1.2 The rise of e-cigarettes has coincided with a sharp decline in smoking in Britain

The British prevalence data⁶ suggest that many are successfully adopting this approach. In 2016, there were 8.2 million smokers and 2.8 million vapers, of which 1.5 million were ex-smokers. Over the period that vaping has risen sharply, we have seen sharp falls in adult smoking. The number of vapers who are ex-smokers (1.5m) now exceeds the number who are also current smokers (1.1m) and the vaping population, the population grew by 1.0 million or 1,380 per day from 2014 and 2016.

Proportion of whom are current vapers	Current smoker	Ex-smoker	Never-smoked	Adult population
2014	10.6%	6.8%	0.2%	3.7%
2015	14.4%	7.7%	0.2%	4.5%
2016	13.7%	12.1%	0.6%	5.5%
Number of vapers (thousand persons)				
2014	1,029	745	48	1,821
2015	1,299	908	59	2,267
2016	1,123	1,524	181	2,828

Figure 2: The recent rise of vaping in Britain

Over this short period, the number of smokers in the adult population has fallen by 1.5m from 9.7m to 8.2m, while the number of ex-smokers has increased by 1.7m from 10.9m to 12.6m

Population by smoking status	Current smokers	Ex-smokers	Never-smoked	Adult population
2014	9,689	10,910	29,168	49,767
2015	9,021	11,797	29,744	50,562
2016	8,198	12,594	30,190	50,982

Figure 3: The recent decline of smoking in Britain

1.3 A similar effect has been seen in the United States – for adults *and* youth

Though the e-cigarette usage data are not as readily accessible in the United States, there has also been a rapid decline in smoking coinciding with the rise of vaping. Adult smoking prevalence fell from 19.4% in 2010 to 15.1% in 2015⁷. An analysis of the data suggests there were 8.3 million vapers by 2015 of which 2.5 million were former smokers⁸.

Although much has been made of the risk to adolescents posed by the rise of vaping in the United States, the true picture is of rapidly declining adolescent smoking coinciding with rising vaping among young people. There is no sign of a “gateway effect” and the trends are consistent with vaping displacing smoking among adolescents. See [Appendix 1](#) for more data and graphics.

⁶ Office for National Statistics (UK). E-cigarette use in Great Britain. 2016, 2015, 2014 15 June 2017. Table 2a E-cigarette use, by sex and cigarette smoking status [\[link\]](#)

⁷ National Center for Health Statistics, National Health Interview Survey [\[link\]](#), Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2016. [\[data\]](#) Accessed June 2017. The prevalence figure (15.8%) for 2016 is not comparable due to a change in sampling methodology.

⁸ CDC, National Health Interview Survey, 2015 Data Release [\[link\]](#), Analysis by Rodu B. How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015, Tobacco Truth 17 July 2016 [\[link\]](#)

1.4 Rapidly declining UK smoking prevalence reaches parity with Australia

The UK trend has meant that the decline in smoking prevalence in the UK has been faster than in Australia and, on an equivalent basis (current adult smokers age 18 and over), the UK has now reached parity with Australia, which has had lower smoking rates than the UK since records began. Comparing smoking prevalence on a like for like basis in UK⁹ and Australia¹⁰.

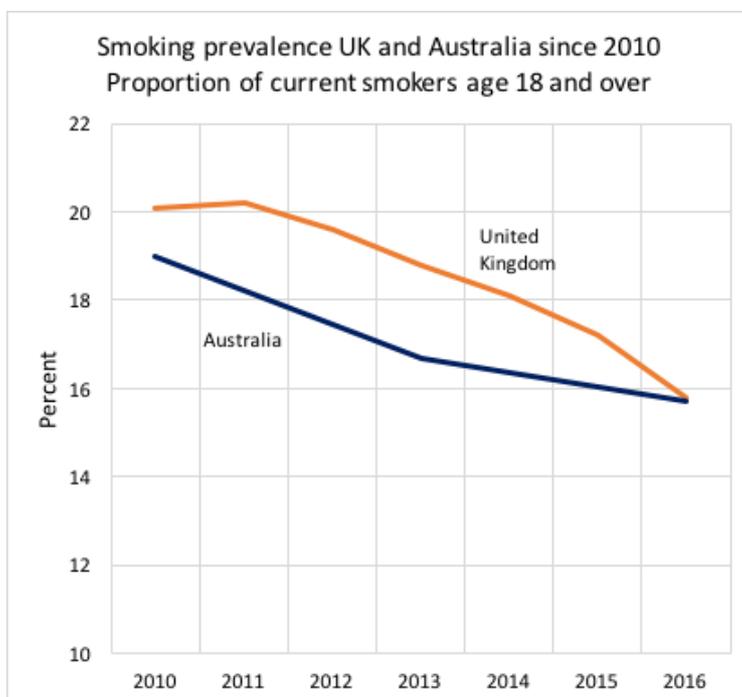


Figure 4: Decline of smoking in Australia and the United Kingdom

The rate of decline in the UK since 2013 has been three times as great as in Australia (UK average - 1.0 percentage points per year compared to -0.33). This is despite Australia's aggressive tobacco control policies, including plain packaging (December 2012) and four 12.5% tax increases in December 2013 and September 2014, 2015 and 2016, amounting to 60% in total¹¹. Average UK cigarette prices rose by 18% from 2013 to 2016. Plain packaging was introduced in December 2016.

1.5 The testimonies of vapers place the burden of proof on those favouring prohibition

The testimonies of vapers are sometimes dismissed as 'anecdotes' by anti-vaping activists, but there are good scientific reasons for considering such qualitative accounts within the overall assessment of evidence. There are thousands of personal testimonies that show that the vaping works well *for at least some people*. Vapers in Australia¹², the United Kingdom¹³ and the United States¹⁴ provide often moving and inspiring testimony of their experience in using e-cigarettes to quit smoking and legislators are recommended to view these to provide context and a citizen perspective.

⁹ Office for National Statistics (UK). Smoking habits in the UK and its constituent countries, 2016. 15 June 2017 [\[link\]](#)

¹⁰ Australian Institute of Health and Welfare, National Drug Strategy Household Survey, 2016. Datasets [\[link\]](#)

¹¹ Australian Government, Department of Health: Plain packaging of tobacco products [\[link\]](#); Tobacco taxation [\[link\]](#)

¹² AussieVapers forum, Your story.

¹³ Counterfactual. UK vaping testimonies.. [\[link\]](#)

¹⁴ Consumer Advocates for Smoke-free Alternatives Association (CASAA), E-cigarette user testimonials. [\[link\]](#)

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More systematic surveys also suggest that vapers believe they have quit smoking through vaping. Analysis of European Union survey data found¹⁵:

An estimated 6.1 and 9.2 million EU citizens had quit and reduced smoking with the help of e-cigarettes, respectively.

An online survey of users found¹⁶.

The results of this worldwide survey of dedicated users indicate that ECs are mostly used to avoid the harm associated with smoking. They can be effective even in highly-dependent smokers and are used as long-term substitutes for smoking.

Why testimonies matter. The reason that such testimonies are important to Australia’s legislators is that it is the policy of the government to try to purposefully deny these highly positive experiences to Australians. That begs the question: why and on what basis? The evidence of highly positive experiences demands that some commensurately negative effect is found to justify the *de facto* prohibition built in to Australia’s regulatory regime. But no such negative case exists to justify overriding the rights and options of those who wish to use these products.

1.6 The challenge of assessing the population impact of vaping products

Critics have stressed the small number of randomised controlled trials available to provide supporting evidence of e-cigarette effectiveness, arguing that evidence is weak. In reality the impact of e-cigarettes and personal vapourisers is inherently difficult to study. The main reason is that these products do not work like medical drugs in which a pharmacologically active substance changes the body irrespective of what the user does or what is going on in their surroundings. The introduction and diffusion of a new technology functions as a perturbation of a complex behavioural eco-system and many changes happen simultaneously.

In contrast to a typical drug, the impact of vapour products on smoking behaviour is not determined solely by the product itself, but by a wide range of influences on behaviour that are independent of the product. These include the influence of news and commentary on risk perceptions, taxation and pricing, ease of access and availability of retail or internet sales, vaping policies in public or work places, peer support (e.g. through social media or vape shops) and the strengths of brands. Vapers will typically progress from a simple device to a more complicated ‘tank’ system and may change the strength and volume of liquid consumed over time. In the real world, there is a ‘learning curve’ to master as a vaping novice learns how to use the product to replace the experience of smoking. If learning takes too long, then they may relapse to smoking. This complexity does not lend itself to randomised controlled trials (RCTs), the common approach for evaluating medicines, because it is impossible and unrealistic to control for all these variables.

¹⁵ 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; [\[link\]](#)

¹⁶ 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*. 2014 Apr 22;11(4):4356–73. [\[link\]](#)

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Just as diet soda makers do not make claims about obesity, vaping manufacturers rarely make therapeutic claims for vaping products so there is no obligation on them to run expensive trials to prove claims that they do not make.

There is already some evidence that vaping products differ in effectiveness according to the regulatory regime of the country in which they are used. Yong et al (2017)¹⁷ found that vaping was less effective in Australia and Canada than in the UK and United States – not because of the products, but the policy-induced barriers to using them effectively.

1.7 Common misunderstandings about studies on vaping ‘effectiveness’

The Committee may receive submissions citing studies that purport to show that e-cigarettes do not work, show gateway effects or that much safer products somehow cause people to smoke more. There is no sign of this happening in the respective trends in smoking and vaping described above. If vaping is causing more smoking, where are all the new smokers?

When subjected to careful examination, such studies do not bear out the claims of activists. The following types of error are evident throughout the literature:

- *Confusion over association and causation.* Several studies find that vapers are more likely to smoke and smoke more, and some make the inappropriate step of assuming the vaping is causing the smoking. It is more likely that inclination to vape and inclination to smoke are both driven by the same *independent* risk factors (parental smoking, peer group, culture, educational attainment, mental health issues, etc).
- *Selection bias.* In some observational studies, the people using vaping products may be an unusual subset of the population or smoker population. For example, they may have tried everything else and be more dependent. Some studies focus only on those who have failed to quit or have called help lines – again making them a specific atypical subset.
- *Reverse causation.* Smoking may be common among vapers because smokers are trying to use vaping to quit. The smoking causes the vaping.
- *The missing counterfactual.* The question ‘what would have happened in the absence of vaping’ is the most useful question for interrogating studies that purport to show vaping have a causal effect on smoking. Often the answer is that people found to be smoking after vaping would have smoked anyway.
- *Poor definitions.* Studies claiming find gateway effects usually fail to define terms like ‘gateway effect’ with any rigour and sometimes not at all. This prompted Public Health England’s expert review to conclude¹⁸

The gateway theory is ill defined and we suggest its use be abandoned until it is clear how it can be tested in this field.

¹⁷ Yong H-H, Hitchman SC, Cummings KM, Borland R, Gravely SML, McNeill A, et al. Does the Regulatory Environment for E-Cigarettes Influence the Effectiveness of E-Cigarettes for Smoking Cessation?: Longitudinal Findings From the ITC Four Country Survey. *Nicotine Tob Res*; 2017 Apr 5;25(e1):e1–2. [\[link\]](#)

¹⁸ McNeill A, Brose LS, Calder R, et al. E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#)

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The population effect of vaping. As should be expected by default, it does seem that people use safer products to reduce their risks, not to increase them. Adult smokers are quite capable of being rational guardians of their own welfare and it should be assumed that they will seek out satisfactory ways of using nicotine that are less harmful, less stigmatised and less expensive unless there is evidence to the contrary.

The Royal College of Physicians reviewed and summarised the evidence as follows¹⁹, finding no evidence that negative population effects were dominating beneficial effects.

There are concerns that e-cigarettes will increase tobacco smoking by renormalising the act of smoking, acting as a gateway to smoking in young people, and being used for temporary, not permanent, abstinence from smoking.

To date, there is no evidence that any of these processes is occurring to any significant degree in the UK. Rather, the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely.

1.8 Conclusion: insights from UK and US experience relevant to legislators in Australia

The United Kingdom and United States have both experienced very substantial and positive movement in smoking behaviour during the rise in popularity of vaping and many users say they are using these products to reduce harm and quit smoking. The data is consistent with vaping causing the rapid decline in smoking and this would be a common sense interpretation of the trends and testimonies of vapers. However, this type of data cannot *formally prove* that vaping is *causing* the decline in smoking and we should acknowledge that it is inherently difficult to make this assessment.

But the data do suggest two significant conclusions for Australian legislators:

1. Nothing is going wrong and much appears to be going very well in the UK and United States where e-cigarettes and personal vaporisers have been widely available and regulated as consumer products (until 2016). Both adult and youth smoking rates have been falling rapidly. Despite exhaustive efforts to identify problems with vaping, the reality is highly positive.
2. It is hard to see how the government could justify *preventing* Australian citizens having access to e-cigarettes and personal vaporisers products given much lower individual risk (see [next section](#)) and the positive experience of these products in the UK and US. The burden of proof should rest with those insisting that a much safer alternative to smoking should be banned while leaving cigarettes freely available. The supporters of the *status quo* in Australia are proposing a to maintain a prohibition on a much safer product than the market leader. This is a bizarre approach – why protect the cigarette trade and deny smokers the safer alternative? It is up to them to justify it by providing evidence showing material net harms are likely, which they cannot. The supporters of prohibition need to assume some responsibility for the potential for increased smoking if their preferred policy is to deny access to the lower risk products, something they appear unwilling to do.

¹⁹ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Key recommendations [\[link\]](#)

2 The health impacts of the use of E-cigarettes and personal vaporisers

2.1 Why vaping should be understood to pose lower risk to health than smoking

It is impossible to know with certainty what the ultimate health impact of products like e-cigarettes will eventually be – we cannot travel fifty years forward in time to observe what has still to happen. There are likely to be some negative effects with long term use, but these are likely to be greatly offset by reduced risks from smoking.

Of course, this limitation applies to anything new and we routinely make judgements in the face of unavoidable uncertainty rather than allowing uncertainty to provoke paralysis in the face of innovation. To make progress we generally make assessments of risk, not wait for final certainty.

While it is impossible to know everything about the health effects of vaping relative to smoking, this does not mean we know nothing. The case that e-cigarettes and personal vaporisers are much less hazardous than cigarette smoking rests on three main pillars, drawing on what is already known:

1. **The physical and chemical processes are very different.** E-cigarettes use electrical heating to create a nicotine-bearing aerosol from an inert liquid at temperatures of 100-250°C with little chemical change at normal operating temperatures. In contrast, cigarette smoke is created by combustion of tobacco leaf at 600-900°C with partial or complete combustion reactions creating thousands of new and hazardous chemicals in the form of smoke particles and toxic gases. It is these products of combustion that do most of harm to smokers²⁰. We would not expect e-cigarettes and cigarettes to have remotely similar risks based on these physical and chemical differences. It is also likely that the much simpler chemistry of e-cigarette aerosol will be much easier to modify than cigarette smoke should an unforeseen problem emerge – for example by modifying ingredients, controlling temperature or changing the base diluent liquid.
2. **The respective toxic properties of cigarettes and e-cigarettes.** It is possible to run many different toxicology tests on the chemical properties of e-cigarette vapour and cigarette smoke. A range of review articles has summarised the literature and found that most toxic agents in cigarette smoke are not present and detectable levels or are present at levels that are one to three orders of magnitude lower. The literature makes a compelling case that the toxic effects of vaping would be much lower^{21 22 23 24 25}.

²⁰ U.S.DHSS. How Tobacco Smoke Causes Disease The Biology and Behavioral Basis for Smoking-Attributable Disease A Report of the Surgeon General. Public Health. U.S. Dept. of Health and Human Services, Public Health Service, Office of the Surgeon General; 2010. 792 p. [\[link\]](#)

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 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. [\[Link\]](#)

²³ 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 [\[link\]](#)

²⁴ 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 Oct17;29(10):1662–78. [\[link\]](#)

²⁵ 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. [\[link\]](#)

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3. **Effects on the human body.** There is evidence that chronic conditions improve when smokers switch to vaping, for example in the case of asthma²⁶, breathing problems²⁷ and lung function²⁸. It is possible to compare salivary or urine biomarkers to assess bodily exposure to hazardous agents. Again, the findings are very encouraging²⁹.

The e-cigarette-only and NRT-only users had significantly lower metabolite levels for TSNA (including the carcinogenic metabolite 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanol [NNAL]) and VOCs (including metabolites of the toxins acrolein; acrylamide; acrylonitrile; 1,3-butadiene; and ethylene oxide) than combustible cigarette-only, dual combustible cigarette-e-cigarette, or dual combustible cigarette-NRT users. The e-cigarette-only users had significantly lower NNAL levels than all other groups.

2.2 E-cigarette use is likely to be at least 95% lower risk than smoking

Figures for relative risk of smoking and vaping have been developed by the expert community in the United Kingdom. It is important to understand the origin and purpose of these estimates as these have often been misrepresented by anti-vaping activists.

Perceptions of harm are dramatically misaligned with reality. Despite overwhelming evidence that e-cigarettes are likely beyond any reasonable doubt to be much less hazardous than smoking, health and medical organisations in the UK have been concerned that many smokers believe that e-cigarettes are no less risky than smoking. Furthermore, the gulf between public perception and reality is widening even though evidence that e-cigarettes are much less risky has been accumulating – see figure below on British smokers' perceptions of the comparative risks of smoking and vaping³⁰.

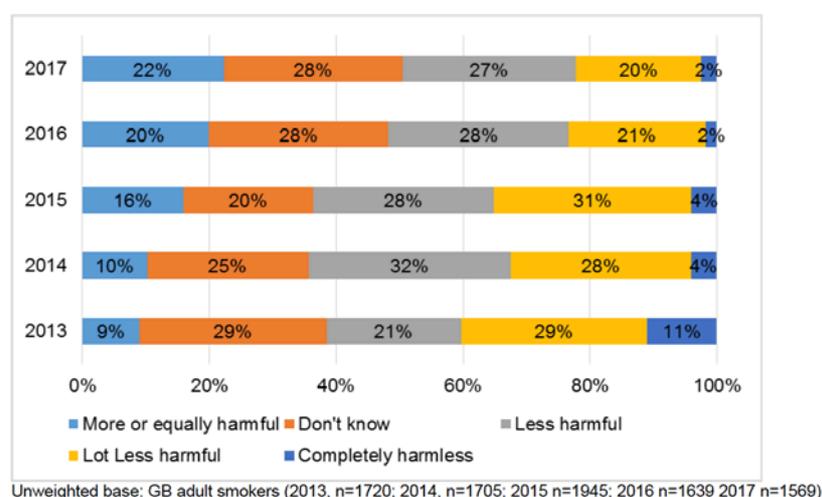


Figure 5: Smokers' perceptions of harm from e-cigarettes

²⁶ Polosa R, Morjaria J, Caponnetto P, Caruso M, Strano S, Battaglia E, et al. Effect of smoking abstinence and reduction in asthmatic smokers switching to electronic cigarettes: Evidence for harm reversal. *Int J Environ Res Public Health*. Switzerland; 2014 May;11(5):4965–77. [\[link\]](#)

²⁷ Campagna D, Cibella F, Caponnetto P, Amaradio MD, Caruso M, Morjaria JB, et al. Changes in breathomics from a 1-year randomized smoking cessation trial of electronic cigarettes. *Eur J Clin Invest*. 2016 Jun 20; [\[link\]](#)

²⁸ Polosa R. Electronic cigarette use and harm reversal: emerging evidence in the lung. *BMC Med*.; 2015;13(1):54. [\[link\]](#)

²⁹ 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. [\[link\]](#)

³⁰ ASH (UK) / YouGov. Use of e-cigarettes among adults in Great Britain 2017. 8 May 2017. Figure 9 [\[link\]](#)

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Only 20% of smokers accurately believe that e-cigarettes are a lot less harmful than cigarettes, the number believing they are harmless is negligible, but half of all smokers believe they are the same or more risky or don't know.

The importance of an anchor for risk perception. The misunderstanding of relative risk is a serious deterrent to trying a safer alternative and a reason to continue smoking. It is in the light of these misperceptions that leading public health and medical organisations in the UK have tried to provide clear direction to smokers, practitioners and policy makers to help them make properly informed decisions respectively about product choices, professional practice and policy.

In its August 2015 expert evidence review, Public Health England provided a working guideline³¹

..the current best estimate is that e-cigarettes are around 95% less harmful than smoking

Public Health England's experts followed this up with an explanation of the reasoning behind this³², that showed it was a conservative and cautious estimate with a significant safety margin.

the constituents of cigarette smoke that harm health – including carcinogens – are either absent in e-cigarette vapour or, if present, they are mostly at levels much below 5% of smoking doses (mostly below 1% and far below safety limits for occupational exposure)

The Royal College of Physicians (London) had similar concerns. It also provided a carefully worded statement designed to anchor risk perceptions in a more realistic range in its April 2016 report³³:

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.

The wording of the RCP statement carefully acknowledges uncertainty while giving a cautious estimate and a steer to users that the products are likely to be considerably safer, but should not be assumed safe. This is the statement that I recommend people use to discuss risks with friends or family members who smoke. Statements of this nature are not intended to provide pinpoint accuracy, and they are carefully qualified to avoid suggesting they do. However, they are serious public health interventions designed to help the public and non-specialists make informed decisions with potential life or death consequences, drawing on the insights and specialist knowledge of experts. The alternative is fear and confusion, driven by media and alarmist commentators.

2.3 So-called “dual use” of e-cigarettes and cigarettes

Anti-vaping activists have made much of the fact that some vapers also smoke, at least if a snapshot is taken at any point in time. They have claimed that this “dual use” provides no benefits to health and even that it is a deliberate ploy by tobacco companies to keep people both smoking and vaping.

³¹ Public Health England. E-cigarettes around 95% less harmful than tobacco estimates landmark review. [\[link\]](#) Public Health England. E-cigarettes: an evidence update 19 August 2015. [\[link\]](#)

³² McNeill A, Hajek P. Underpinning evidence for the estimate that e-cigarette use is around 95% safer than smoking: authors' note, 28 August 2015 [\[link\]](#)

³³ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Section 5.5 page 87. [\[link\]](#)

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This is a case of a misunderstanding of the pathways that people follow from smoking to not smoking combined with a naivety about how competitive markets work.

Consider the following observations about dual use:

- It is argued that studies of cutting down show no health benefits. However, cutting down with an alternative nicotine source is different to cutting down without. This is because consumers are generally seeking a desired dose of nicotine and adjust their smoking behaviour accordingly. It is possible to cut down number of cigarettes and not actually reduce *exposure* because of a compensatory effect of smoking more intensively. Such an effect is less likely if there is an alternative nicotine source. It is impossible to transfer conclusions from the studies without alternative nicotine to situations where there is, for example from e-cigarettes.
- There are many smoking-related diseases, such as cancer, for which a linear exposure-risk relationship is understood. Cutting down with alternative nicotine should reduce these risks if it reduces the nicotine taken in from cigarettes, and by implication the exposure to smoke.
- Dual use can be many different things – ranging from nearly always vaping and occasional smoking to the opposite. These are *completely* different behaviours and it is obvious that cutting down from smoking a pack a day to two cigarettes a week will make a significant difference to health – though the user would still be considered a ‘dual-user’. The behaviour referred to as ‘dual use’ needs to be disaggregated by frequency of use.
- Vapers who continue to smoke may be undergoing a longer-term transition from smoking to non-smoking – the system is ‘dynamic’ and users may be moving through different stages of use that are not evident in a snapshot survey. There is some evidence that dual users have an increased likelihood of going on to quit³⁴ and cutting down is an stated purpose for some NRT products in some jurisdictions, with a view to making quitting easier³⁵.
- Almost everyone who quits smoking *by any method* carries on smoking for months or years while they do it – this is because success rates are so low with all established methods including NRT, prescription drugs, behavioural support and ‘cold turkey’. People will quit and relapse back to smoking multiple times before they finally quit, if they ever do.
- Unless a product was 100% immediately successful, and nothing is, then some sort of dual use or continued smoking is inevitable – so an artificial and unrealistic expectation has been fabricated to imply some kind of inadequacy in these products – a straw man – given it applies equally to everything else done in tobacco control.
- Tobacco companies do not have control over consumers preferences in a competitive market and they cannot sell unsatisfying products to consumers even if they wanted to, and there is no evidence they do want to. They would simply lose out to competitors with superior products.

³⁴ Manzoli L, Flacco ME, Ferrante M, Vecchia CL, Siliquini R, Ricciardi W, et al. *Cohort study of electronic cigarette use: effectiveness and safety at 24 months*. Tobacco Control. 2016 [\[link\]](#)

³⁵ For example, NiQuitin Patient Information leaflet [\[link\]](#). [product can be used to] “cut down on smoking, perhaps before you go on to stop completely (*reducing to quit* or just *reducing*). Reducing the number of cigarettes smoked can increase the chances that you will go on to quit completely.”

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2.4 Common errors in reporting health effects of e-cigarettes and personal vaporisers

There is a considerable volume of misinformed and misleading commentary about the health effects of e-cigarettes and their impact on public health. In some frustration, the editor of the journal *Addiction* set out some of the typical errors found in literature and commentary in an editorial for a virtual edition of the journal devoted to e-cigarettes³⁶:

Failure to quantify: e.g., statement that e-cigarette vapour contains toxins so creating the impression that they are dangerous as cigarettes, without indicating that the concentrations are typically orders of magnitude less than tobacco smoke.

Failure to account for confounding and reverse causality: e.g., arguing that use of e-cigarettes reduces chances of stopping because in cross-sectional surveys the prevalence of e-cigarette use is higher in smokers than in recent ex-smokers.

Selective reporting: e.g., focusing on studies that appear to show harmful effects while ignoring those that do not.

Misrepresentation of outcome measures: e.g., claiming that e-cigarette use is prevalent among youth by using data on the proportion who have ever tried and creating the misleading impression that they are all current e-cigarette users.

Double standards in what is accepted as evidence: e.g., uncritically accepting conclusions from observational studies with major limitations when these claim that electronic cigarettes are causing harm, but discounting similar or better controlled studies when these appear to show the opposite.

Discrediting the source: e.g., arguing that researchers who have received financial support from e-cigarette manufacturers (and even companies that do not manufacture e-cigarettes) are necessarily biased and their results untrustworthy, and presenting themselves as having no conflicts of interest when their professional and moral stance represents a substantial vested interest.

Figure 6: Getting the science right and communicating it accurately

A more comprehensive guide to common errors in the science and scientific reporting of e-cigarettes and personal vaporisers is available, *The critic's guide to bad vaping science*³⁷. The overview of this guide's approach to interrogating scientific claims is reproduced at [Appendix 2](#).

Some of the debate in Australia about tobacco policy and alternative strategies like tobacco harm reduction has descended to lamentable standards of scientific literacy and risk communication³⁸. We hope the committee will find these guides useful in assessing the evidence presented to the inquiry by both sides of what has become a needlessly acrimonious debate.

³⁶ West R, Electronic cigarettes: getting the science right and communicating it accurately, *Addiction*, virtual edition on e-cigarettes, December 2014. [\[link\]](#)

³⁷ Bates CD. The critic's guide to bad vaping science, *Counterfactual*, December 2016 [\[link\]](#)

³⁸ For an example of this style of argument see Professor Simon Chapman in the *Sydney Morning Herald*, *Keep TGA control of e-cigarettes or risk repeating the smoking health disaster*, 20 June 2017 [\[link\]](#). My line-by-line response: Bates CD. *A critical review of an Australian anti-vaping polemic*, *Counterfactual*, 21 June 2017 [\[link\]](#)

3 International approaches to regulating the use of e-cigarettes and personal vaporisers

3.1 Regulatory approaches adopted so far and their weaknesses

Regulatory approaches adopted. The Institute for Global Tobacco Control at Johns Hopkins Bloomberg School of Public Health maintains a rolling scan of e-cigarette policies³⁹ and publishes snapshots from time to time⁴⁰. At the time of writing the scan covered the following:

There are 79 countries that have national/federal laws regulating e-cigarettes including laws related to the sale (including minimum age), advertisement, promotion, sponsorship, packaging (child safety packaging, health warning labeling and trademark), product regulation (nicotine volume/concentration, safety/hygiene, ingredients/flavors), reporting/notification, taxation, use (vape-free) and classification of e-cigarettes

Regulatory approaches adopted so far have been subject to criticisms. Regulations relating to the product itself have generally take several forms:

- *Consumer protection legislation* (e.g. United States, European Union pre-2016). This approach draws on the body of legislation that applies to all consumer products. For example, in the European Union at least sixteen directives apply to e-cigarettes and personal vaporisers by default⁴¹. This approach is better than all others adopted so far, but is unlikely to be optimum – some level of specialised regulation will provide meaningful extra protection to consumers.
- *Standards and notification system* (e.g. European Union post 2016). This EU directive has been extensively criticised for its arbitrary standards, bureaucratic burdens for which no clear purpose exists, and excessive restrictions on advertising and trade^{42 43}.
- *Product by product authorisation* (e.g. United States FDA deeming rule). The FDA’s approach has attracted considerable criticism⁴⁴ and legal action⁴⁵ for both its costs and burdens, and for the opaque nature of the authorisation process which makes the process highly risky for all but the largest manufacturers, the tobacco companies..

³⁹ Institute for Global Tobacco Control. Country Laws Regulating E-cigarettes: A Policy Scan. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. June 5, 2017. Accessed 1 July 2017 [\[link\]](#)

⁴⁰ Kennedy RD, Awopegba A, De León E, Cohen JE. Global approaches to regulating electronic cigarettes. *Tob Control*. 2017 Jul;26(4):440–5. [\[link\]](#):

⁴¹ For example, the following European Union Directives apply: General Product Safety [2001/95/EC](#); Technical Standardisation [1025/2012](#); Classification, Labelling and Packaging CLP [1272/2008](#); REACH [1907/2006](#); Low Voltage [2006/95/EC](#); Electro-Magnetic [2004/108/EC](#); RoHS [2011/65/EU](#); WEEE [2012/19/EU](#); Batteries [2006/66/EC](#); Weights and measures [76/211/EEC](#) [2007/45/EC](#); Sale of goods [99/44/EC](#); Distance Selling [97/7/EC](#); Electronic Commerce [2000/31/EC](#); Misleading Advertising [2006/114/EC](#); Unfair Commercial Practices [2005/29/EC](#); Protection of Personal Data [95/46/EC](#)

⁴² Bates CD. What is wrong with the Tobacco Products Directive for vapour products? Counterfactual. 22 May 2015 [\[link\]](#)

⁴³ Snowdon CJ. E-cigarettes and Article 20 of the Tobacco Products Directive. European Policy Information Center (EPICENTER), September 2015. [\[link\]](#)

⁴⁴ Bates CD. Lehrer E. Sweanor DT. Reshaping American Tobacco Policy: Eight federal strategies to fight smoking and ignite a public health revolution, February 2017 [\[link\]](#)[\[PDF\]](#) Bates CD. Rethinking nicotine: implications for U.S. federal tobacco policy – A discussion paper. June 2017 [\[link\]](#)[\[PDF\]](#)

⁴⁵ Nicopure Labs et al vs Food and Drug Administration et al, Motion for Summary Judgement, 8 July 2016 [\[link\]](#) Brief of amici curiae of Clive Bates and other in support of plaintiffs’ motion for summary judgement, 5 August 2016 [\[link\]](#)

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- *De facto prohibition via regulating e-cigarettes as medicines* (e.g. Australia and Canada). Medical regulation has in fact functioned as a prohibition. Manufacturers are not making therapeutic products and they do not fit the definition of a medicine. The medicine framework is inappropriate for these products⁴⁶ and has functioned as a *de facto* prohibition.
- *Outright prohibition of manufacturing, import and sale* (e.g. in the Persian Gulf states). This strategy appears to have the tacit approval of the WHO, but WHO has been subject to intense expert criticism for the quality of both its interpretation of evidence and the policy conclusions it has drawn as a result⁴⁷. It is also possible that such prohibitions (and by implication *de facto* prohibitions) are unlawful under WTO agreements^{48 49}.

Arguably, the most successful approach to date has been to rely on *no additional regulation* other than the consumer protection regulation that applies by default. This has been the situation in the United Kingdom and the United States until mid-2016, the period over which there has been most rapid growth in e-cigarette use combined with rapid falls in adult and youth smoking.

Regulatory purpose often unclear. The purpose of regulation of these products should be to mitigate a risk (e.g. of exposure to contaminants or battery fires) or to realise an opportunity (e.g. to standardise rules to promote competition and encourage people to switch to lower risk products). Much of the problem with international approaches to regulation stems from inadequate specification of risks, with over-reaction to negligible or theoretical risks, combined with indifference to the opportunities.

3.2 The key challenge in regulatory practice: unintended consequences

The main problem with all the regulatory schemes developed so far is insufficient sensitivity to unintended consequences of regulation. The Royal College of Physicians explains how regulation could implicitly support continued smoking and protect cigarette sales if it comprised key attributes of e-cigarette use⁵⁰:

A risk-averse, precautionary approach to e-cigarette regulation can be proposed as a means of minimising the risk of avoidable harm, eg exposure to toxins in e-cigarette vapour, renormalisation, gateway progression to smoking, or other real or potential risks. However, if this approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

⁴⁶ Bates CD, Stimson G. Costs and benefits of medicines regulation for e-cigarettes, *Nicotine Science and Policy*, 20 September 2013 [\[link\]](#)

⁴⁷ Britton, J, McNeill, A, Bauld L, Bogdanovica I Commentary on WHO report on Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems, UK Centre for Alcohol and Tobacco Studies, 26 October 2016 [\[link\]](#)[\[PDF\]](#)

⁴⁸ Foltea M, Markitanova A. The “Likeness” of New and Conventional Tobacco Products in the WTO. In: *Society of International Economic Law (SIEL)*, 2016. [\[link\]](#)

⁴⁹ Bates CD, Lehrer E, Sweanor DT. Reshaping American Tobacco Policy: Eight federal strategies to fight smoking and ignite a public health revolution, February 2017, Proposal 8: Challenge vapor and smokeless prohibitions under WTO rules [\[link\]](#)[\[PDF\]](#)

⁵⁰ Royal College of Physicians (London), *Nicotine without smoke: tobacco harm reduction*. 28 April 2016. Section 12.10 page 187 [\[link\]](#)

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The failure to assess unintended consequences. A pre-requisite for “Getting this balance right”, to quote the RCP, is an understanding that there is a balance to be struck in the first place. Yet there is scant evidence that regulators anywhere have recognised the possibility that regulation will make matters worse than having no regulation, and internalised this insight into their decision-making.

Given the very high risks associated with smoking and the low risks associated with vaping, it requires only small unintended consequences of the type mentioned by the RCP to swamp any intended benefits claimed for regulation itself. None of the main regulatory schemes proposed so far (including EU Tobacco Products Directive, US FDA deeming rule, Australia’s TGA and all the policy advice provided by WHO), have made any attempt to recognise or assess these unintended consequences. It follows therefore that none have a rational case that their measures are justified or optimal.

Belatedly, the UK government has acknowledged the potential for unintended consequences associated with the EU Tobacco Products Directive provisions that relate to e-cigarettes⁵¹ but by then, the directive had already been European law for two years and the provisions binding on the UK.

117. [...] There may also be potential negative health implications if the restrictions on advertising reduce the number of consumers switching from tobacco products to e-cigarettes. [...]

207. There is a risk that due to the potential price increase and reduction of choice of e-cigarettes, people will choose to switch back to smoking, thus harming their health. This possibility is considered in the sensitivity analysis.

208. There is a risk that a black market will develop with potentially harmful e-cigarette products, due to consumers no longer having the same degree of choice in the legal market

It is important that recognition of unintended consequences *precedes* regulatory intervention and is incorporated into the deliberations of regulators and informed by consumers as a regulator framework is defined.

A more complete account of plausible unintended consequences is provided at [Appendix 3](#).

⁵¹ Department of Health, MHRA (UK), Tobacco Products Directive, Impact Assessment, 18 April 2016. [\[link\]](#)

4 The appropriate regulatory framework for E-cigarettes and personal vaporisers in Australia

4.1 The nicotine rescheduling proposal put to the Therapeutic Goods Administration

The most important regulatory intervention for Australia is to reschedule nicotine e-liquids so that they are no longer classified as poisons. A proposal was made to the Therapeutic Goods Administration (TGA) to amend Australia's Poisons Schedule to reschedule nicotine-based e-liquids up to 3.6% nicotine, with a range of additional safeguards. This would have extended the exemption granted to "tobacco prepared and packed for smoking" (i.e. cigarettes) to much safer alternatives.

Schedule 7 - Proposed amendment

NICOTINE except:

- a. when included in Schedule 6 [an exception for nicotine used to treat animals];
- b. in preparations for human therapeutic use; or
- c. in tobacco prepared and packed for smoking; **or**
- d. in preparations for use as a substitute for tobacco when packed and labelled:**
 - i. for use in an electronic nicotine delivery system (ENDS)**
 - ii. nicotine concentration up to 3.6%**
 - iii. maximum nicotine per container: 900 mg**
 - iv. in a child resistant container**
 - v. labelled with the concentration of nicotine and other ingredients**
 - vi. labelled with the statement 'Keep out of reach of children'**
 - vii. labelled with the statement 'Not to be sold to a person under the age of 18 years'.**

The TGA examined then rejected this proposal outright⁵² despite extensive expert evidence provided to justify it⁵³. While it is possible that TGA could have made a case for the refusal, its reasoning was wholly inadequate. Following publication of its interim decision⁵⁴, an expert group provided a detailed critique of the TGA's reasoning⁵⁵ and others provided similar analysis. I do not believe the arguments put to the TGA and its committees were assessed through an appropriate public health lens, in which smoking is properly recognised as the underlying problem and the needs and rights of Australia's 2.8 million smokers were given due emphasis. This proposal was a perfectly good proposal for a first step in reregulating e-cigarettes in Australia and should not have been rejected.

⁵² Therapeutic Goods Administration (Australia), Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #14) Final decisions on matters referred to an expert advisory committee: 2.1 Nicotine. 23 March 2017 [\[link\]](#)

⁵³ Submission by forty international and Australian experts. Proposed Amendments to the Poisons Standard. Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine. 31 August 2016 [\[link\]](#)

⁵⁴ Therapeutic Goods Administration (Australia), Joint Advisory Committee on Chemicals and Medicines Scheduling (ACCS-ACMS #14) Interim decisions on matters referred to an expert advisory committee: 2.1 Nicotine. 2 February 2017 [\[link\]](#)

⁵⁵ Submission by twenty-one international and Australian experts. 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. 16 February 2016. [\[link\]](#)

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4.2 Regulatory options for Australia

Because of the possible unintended consequences of intervention, the 'do nothing' option should figure prominently in any regulatory impact assessment. In this case 'do nothing' would mean applying the rules that already apply to consumer products, advertising, fair trading practices, etc. However, the sections below briefly discuss seven aspects of regulatory intervention

- Product standards for liquids and devices
- Corporate responsibility and quality control
- Controls on e-cigarette and personal vaporiser marketing
- Warnings, risk communication, and health claims
- Use in public places
- Taxation
- Advice to health care professionals and the public

4.3 Product standards for liquids and devices

It is possible to set standards to limit any thermal, mechanical, chemical or electrical risks. The constituents of the liquid should match the description, and any warnings needed should be specified. This could set quality standards for liquids, specifying maximum levels of contaminants define a list of proscribed ingredients, and define the information that should be supplied in the packaging – for example, the strength of nicotine, information on how to respond if swallowed etc.

Standards in practice. The most highly evolved standards to date have been developed by the French national standards body AFNOR for devices and liquids, and related testing measures⁵⁶. There have been e-cigarettes standards initiatives in the UK⁵⁷ and now the EU standardization body (CEN) is developing an e-cigarettes standard⁵⁸. The American E-liquid Manufacturing Standards Association (AEMSA) has developed an industry standard for e-liquids and related manufacturing processes⁵⁹ and several respected American businesses have adopted this. There are many relevant electrical standards.⁶⁰ There are ISO standards for child-resistant packaging⁶¹.

4.4 Corporate responsibility and quality control

It is important that the companies engaged this business are responsible, identifiable and have good quality control procedures in place. These include:

⁵⁶ AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [\[link\]](#), XP D90-300-2 Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [\[link\]](#) March 2015, XP D90-300-3 Part 3: Emissions testing requirements and methods, July 2016 [\[link\]](#)

⁵⁷ BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [\[link\]](#) July 2015

⁵⁸ European Centre for Standardisation, CEN/TC 437 - Electronic cigarettes and e-liquids [\[link\]](#)

⁵⁹ AEMSA E-liquid manufacturing standard Version 2.3.2 - March 8, 2017 – accessed 17 May 2013 [\[link\]](#)

⁶⁰ International Electrotechnical Commission (IEC) standards. For example: IEC 60335-1 2010 (safety of appliances) [\[link\]](#); IEC 60335-2-29:2016 (safety of battery chargers) [\[link\]](#); IEC 62133-1&2:2017 (safety of portable batteries) [\[Part 1: Nickel\]](#) [\[Part 2: Lithium\]](#); IEC 61558-1:2005 (safety of AC adaptors) [\[link\]](#); IEC 61000 series (electromagnetic compatibility) [\[link\]](#)

⁶¹ ISO 8317:2015 Child-resistant packaging -- Requirements and testing procedures for reclosable packages [\[link\]](#) and related standards, 55.020 - Packaging and distribution of goods in general [\[link\]](#)

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- **Identification.** Registered address, contact information and ‘responsible person’ identified.
- **Quality control.** Manufacturers should meet a quality management standard, for example, ISO9000:2015⁶²

4.5 Controls on e-cigarette and personal vaporiser marketing

While it may be tempting to ban e-cigarette advertising by simply extending the prohibition of tobacco advertising⁶³, this would be disproportionate and counter-productive. Firstly, it would lack a rationale: cigarette smoking is extremely harmful and this provides the basis for banning its advertising, but no serious risks with vaping have so far been established. Secondly, a ban would have the undesirable effect of preventing companies from encouraging smokers to switch protecting the incumbent cigarette trade from competition. Thirdly, it would make it harder to communicate innovation, including innovation in health and safety, ease of use and experience relative to smoking. In doing so it could slow the steady displacement of smoking by vaping. Finally it would prevent the building of trusted brands and so lower customer confidence and the return to investment in high quality products.

It is appropriate to think of e-cigarette advertising as ‘anti-smoking’ – it is generally negative about smoking and encourages quitting - but to provide some protections that limit the appeal to children. Such a system would be based on Australia’s normal controls guaranteeing advertising is legal, honest, decent and truthful⁶⁴ with some additional restrictions that control themes, timing and placement of advertising to prevent appeal to children or irresponsible marketing of e-cigarettes.

The UK Committee on Advertising Practice produced useful guidelines on advertising provide a reasonable balance of interest between protection of minors and promotion of new low-risk products to smokers, somewhat similar to the controls on alcohol advertising⁶⁵. In Australia, the approach used to regulate the advertising of alcohol would provide a reasonable starting place (though e-cigarettes are likely to be much less harmful overall than alcohol)⁶⁶.

4.6 Warnings, risk communication and health claims

The aim should be to provide users with the basis for making an informed choice – reflecting both risks and benefits. Consumer information should not be misused to achieve a particular behavioural outcome – for example exaggerating risks to deter use. Warnings should refer to known risks – aiming to be both truthful and correctly understood: some truthful statements can be highly misleading, for example “this product is not a safe alternative to smoking”⁶⁷. Some understanding of the possible perverse effects of warnings is essential. For example in the UK, European Union regulation requires a warning label on e-cigarettes and e-liquids that emphasises addiction.

⁶² International Organization for Standardization. ISO 9000:2015 Quality Management, 23 September 2015 [\[link\]](#) ISO 9001:2015 for Small Enterprises - What to do? [\[link\]](#)

⁶³ Tobacco is advertising in banned in Australia, Tobacco Advertising Prohibition Act 1992 [\[link\]](#)

⁶⁴ Australian Competition and Consumer Commission, under the Competition and Consumer Act 2010 [\[link\]](#)

⁶⁵ Committee on Advertising Practice (UK), UK 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 [\[link\]](#)

⁶⁶ The Alcohol Beverages Advertising Code Scheme (Australia) [\[link\]](#), ABAC Responsible Alcohol Marketing Code [\[link\]](#)

⁶⁷ Kozlowski LT, Sweanor DS. Withholding differential risk information on legal consumer nicotine/tobacco products: The public health ethics of health information quarantines. Int J Drug Policy. Elsevier [\[link\]](#)

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However, UK survey data⁶⁸ suggests the most important reason for smokers not switching to e-cigarettes is fear of substituting one addiction for another.

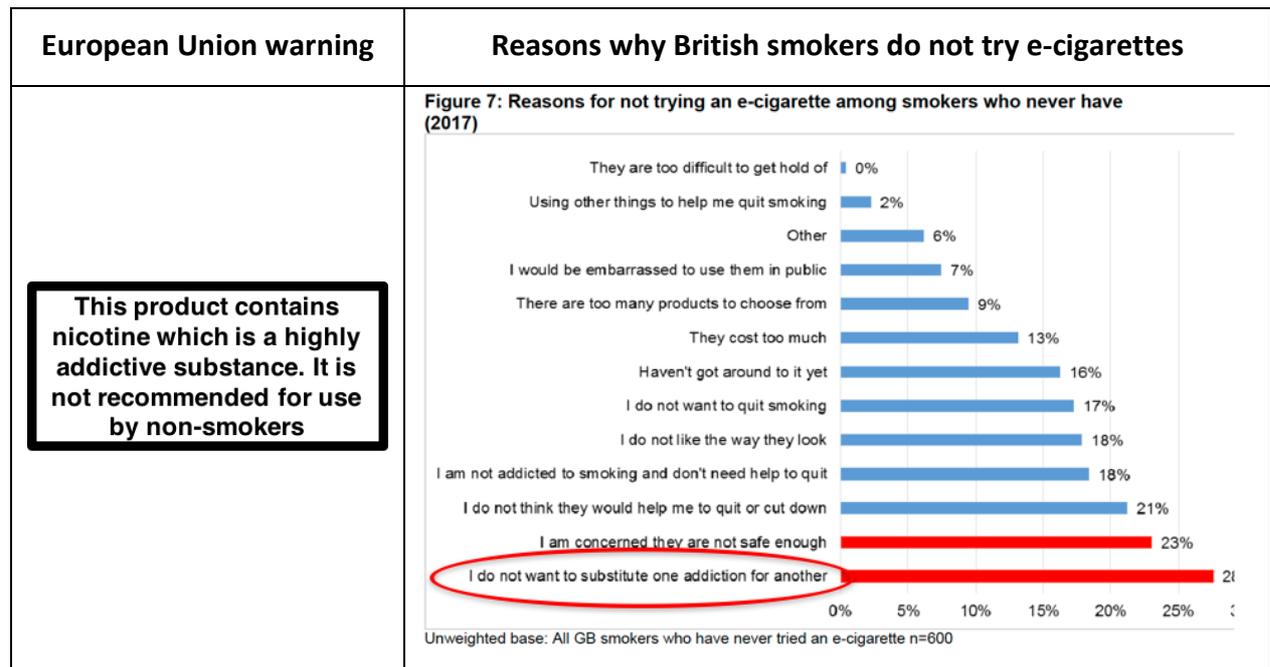


Table 1: Impact of warnings on attitudes to vaping

The second most common concern is belief that the products are not safe enough. Again this suggests that great care is required in mandating health warnings on e-cigarettes to ensure the much lower risk relative to smoking is properly understood. In defining risk communications, regulators and legislators should to consider three elements:

- The information that must be placed on the pack – this should not unduly frighten users or create a disproportionate impression of risk.
- The claims a manufacturer can make and in what circumstances – manufacturers should be free to make statements that are true and not misleading, but therapeutic claims should require evidence and an approval regime.
- The information the authorities provide for consumers. Governments or their agencies should take on the role of informing consumers with unbiased evidence-based information that can be readily understood. The regulator would mandate true statements approved for use by e-cigarette manufacturers. For example, the following statements might be approved for use:

No inhaled nicotine product is completely safe, but use of this product is likely to be much less harmful than smoking

The combination of these three elements should aim to provide the consumer with an accurate picture of risks, relative risk compared to smoking and a sense of the opportunities as well as risks.

⁶⁸ Action on Smoking and Health, Fact sheet: ASH Fact Sheet on the use of electronic cigarettes among adults in Great Britain [\[link\]](#)

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4.7 Point of sale and retail restrictions

There are a number of possible controls on sales of e-cigarettes applied at the point of sale.

- **Age restrictions.** Almost everyone involved favours restricting e-cigarette sales to people age 18 and over. However, even this is open to question on public health grounds. There are already studies^{69 70} from the United States suggesting *smoking has increased* among teenagers where age restrictions have been placed on sales of e-cigarettes. This may be considered part of the ‘license to operate’.
- **Retail accessibility.** E-cigarettes should be at least as easily available as cigarettes. Proposals to sell only in pharmacies, for example, should be rejected. There is no case for banning display or point of sale advertising. In fact, there is a strong case to encourage switching in the store where cigarettes are on sale. Specialist vape stores combine a wide range of products with coaching and advice on selection and use of products, creating what amounts to a smoking cessation service offering.
- **Internet sales.** Sales over the Internet are integral to the e-cigarette business model and are especially important for the more experienced users or those remote from vape towns capable of supporting a vape store. This is because the density of customers is lower, the diversity of stock much greater, and the rate of innovation much higher. Each of these favours large concentrations of stock rather than stock held in convenience stores serving small customer populations.

4.8 Use of e-cigarettes in public places – applying the ‘harm principle’

E-cigarettes release emissions into the atmosphere, which can affect air quality indoors. Should this be permitted? There are essentially two approaches to this:

1. A government or regulator determines that e-cigarettes cannot be used in certain public (often privately owned) places – often applying a broad prohibition or imposing the same bans on use that apply to smoking.
2. The owners or managers of each place decide whether to allow e-cigarettes use or not – taking account of the type of place, their clients and their commercial interests. This does not imply a ‘right to vape’, but leaves the decision to a property owner or manager.

Generally, governments should support option one only where there a material risk to bystanders has been established and the government has a proper justification to override the preferences of owners or managers. This type of state action requires a justification – and this is usually found in the ‘harm principle’ first articulated by John Stuart Mill⁷¹

That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.

⁶⁹ Friedman AS. How does Electronic Cigarette Access affect Adolescent Smoking? *J Health Econ* Published Online First: October 2015. [[pubmed](#)]

⁷⁰ 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 [[pubmed](#)]

⁷¹ Mill JS. On Liberty, 1859. [[link](#)]

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Applying this principle, there is no case for banning vaping by law or a blanket prohibition – the case for banning smoking by law rests on material harm to others, and the evidence suggests that e-cigarettes cause is no material risk to bystanders. In his detailed review of the toxicity evidence, Igor Burstyn concluded that risks to active vapers were well below thresholds used to set workplace exposure standards and concluded that for passive vaping⁷²:

Exposures of bystanders are likely to be orders of magnitude less, and thus pose no apparent concern.

It is true that not everyone wishes to be exposed to someone else’s exhaled vapour. The issue is thus one of nuisance and etiquette, not a matter in which legislators should intervene to override the preferences of owners or managers of public spaces to protect bystanders or workers, for whom vaping represents a minor occupational exposure.

There are many places, times, events, and circumstances where vaping may be reasonable or commercially valuable and should not be ruled out by a blanket ban and that a centrally directed prohibition would be clumsy and inappropriate. The figure below gives examples of reasonable vaping policies that owners or managers of space may adopt given the choice.

Real world examples of options for vapour policy set by owners and managers
1. A bar wants to have a vape night every Thursday
2. A bar wants to dedicate one room where vaping is permitted
3. In a town with three bars, one decides it will cater for vapers, two decide they will not allow vaping
4. A bar manager decides on balance that his vaping customers prefer it and his other clientele are not that bothered – he’d do better allowing it
5. A hotel wants to allow vaping in its rooms and in its bar, but not in its restaurant, spa, and lobby
6. An office workplace decides to allow vaping breaks near the coffee machine to save on wasted smoking break time and encourage smokers to quit by switching
7. A care home wants to allow an indoor vaping area to encourage its smoking elderly residents to switch during the coming winter instead of going out in the cold
8. A vape shop is trying to help people switch from smoking and wants to demo products in the shop
9. A shelter for homeless people allows vaping to make its clients feel more welcome
10. A supermarket does not allow vaping, but a bookshop keen to attract browsers does

Table 2: Examples of options for vaping policies

The purpose of a blanket ban would be to prevent managers and owners making these nuanced and reasonable decisions (as above) using broad provisions and the force of law. In the absence of harm, the appropriate policy is to allow owners and operators to decide their policy and make informed judgements, including the welfare value to vapers and smokers and make clear whether vaping is permitted or not. The role of the government should be limited to providing guidance to assist in making such decisions, an approach that has been adopted in England^{73 74}.

⁷² 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 [\[link\]](#)

⁷³ See ASH structured questions: Will you permit or prohibit e-cigarette use on your premises? 2014 [\[link\]](#)

⁷⁴ Public Health England, Use of e-cigarettes in public places and workplaces, 6 July 2016 [\[link\]](#)

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4.9 Taxation – an appropriate fiscal regime

There are strong practical and principled reasons not to tax e-cigarettes at all, above normal sales taxes⁷⁵. If it is accepted they are assisting with smoking cessation, then economically they should be treated as if they create societal benefits commensurate with smoking cessation. Smoking cessation tends to attract *public spending* rather than taxation through campaigns or the healthcare system. However, in practice governments are likely to approach taxation of e-cigarettes products with four contending objectives in mind: raising revenue; public health impact; cost of administration; potential for black market. In making these trade-offs, the following considerations should apply:

1. **Comparison with smoking – societal harm.** Experts in tobacco taxation argue that tax should reflect risks, and therefore that e-cigarettes should be taxed at a significantly lower rate than cigarettes⁷⁶. This will provide a fiscal incentive to switch. Vapour product use is likely to have at least a 95% lower risk than smoking. If tax was set proportionate to risk as some proportional deterrent, then the tax yield for e-cigarettes would be so low it would not be worth the cost of collecting. The only way to make a tax viable is to tax vaping *disproportionately* to risk. This means applying a disproportionately large deterrent to e-cigarette use.
2. **Comparison with NRT – therapeutic value.** E-cigarettes in fact produce a *net health benefit* by reducing smoking – their risk is on average *negative*. From an economic and tax perspective, e-cigarettes should be viewed more like over-the-counter medicines. Some jurisdictions apply a reduced sales tax to NRT⁷⁷ - a tax subsidy. In the UK, NRT attracts a sales tax (VAT) of 5% compared to the 20% standard rate.
3. **Replacing lost cigarette tax revenue.** The argument that because tax-take is falling from cigarettes as people switch, then excise duty should be applied to e-cigarettes is appealing but does not have an economic rationale, even if superficially appealing. Tax should be raised from the least distorting and most efficient tax base available, or from cuts in inefficient public spending: there is no reason why cigarette excise losses should be recovered from taxes on e-cigarettes, but could be raised from, say, a carbon tax or aggregates tax, or offset by cutting inefficient public spending.
4. **Comparison with consumer goods.** E-cigarettes carry relevant sales taxes. What rationale is there for taking more than the standard level of tax from these products, given they do little harm and probably more good than most consumer products?

4.10 Official guidance to healthcare professionals

There is now recognition among tobacco control professionals and public sector practitioners that e-cigarettes can be used constructively to reduce harm. For example, in Britain the National Centre for Smoking Cessation and Training and Public Health England, the government's public health agency, has developed evidence-based guidance for health professionals. It provides a clear and measured

⁷⁵ New Nicotine Alliance. Revision of the Tobacco Excise Directive (EU), Implications for low-risk nicotine products, December 2016 [[link](#)][[full report - PDF](#)]

⁷⁶ Chaloupka FJ, Sweanor D, Warner KE. Differential Taxes for Differential Risks--Toward Reduced Harm from Nicotine-Yielding Products. *New England Journal of Medicine* 2015;373:594–7. [[link](#)]

⁷⁷ In the UK, NRT sold OTC is subject to a reduced 5% rate of Value Added Tax

Annex 1: Submission to House inquiry into the Use and Marketing of Electronic Cigarettes etc

assessment of the state of science and best practice. This guidance could be valuable to any country wishing to exploit the opportunities and minimise the risks⁷⁸.

The following table is a summary of the official guidance given to UK health professionals by the NCSCT and Public Health England.

<p><i>Recommendations for practice</i></p> <ol style="list-style-type: none"><i>1. Be open to e-cigarette use in people keen to try them; especially in those who have tried and failed to stop smoking using licensed stop smoking medicines.</i><i>2. Provide advice on e-cigarettes that includes:</i><ul style="list-style-type: none"><i>• E-cigarettes provide nicotine in a form that is much safer than smoking.</i><i>• Some people find e-cigarettes helpful for quitting, cutting down their nicotine intake and/or managing temporary abstinence.</i><i>• There is a wide range of e-cigarettes and people may need to try various types, flavours and nicotine dosages before they find a product that they like.</i><i>• E-cigarette use is not like smoking and people may need to experiment and learn to use them effectively (e.g. longer ‘drags’ may be required and a number of short puffs may be needed initially to activate the vaporiser and improve nicotine delivery). They may also need to recognise when atomisers need replacing.</i><i>• People previously using e-cigarettes while smoking (e.g. to reduce the number of cigarettes that they smoke) may need to consider changing devices and/or nicotine concentrations when making a quit attempt.</i><i>• Although some health risks from e-cigarette use may yet emerge, these are likely, at worst, to be a small fraction of the risks of smoking. This is because e-cigarette vapour does not contain the products of combustion (burning) that cause lung and heart disease, and cancer.</i>

Figure 7: Guidance on e-cigarettes to health and smoking cessation professionals in England

This is a balanced and open-minded approach, and reflects an emerging consensus on how to exploit the opportunities of e-cigarettes while containing any risks. The guidance is notable for a number of balanced statements about vaping that successfully blend scientific evidence and empathy for smokers’ and their efforts to use vaping to protect their health⁷⁹. It is a model that could be adopted in Australia.

⁷⁸ McRobbie H. McEwen A. E-cigarette briefing (Version 2). National Centre for Smoking Cessation and Training, Public Health England. London, February 2016 [\[link\]](#)

⁷⁹ Bates C. Blending evidence and empathy – a new guide to e-cigarettes, Counterfactual, February 2016 [\[link\]](#)

5 Any other related matter

5.1 Broaden the scope to other low-risk alternatives to smoking

Any reconsideration of policy in this area should extend to all tobacco / nicotine products that are prohibited by virtue of poison scheduling. Schedule 7 allow for recreational nicotine only in a form that is “prepared and packed for smoking”. This prohibits several important low-risk product categories that fall outside the definition of “prepared and packed for smoking” and also the focus of this inquiry in “electronic cigarettes and personal vaporisers”. These products are other forms of tobacco or nicotine that do not involve combustion – smokeless tobacco, the newly emerging heated tobacco products and consumer nicotine products. A segmentation is illustrated below.



Figure 8: alternative low-risk nicotine products

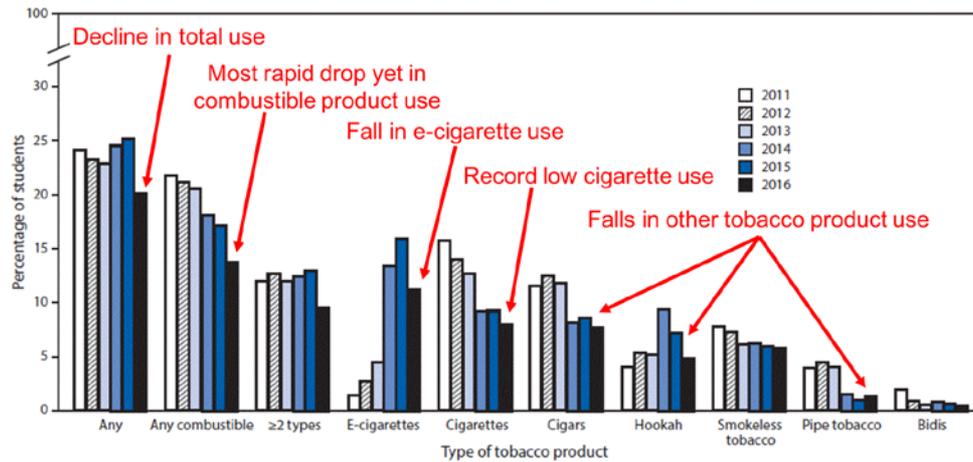
All of these products share one important characteristic – they provide nicotine *without the combustion of tobacco*. As a result, they offer much lower levels of toxicity and health risk. The second characteristic they share is that all are prohibited in Australia even though cigarettes are permitted, *and they are banned precisely because they are not for smoking*.

The idea of allowing the availability of such products is to increase the options available to Australians to stop smoking. For example, it is possible that heated tobacco products can mimic the sensation of smoking more closely than e-cigarettes, so there may be a prospect of attracting more committed smokers to a greatly reduced risk product. Different people may want different products at different times of day and at different points in a transition from smoking to not smoking. Given the risks are one to three orders of magnitude lower than smoking, there is no reason for the government to actively prevent people accessing these alternatives. Many of the approaches suggested for regulation of e-cigarette would work well if adapted for these products.

Appendix 1: Trends in youth tobacco and nicotine use in the United States

The two charts that follow are annotated to show salient features of the most recent data on youth smoking in the United States. The first chart is from the National Youth Tobacco Survey, published June 2017⁸⁰.

FIGURE 1. Estimated percentage of high school students who currently use any tobacco products,* any combustible tobacco products,[†] ≥2 tobacco products,[‡] and selected tobacco products – National Youth Tobacco Survey, United States, 2011–2016^{§,¶,||}



* Any tobacco product use is defined as past 30-day use of electronic cigarettes, cigarettes, cigars, hookahs, smokeless tobacco, pipe tobacco and/or bidis.

Figure 9: changes in patterns of youth nicotine use United States 2011-16

The second is from the 2016 University of Michigan Monitoring the Future survey, which has a time series dating back to 1975 for 12th grade smoking⁸¹.

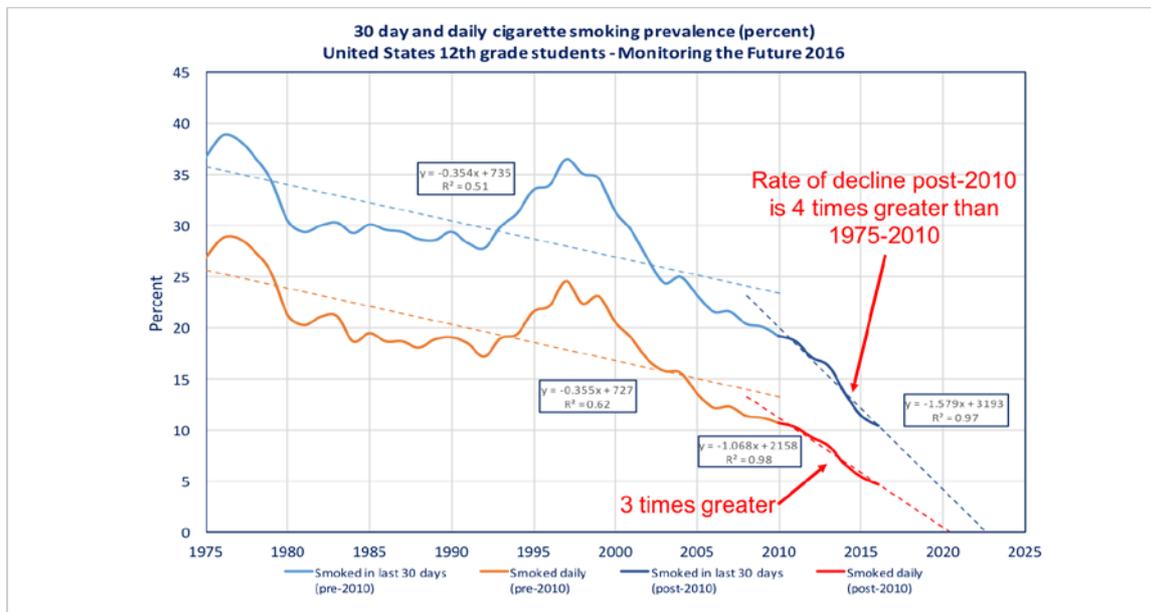


Figure 10: Accelerating decline in 12th grade smoking United States post-2010

⁸⁰ Jamal A, Gentzke A, Hu SS, Cullen KA, Apelberg BJ, Homa DM, et al. Tobacco Use Among Middle and High School Students - United States, 2011-2016. *MMWR Morb Mortal Wkly Rep.* 2017 Jun 16;66(23):597–603. [[link](#)]

⁸¹ 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. University of Michigan; Ann Arbor: 2016. [[Tables](#)][[Dataset](#)].

Appendix 2: The critic's guide to bad vaping science

1 Toxic chemicals have been identified in e-cigarette vapor or e-liquids

- 1.1 Did they show potentially harmful *exposure* not just the *presence* of a chemical? "The dose makes the poison".
- 1.2 How risky is the exposure compared to smoking?
- 1.3 How risky is the exposure compared to other risks such as those accepted under occupational health limits?
- 1.4 Were measurements made in realistic human operating conditions or in extreme or unrealistic conditions?
- 1.5 Are inappropriate proxies being used for risk – for example effects that are also seen with coffee or exercise?
- 1.6 Are flawed analogies being used – for example assuming all ultrafine particles are equally toxic?

2 Adverse health effects from e-cigarettes are reported

- 2.1 Was vaping the real cause?
- 2.2 Was the person suffering from adverse impacts of being a smoker before using e-cigarettes?
- 2.3 Is the study just observing the effect of nicotine on the body (though no serious disease is caused by nicotine)?
- 2.4 Is there evidence of actual harm or is it just a *change* in the body or brain?
- 2.5 Is it based on a cell culture study are the limitations recognized and was exposure realistic proxy for human use?
- 2.6 Is it based on an animal study and are the limitations recognized?

3 Claims second-hand vapor is toxic and indoor vaping should be banned

- 3.1 Are vapor exposures to bystanders potentially harmful given they pose little risk to direct users?
- 3.2 Is the difference between risk or harm and nuisance or personal preference recognized?
- 3.3 Have false choices been proposed? e.g. between a ban and *laissez faire*.

4 Nicotine damages the adolescent brain

- 4.1 What is the specific nature of the detriment to human health?
- 4.2 Where is the evidence for the brain damage from nicotine in the longstanding human population of smokers?
- 4.3 How does this compare to damage from alcohol, cannabis or caffeine?

5 More children using e-cigarettes and gateway effects

- 5.1 Did they characterize use properly? For example, 'ever use' of an e-cigarette is a marker of experimentation.
- 5.2 Could the rising use of e-cigarettes be a good thing if it is displacing smoking?
- 5.3 High level of smoking associated with vaping – but is this due to independent common factors (confounding)?
- 5.4 Have they defined a gateway effect?
- 5.5 Are they assuming prior behaviour caused the later behaviour?

6 E-cigarettes keep people smoking and reduce quit rates

- 6.1 Has vaping been wrongly conceptualized as though it is a medical intervention?
- 6.2 Has the importance of product's consumer appeal been recognized?
- 6.3 Was "dual use" described as problematic – any cutting down is beneficial and may be part of a longer transition?
- 6.4 Did they claim there are no benefits to cutting down?
- 6.5 Have the limitation of randomized controlled trials been acknowledged?.

7 Flavours and e-cigarette marketing aimed at children

- 7.1 Do they assume it is just obvious that childish names appeal to kids?
- 7.2 Why would adolescents try to emphasize their childishness?
- 7.3 Have *preferences* for particular flavours been misrepresented as a *cause* of vaping?
- 7.4 Could it be a benefit that some flavours are attractive to adolescents if it means they don't smoke?
- 7.5 Is an e-cig advertising in effect an anti-smoking ad?

8 Citing uncertainty and appeal to the 'precautionary approach'

- 8.1 Have they understood what is known and recognized the physical processes in vaping are different to smoking?
- 8.2 Are they asking the impossible? E.g., by saying we will only know the risks when we have 40 years of data?
- 8.3 Do they realize that 'precautionary approach' can do be harmful if it blocks access to beneficial technology?

9 Tobacco industry involvement implies inevitable harm

- 9.1 Is the malign influence of tobacco companies assumed or demonstrated?
- 9.2 Is there over-reliance on decades old industry statements, documents or behaviours?
- 9.3 Is there a proper understanding of how the nicotine and tobacco market works?
- 9.4 Are the authors concerned about the right things? For example, are they fighting ill-health or capitalism?

10 Policy recommendations in a scientific paper

- 10.1 Do policy recommendations go beyond what their research justifies?
- 10.2 Have policy-making disciplines been followed – options generation, impact assessment, consultation etc.?
- 10.3 Are the authors' policy positions revealing their biases and priors?
- 10.4 Have unintended consequences been ignored? Many e-cigarette policy proposals could lead to more smoking.

Figure 11: Overview of the questioning approach to interrogating vaping science

Appendix 3: Plausible unintended consequences of regulation

Policy	Plausible unintended consequence
High compliance costs or barriers to entry	A loss of product diversity means consumers are unable to personalise the vaping experience or find products that they enjoy and find it less satisfactory, so continue to smoke or relapse.
Restrictions on liquid strength	Smokers are unable to sustain a satisfactory nicotine experience during the first stages of switching or while they are learning to vape, so relapse to smoking or give up on vaping. May drive users to black market and/or home mixing with high strength liquids
Limits on container and tank size	The experience of vaping becomes more inconvenient and so less attractive. More filling operations are required and the likelihood of running out of liquid is increased.
Ban e-cigarette use in public places	Diminishes value proposition of e-cigarettes to users and ‘denormalises’ vaping, a much less risky option, and so diminishes the appeal of vaping relative to smoking, May promote relapse in existing vapers if they cannot maintain adequate nicotine levels or if they join smokers outside.
Restrictions on advertising, promotion and sponsorship	Reduces the ability of e-cigarette brands to compete with cigarettes (the market incumbent) and diminishes means to communicate the value proposition to smokers. May reduce means to communicate innovation or build trusted brands. If subjected to excessive control products may become dull and sterile, diminishing appeal.
Bans on online sales	Because vaping options are highly diverse, user density still quite low, and technological evolution rapid, the internet-based business model is important to provide the greatest choice and convenience to users. If users are forced to purchase from ‘bricks and mortar’ outlets but do not have a specialist shop nearby they are likely to see their options limited and vaping relatively less attractive
Policy compliance burdens and other costs - leading to black markets	Black markets develop in response to restrictive or costly regulation or taxation. Black markets can to some extent compensate for poorly designed policy and they are likely to emerge as the TPD is implemented. However, they also cause harms through trade, transit and handling of high strength liquids, product quality, poor labelling, inferior packaging. They may exacerbate risks the policy is designed to mitigate.
Product design restrictions and requirements – testing and paperwork	There are numerous subtle trade-offs in product design between safety and appeal and cost. For example, the perfectly safe product that no-one wants to buy may be worse for health if it means more people smoke. Excessive design regulation can impose high costs, burdens and restrictions, slow innovation and drive good products and firms out of the market through ‘regulatory barriers’ to entry. Very high spec regulations will tend to favour high volume, low diversity commoditised products made by tobacco or pharmaceutical companies. Regulation can adversely reshape the market and reduce the pace of innovation.

Annex 1: Submission to House inquiry into the Use and Marketing of Electronic Cigarettes etc

Policy	Plausible unintended consequence
Bans on flavours	All e-cigarettes and liquids are flavoured with something – and this forms a key part of the appeal. Many former smokers report switching to non-tobacco flavours as a way of moving permanently away from smoking. There is a significant risk that loss of broad flavour categories will cause relapse among e-cigarette users, fewer smokers switching, and development of DIY and black market flavours – which may be more dangerous.
Bans on refillable systems	This idea has been proposed by tobacco companies for commercial and anti-competitive reasons. It means removing the ‘open system’ 2 nd and 3 rd generation products that increasingly dominate the market. Many vapers report these are more effective alternatives to smoking. Any (minor) risks of poisoning, dermal contact, DIY mixing etc have to be set against the likely black market response, and the substantial benefits arising from personalisation and huge extension to the diversity of products available.
Health warnings	Alarmist health warnings, even if technically correct, can be misleading and misunderstood by the public. This has always been the case with smokeless tobacco – warnings do not adequately communicate relative risk and, therefore, understate smoking risks or the advantage of switching. They may obscure much more important messages about relative risk compared to smoking that is not provided in official communications.
Ban sales to under-18s	There is near universal support for this policy. But US studies found that in areas where e-cigarette sales to under-18s had been banned the decline in smoking was slower than in areas where it was not banned. However, it is worth noting that NRT is made available to people over 12 years in some jurisdictions – because young smokers also need to quit. It should not be assumed that ‘harm reduction’ should start at 18.
Prohibit health or relative risks claims	This denies smokers real world truthful information about relative risk and may cause more smoking. It is uncontroversial that e-cigarettes are safer than smoking – the debate is over where in the range 95-100% less risky. This erects high and unnecessary regulatory barrier to truthful communication - and therefore obscures the most important consumer benefit from consumers. The authorities could address this by providing authoritative advice on relative risk - for example of the type provided by Public Health England or the Royal College of Physicians, which could be used in communication with consumers.
Raise taxes on e-cigarettes	This reduces the financial incentive to switch from smoking to vaping unless the tax on smoking is also increased. But these taxes if raised too far will tip users into other forms of unintended behaviour – accessing the black market, switching to rolling tobacco, or create cottage industries producing e-liquids in garages. It may also favour smoking cessation medications that are less effective on average, such as NRT (which in the UK actually receives an unjustified VAT discount)

About the author

Clive Bates is director of Counterfactual, a consulting and advocacy practice focused on a pragmatic approach to sustainable development, energy policy and public health that he founded in 2013. He has had a diverse career in the public, private and non-profit sectors. After securing a degree in engineering from Cambridge University, he worked in information technology for IBM before moving on to work as an energy specialist with several environmental non-profits. From 1997 to 2003, he was the United Kingdom's director of Action on Smoking and Health, campaigning to reduce the harms caused by tobacco. In 2003, he joined Prime Minister Tony Blair's Strategy Unit as a civil servant and worked in several roles in the public sector in the United Kingdom and for the United Nations in Sudan.

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**Annex 2: Submission of 40 experts to the Therapeutic Goods Administration
arguing for rescheduling of nicotine to lift the *de facto* prohibition**

September 2016

Proposed Amendments to the Poisons Standard

Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine

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Proposed Amendments to the Poisons Standard

Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine

Summary

The signatories above submit this comment in support of the application to amend Schedule 7 of the Poisons Standard to exempt nicotine in preparations with concentrations under 3.6 percent, the levels typically used in electronic nicotine delivery systems (ENDS). The comment is organised under the six headings covering matters the Minister should take into account when considering an application to amend Schedule 7.

(a) the risks and benefits of the use of a substance

The exemption would beneficially mitigate two important risks. Firstly, it would allow many more of Australia's 2.8 million smokers to legitimately switch from cigarettes to ENDS use ('vaping') and so substantially reduce their health risks. The Royal College of Physicians (London) recently stated that the risk of vaping is unlikely exceed 5 percent of the risk of smoking and may be substantially lower than that. However, the Poisons Standard creates a *de facto* prohibition on smokers adopting this option in Australia. Secondly, it would mean that Australians could purchase regulated nicotine liquids for vaping legitimately from Australian business and so avoid risks associated with a grey or black market supply chain and risks associated with handling and mixing of higher strength liquids.

(b) the purposes for which a substance is to be used and the extent of use of a substance

Nicotine liquids are used for the purpose of "tobacco harm reduction" – an approach that is proving popular and successful with smokers in the Europe and the United States without any major adverse consequences. Use of these products is making substantial inroads into the cigarette market and adult and adolescent smoking trends are consistent with ENDS use displacing smoking.

(c) the toxicity of a substance

The toxicity of nicotine liquids at the low concentrations proposed presents no significant risks beyond those already widely present in the home, for example from medicines or cleaning products, and these can be mitigated through straightforward packaging and labelling obligations.

(d) the dosage, formulation, labelling, packaging and presentation of a substance

An amendment to the schedule should include some supporting safeguards and standards that would be based on consumer protection concepts, such as clear labelling, accurate description of contents and secure packaging. Australia has the opportunity to assume leadership in regulation of nicotine products to optimise their potential for public health.

(e) the potential for abuse of a substance

Nicotine use through cigarette smoking can cause dependence. Nicotine liquids would be primarily used to reduce harm to smokers who cannot easily quit nicotine use or choose not to. If the harms associated with ENDS use are much lower, then the negative consequences of any residual nicotine dependence are greatly reduced.

(f) any other matters that the Secretary considers necessary to protect public health

There is a strong public health, ethical and pragmatic case to amend the schedule and to allow Australians access to much less risky ways to consume nicotine than smoking. The case for a *de facto* prohibition and denying Australians this option is very weak.

Proposed Amendments to the Poisons Standard

Comment on a proposal to amend the Poisons Standard Schedule 7 entry for nicotine

Introduction

This is a comment on the proposal to amend Schedule 7 of the Poisons Standard¹ to exempt nicotine in preparations for use as a substitute for tobacco in concentrations up to 3.6 percent - the concentrations commonly used in personal vaporisers or e-cigarettes.

We strongly support an amendment to exempt nicotine in low-concentrations for use in Electronic Nicotine Delivery Systems (ENDS) from Schedule 7 of the Poisons Standard.

Under Section 52E of the Therapeutic Goods Act, in exercising the power to amend Schedule 7, the Secretary (minister for health) must take the following matters into account (where relevant)²:

- (g) the risks and benefits of the use of a substance;*
- (h) the purposes for which a substance is to be used and the extent of use of a substance;*
- (i) the toxicity of a substance;*
- (j) the dosage, formulation, labelling, packaging and presentation of a substance;*
- (k) the potential for abuse of a substance;*
- (l) any other matters that the Secretary considers necessary to protect public health.*

This comment follows the structure of this section of The Act.

(a) The risks and benefits of the use of nicotine

a.1 Benefit of clean nicotine availability: mitigation of smoking-related risks

In 2014-15, 16 percent of Australian adults aged 18 years and over, 2.84 million people, were current smokers³. These are people using the mildly psychoactive drug nicotine via its most harmful and its least regulated and controllable delivery system – that is by inhaling tobacco smoke, mainly from cigarettes. The harms associated with nicotine use are overwhelmingly caused by its delivery to the lungs via toxic particles and gases that contain products of combustion of tobacco leaf, not the nicotine itself. The harms are significant and well documented⁴ – smoking is a major cause of cancer, cardiovascular disease and respiratory illness, as well as degraded welfare and wellbeing. Each year, smoking kills an estimated 15,000 Australians and costs Australia \$31.5 billion in social (including health) and economic costs⁵.

In addition to the harms caused directly by smoking, there are additional harms to continuing smokers arising from the *policy response* that aims reduce smoking – for example through high and regressive tobacco taxation or the stigma or alienation that many smokers feel through the public

¹ Government of Australia, Therapeutic Goods Administration, The Poisons Standard July 2016. Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) [\[link\]](#) made under 52D(2)(b) of the *Therapeutic Goods Act 1989* [\[link\]](#)

² Therapeutic Goods Act, 1989 section 52E [\[link\]](#)

³ Australian Bureau of Statistics, National Health Survey: First Results, 2014–15 — Australia. Table 9. [\[link\]](#)

⁴ Surgeon General of the United States. The Health Consequences of Smoking—50 Years of Progress. Centers for Disease Control and Prevention (US) 2014. [\[link\]](#)

⁵ Australian Government, Department of Health, Tobacco Control key facts and figures, accessed 16 August 2016 [\[link\]](#)

Annex 2: Comment on proposal to amend the Poisons Standard entry for nicotine

health strategy of ‘denormalising’ smoking. While these policy impacts may be considered a price worth paying to reduce smoking, they are nevertheless a significant detriment to those who continue to smoke.

While nicotine is not entirely benign, it accounts for a very small fraction of the direct harm caused by smoking. Studies of the health effects of prolonged NRT use and smokeless tobacco have allowed the nicotine health effect to be isolated from the overall smoking health effect. The Royal College of Physicians (2016) describe the effects of nicotine alone as follows⁶:

As use of nicotine alone in the doses used by smokers represents little if any hazard to the user, complete substitution of smoking with conventional NRT products is, for practical purposes, the equivalent of complete cessation in almost all areas of harm to the user. [Section 8.4.1 p125]

Nicotine is the main reason why people smoke, but not the direct cause of harm. To summarise⁷:

People smoke for the nicotine but die from the tar

In its extensive April 2016 report⁸, the Royal College of Physicians (London) characterised the relative risk of smoking and e-cigarette use 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.

At present, Australia’s legal recreational nicotine market is dominated by cigarettes. There is no justification for purposefully denying smokers access to products that are a much safer way of using nicotine than smoking. The proposed amendment allows for significant individual and population *risk reduction* that is currently blocked by the Poisons Standard.

a.2 Benefit of clean nicotine availability: mitigation of supply chain risks

Australia’s *de facto* prohibition of nicotine liquids for harm reduction does not mean there is no use for this purpose in Australia. In fact, there is a thriving, though unquantified, consumer base of people who are using these products to mitigate their smoking-related risks and to take control of their health outcomes. In doing so, they are forced to circumvent the restrictions of the Therapeutic Goods Act and to purchase internationally from many legitimate websites that cater for this trade or through an unregulated black market.

The economics of the international trade incentivises users to purchase nicotine at higher concentrations (as high as 99 percent), and higher than they would generally use (typically up to 3.6 percent) and then handle, mix and dilute the high strength liquids down to their preferred mix with obvious handling risks. Purchases can be made from many high quality web sites, with prices in multiple currencies, secure payments systems, reputable couriers and paperwork and certification, yet with uncertain quality, ingredients and safety⁹. The example below is a marketing email from a Chinese supplier provided for illustrative purposes.

⁶ Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [\[link\]](#)

⁷ Russell MJ. Low-tar medium nicotine cigarettes: a new approach to safer smoking. *BMJ* 1976;1:1430–3. [\[link\]](#)

⁸ Royal College of Physicians (London) Nicotine without smoke: tobacco harm reduction 28 April 2016 [\[link\]](#) Section 5.5.

⁹ See test purchase experience: Bates C. Regulators and the compliance fallacy - buying 99% nicotine e-liquid from China, *The Counterfactual* [\[link\]](#)

Annex 2: Comment on proposal to amend the Poisons Standard entry for nicotine

Example of unsolicited promotional email for Chinese-supplied e-liquids

We are specializing in 99.95% pure nicotine, PG VG based nicotine liquid from 36mg/ml-600mg/ml and about 500 kinds flavors in China.

About Product details:

Pure nicotine is 99.95% USP grad, 1000mg/ml.

Price is : USD \$196/1.15L

500ml is \$100 (20ml sample for free test)

Flavor is USP grade, pure concentrate liquid.

Flavor Price: Tobacco series & Mint series USD \$75 per liter, 500ml is \$38

Fruit series & Herb & Flowers USD \$62 per liter, 500ml is \$31

Flavor sample: 125ml sample is \$10 per one.

Certificate: COA and MSDS.

Packing: Fluorinated bottle and aluminum foil bag.

Delivery: We always send by FedEx, DHL, TNT, UPS.

The offer of 500ml of 99.95% e-liquid for US\$100 makes this purchasing option *extremely* cost effective. Assuming 99.95% is equivalent to pure nicotine in the calculation below:

- ~100% nicotine liquid = 1000mg/ml
- Half litre = 500ml = 500,000mg nicotine
- Typical daily vaper nicotine consumption = 36mg nicotine¹⁰
- 500,000 mg = 13,889 day supply = 38 years supply or one-year supply for 38 people
- Cost = \$2.60 per person-year

We believe that a regulated domestic market for these liquids would be a preferable way to meet the rational and legitimate expectations of Australians to be able to use products that can dramatically reduce their risks. These products are widely available in Europe and the United States with no material harms arising. The proposed amendment would extend a safe supply to Australians: nicotine liquids could be prepared by local manufacturers and made available locally.

(b) The purposes for which nicotine is to be used and extent of use of nicotine

The primary purpose of the amendment would be to allow Australian smokers to use nicotine through technologies that cause much lower risk to health than through smoking, for example through use of e-cigarettes or personal vaporisers – so called Electronic Delivery Systems (ENDS). These technologies rely on electricity to heat a liquid to create an inhalable aerosol rather than combustion of tobacco to create smoke. These technologies have grown rapidly over the last five years primarily because advances in battery technology have allowed for small devices with sufficient power and battery life to make viable consumer alternatives to cigarettes. Experience from other countries suggests that the products in their current state of advancement can reach many smokers – and given continuing innovation will reach many more in future if the regulation and risk communications are fair and proportionate.

¹⁰ Farsalinos KE, Romagna G, Tsiapras D, *et al.* 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* 2014;**11**:4356–73. Table 2 [\[link\]](#)

Annex 2: Comment on proposal to amend the Poisons Standard entry for nicotine

b.1 United Kingdom experience

We do not have recent detailed data for e-cigarette use in Australia. In 2013, an international survey found that among Australian smokers 9 percent were current users and 24 percent had tried e-cigarettes¹¹. In the United Kingdom where ENDS are widely available, the use of these alternatives is now at a material scale relative to smoking. The Office of National Statistics reported data for 2015¹²

Smoking and e-cigarette users 2015	British adults
Current smokers	8,843,000
Current e-cigarette users	2,201,000
Of the current e-cigarette users:	
Current smokers	1,297,000
Ex-smokers	849,000
Never smokers	56,000
Ex-smokers and ex-e-cigarette users	717,000

Figures rounded to nearest 1,000

The use of ENDS by never-smokers in the UK is very low (0.2 percent of never smokers use e-cigarettes) and even among this group, 39% said they had used e-cigarettes to help them quit smoking. This means the appropriate comparator is with the risks to nicotine users who are smoking. Many of those who are both smoking and using e-cigarettes may be on a path to eventual exclusive use and some evidence suggests that these ‘dual users’ are more likely to go on to quit¹³. The 849,000 current ENDS users and 717,000 former ENDS users who have stopped smoking represent a substantial inroad into the smoking population, though it is not possible to attribute their smoking cessation directly to ENDS use. However, the trend in smoking prevalence is also encouraging. The 8.8m current smokers represents current *record low* adult smoking prevalence of 17.5 percent¹⁴. After stalling in the late-2000s smoking prevalence has been falling rapidly as e-cigarette use has increased from negligible levels in 2011. Throughout this period of widespread ENDS use there have been no major health problems or any other problems – though many ENDS users are now no longer smoking and will be gaining significant benefit from smoking cessation.

b.2 United States experience

Similar patterns are seen in the United States. The National Health Interview Survey¹⁵ shows that U.S. adult smoking prevalence (18 years and over) has fallen from 18.9 percent in 2011 to a record low of 15.1 percent in 2015 – below that of Australia – with an especially sharp decline between 2014 and 2015 – see figure below. As with Britain, the impact of ENDS on the cigarette trade is substantial: in 2015, there were approximately 37.5m smokers, but there were 8.3m e-cigarette users of whom 2.5m were ex-smokers¹⁶.

¹¹ Gravely S, Fong G, Cummings K, *et al.* Awareness, Trial, and Current Use of Electronic Cigarettes in 10 Countries: Findings from the ITC Project. *Int J Environ Res Public Health* 2014;**11**:11691–704. [\[link\]](#)

¹² Office of National Statistics (UK), E-cigarette use in Great Britain, 2015 Dataset. 18 February 2016 [\[link\]](#) Table 2a.

¹³ Manzoli L, Flacco ME, Ferrante M, Vecchia CL, Siliquini R, Ricciardi W, *et al.* *Cohort study of electronic cigarette use: effectiveness and safety at 24 months.* *Tobacco Control.* 2016 [\[link\]](#)

¹⁴ Office of National Statistics (UK), Adult Smoking Habits in Great Britain 1974-2014. 18 February 2016 [\[link\]](#) Table 1.

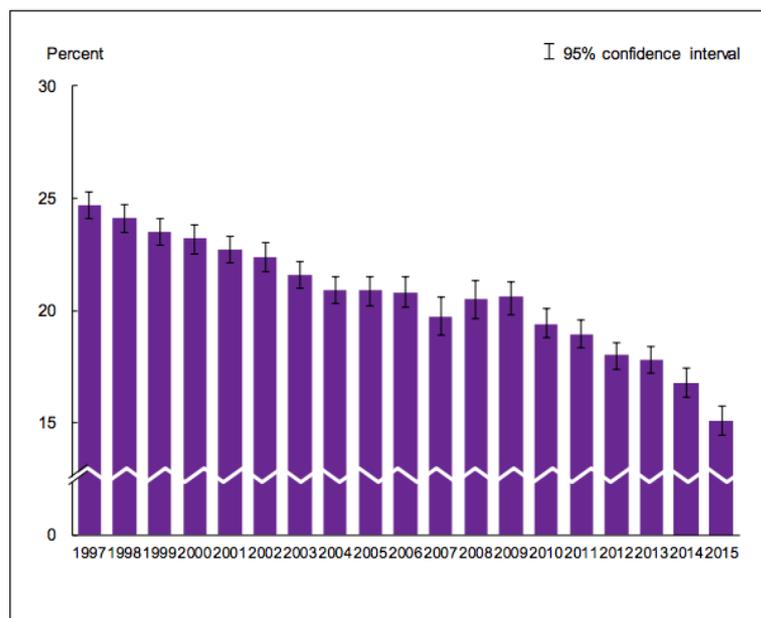
¹⁵ National Center for Health Statistics, *National Health Interview Survey, 1997–2015*, Sample Adult Core component. Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015. [\[link\]](#)

¹⁶ CDC, *National Health Interview Survey, 2015 Data Release* [\[link\]](#); Cited in Rodu B. *How Many Americans Vape? CDC Data Show Fewer Vapers & Smokers in 2015*, *Tobacco Truth* 17 July 2016 [\[link\]](#)

Annex 2: Comment on proposal to amend the Poisons Standard entry for nicotine

Current smoking

Figure 8.1. Prevalence of current cigarette smoking among adults aged 18 and over: United States, 1997–2015



Source: National Center for Health Statistics, *National Health Interview Survey, 1997–2015*

b.3 Adolescent ENDS use

There have been concerns expressed that adolescent uptake of ENDS may be ‘addicting future generations’. However, the data suggest a different pattern. Most use is by teenage smokers and data is consistent with ENDS use displacing smoking.

In the UK, use of ENDS among adolescents is low and confined mainly to young smokers. A March 2015 survey found 2.4 percent of 11-18 year olds had used e-cigarettes in the last month, and these were mainly smokers¹⁷.

In the United States, almost all adolescent users of ENDS are former or current smokers, and therefore ENDS represents a *change* in the way nicotine is used for most. Analysis of CDC 2014 data shows that 90 percent of the 1.96m current e-cigarette high school users are current or former users of other tobacco products¹⁸. Some of the remaining 10 percent may have become smokers in the absence of e-cigarettes. There is no evidence supporting a gateway from ENDS to smoking¹⁹.

In fact, smoking among American adolescents has been falling rapidly. The National Youth Tobacco Survey (CDC)²⁰ shows that between 2011 and 2015, current use of cigarettes by high school students fell from 15.8 percent to 9.3 percent, and use of cigars and pipes also fell. The data are consistent with a decline in smoking partly due to displacement by much lower risk ENDS (an ‘exit gateway’), though it is not possible to attribute causation from this type of survey.

¹⁷ YouGov for Action on Smoking and Health (UK) Smokefree GB Youth Survey. Published in ASH Fact sheet [\[link\]](#)

¹⁸ Rodu, B. Analysis of CDC National Youth Tobacco Survey 2014, The CDC Buries the Lead: Teen E-cigarette Use Rises as More Dangerous Cigarette Use Plumets, 13 October 2015 [\[link\]](#)

¹⁹ McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#) Section 4 *Gateway* page 37

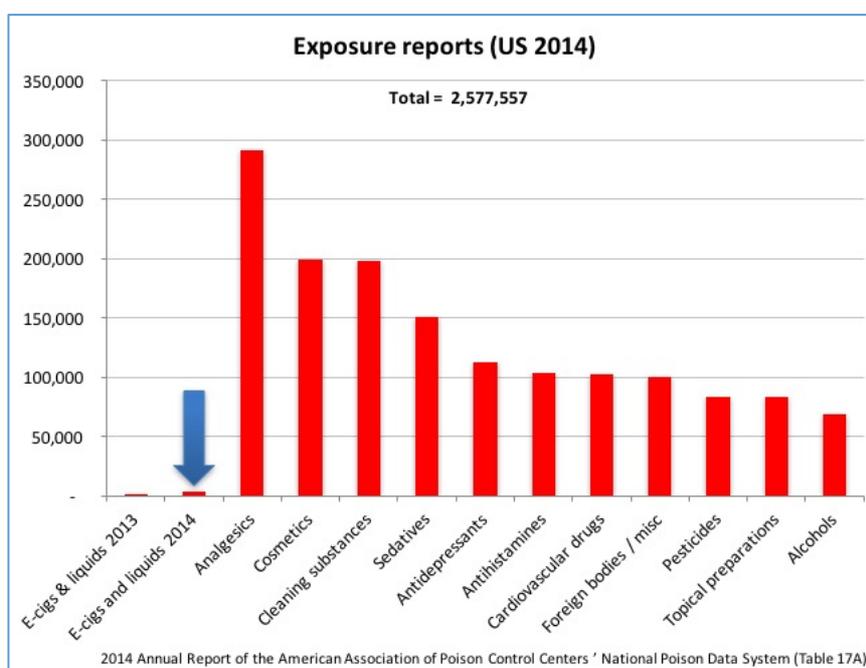
²⁰ Singh T, Arrazola RA, Corey CG, *et al.* *Tobacco Use Among Middle and High School Students — United States, 2011–2015.* MMWR Morb Mortal Wkly Rep 2016;65:361–367. [\[link\]](#)

(c) The toxicity of nicotine

Public Health England's expert review addressed the toxicity risks of nicotine liquids used for personal vaporisers²¹. The review noted that:

- fatal nicotine poisoning is extremely rare
- conventional estimates of LD₅₀ for humans (30-60mg ingestion) are grounded in 'dubious' 19th Century experiments and the likely lethal dose is much higher²²
- that individuals attempting suicide with nicotine have survived very high doses
- nicotine inhalation is self-regulating as users become nauseous
- that nicotine is an emetic and swallowing a significant dose ends in vomiting.

American activists have publicised rapidly rising calls to poison centers as though it a proxy for poisoning risks²³. However, these calls are from a low base, rise in line with growth in the product from 2011 and refer to 'exposures' (any contact) rather than poisoning or harm. E-liquid or e-cigarette related calls to poison centers rose from 271 in 2011 to 3,783 in 2014, though have been declining since²⁴. However, these figures are small compared to other normal household risks²⁵.



Data source: American Association of Poison Control Centers 2014 Annual Report

The approach to poisoning risks with nicotine liquids should be as with other moderate household hazards: child-resistant containers, labelling, and advice on what to do in the event of contact. This can be specified through ordinary consumer regulation, and is done for a large number of consumer products.

²¹ McNeill A, Brose LS, Calder R, *et al.* E-cigarettes: An Evidence Update. A Report Commissioned by Public Health England. London: 2015. [\[link\]](#) Section 9 page 63-67

²² Mayer B. How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century. *Arch Toxicol* 2014;**88**:5-7. doi:10.1007/s00204-013-1127-0 [\[link\]](#)

²³ Campaign for Tobacco Free Kids, Poisoning Cases Related to E-Cigarettes Keep Spiraling Upward, September 2014 [\[link\]](#)

²⁴ American Association of Poison Control Centers, E-Cigarettes and Liquid Nicotine, viewed 21 August 2106 [\[link\]](#)

²⁵ Mowry JB, Spyker DA, Brooks DE, *et al.* 2014 Annual Report of the American Association of Poison Control Centers' National Poison Data System (NPDS): 32nd Annual Report. *Clin Toxicol* 2015;**53**:962-1147.(Table 17A) [\[link\]](#)

(d) The dosage, formulation, labelling, packaging and presentation of nicotine

We support the proposal to exempt nicotine preparations up to 3.6 percent nicotine from schedule 7 of the Poisons Standard for use in ENDS for harm reduction. Given that nicotine “*in tobacco prepared and packed for smoking*” is exempted from Schedule 7, it is discriminatory and ‘anti-proportionate’ to continue to include the much lower-risk commercial alternative.

d.1 Standards to build into the Schedule 7 exemption

Exempting these nicotine liquids from Schedule 7 would approximately recreate the regulatory regime that has worked well in Europe and the United States prior to introduction of the European Union Tobacco Products Directive on 20 May 2016 and FDA Deeming Regulation on 8 August 2016 respectively. Though specifying the exemption provides the TGA with opportunities to specify some conditions regarding the packaging:

- Intended for recreational use in electronic cigarettes, personal vaporizers or other nicotine delivery systems that do not include tobacco prepared and packed for smoking.
- Where no therapeutic claim is made by the manufacturer
- That do not exceed 3.6 percent nicotine concentration (by mass)
- In a child resistant container specified to ISO standard 8317²⁶
- Accurately labelled with nicotine content usually specified as mg/ml
- List of ingredients
- Appropriate warnings regarding children

The threshold of 3.6 percent is sensible and cautious. Though the large majority (>90 percent) of consumers are likely to use liquids under 2.0 percent²⁷, the stronger liquids are important for the more highly dependent nicotine users (and hence more at-risk smokers); for novice users while they learn to use the products; and to support future innovations.

d.2 Towards a world-leading regulatory regime for ENDS

An amendment as proposed also gives Australia an opportunity to define a world-leading proportionate public-health orientated regulatory framework for ENDS. The regime defined in the United States is built on legislation designed for tobacco products before ENDS existed. The European Union Tobacco Products Directive is based on pre-2012 understanding of the risks and potential benefits. Neither provides a model for Australia, or anywhere.

Such an approach would be based on industry-wide standards for ENDS and e-liquids – and could be variations on those developed by British Standards Institute (BSI)²⁸ and in France under the equivalent body, AFNOR²⁹, or a forthcoming European CEN standard.

²⁶ ISO 8317 Child resistant packaging [\[link\]](#)[\[guide\]](#)

²⁷ Action on Smoking and Health, Fact sheet: ASH Fact Sheet on the use of electronic cigarettes among adults in Great Britain [\[link\]](#)

²⁸ BSI PAS 54115:2015 Vaping products, including electronic cigarettes, e-liquids, e-shisha and directly-related products - Manufacture, importation, testing and labelling - Guide [\[link\]](#) July 2015

²⁹ AFNOR (France) Electronic cigarettes and e-liquids Part 1: Requirements and test methods for e-cigarettes XP D90-300-1 March 2015 [\[link\]](#) and Part 2: Requirements and test methods for e-cigarette liquid XP D90-300-2 [\[link\]](#) March 2015

(e) The potential for abuse of nicotine

e.1 Psychoactive properties of nicotine

Nicotine is a mildly psychoactive drug with few side effects or direct harms, and, unlike alcohol, it does not cause intoxication and resulting accidents, violence and vulnerability. According to Benowitz³⁰.

Nicotine induces pleasure and reduces stress and anxiety. Smokers use it to modulate levels of arousal and to control mood. Smoking improves concentration, reaction time, and performance of certain tasks. Relief from withdrawal symptoms is probably the primary reason for this enhanced performance and heightened mood

It may be that these benefits are in fact manifestations of relief from withdrawal or craving – i.e. there no additional benefits compared to being a non-user. However, this interpretation is controversial and for those already dependent on nicotine it is of academic interest only – these are rewards that are experienced directly and contribute to continued use.

e.2 Dependence on smoking

Nicotine is dependence-forming when smoked on account of its activation of reward systems in the brain; the speed with which a peak nicotine blood concentration is reached through lung delivery; the presence of other substances in tobacco smoke (for example, monoamine oxidase inhibitors) that contribute to dependence; sensory effects such as ‘throat hit’; conditioning behaviours and cues that trigger craving.

e.3 Dependence on ENDS

The use of nicotine liquids has been overwhelmingly concentrated in current or former smokers who are already exposed to nicotine and may be dependent on nicotine through smoking. It is likely that nicotine delivered through electronic delivery systems (ENDS) is less dependence-forming than through smoking: there are other agents present in cigarette smoke that contribute to dependence and the pharmacokinetics of nicotine delivery by ENDS is ‘slower’. However, that is not a reliable assumption for the longer term – the success of ENDS as a public health intervention depends on replacing the experience of smoking with a satisfying way to take nicotine that is less harmful.

(f) Any other matters necessary to protect public health

f.1 The value of lifting Australia’s *de facto* prohibition on e-liquids

Policymakers must base decisions with real-world life-or-death consequences on a dispassionate view of the evidence, and the scientific evidence now suggests that electronic nicotine delivery systems (ENDS) could be a benefit to millions of smokers.

- Smokers who switch to ENDS are likely to avoid at least 95% of the major smoking-related risks for cancer, heart disease and respiratory illness. They will also experience significant short-term gains in health and wellbeing and, in high tobacco tax jurisdictions like Australia they are likely to be financially better off. No government should deliberately try to deny smokers this option – now adopted by millions of smokers world-wide.

³⁰ Benowitz NL. Nicotine addiction. *N Engl J Med* 2010;**362**:2295–303. [\[link\]](#)

Annex 2: Comment on proposal to amend the Poisons Standard entry for nicotine

- It is unethical to deny a smoker access to products that are much safer than the dominant product on the market, cigarettes³¹. Outside the field of tobacco and illicit drugs, there are no precedents for banning safer alternatives to widely used products.
- The availability of ENDS is not an alternative to conventional anti-smoking policy but complementary. By providing smokers with an easier way of responding to the pressures of high taxes and other measures, the overall tobacco control policy will become both more responsive and more humane.
- There is no credible evidence to suggest that ENDS undermine tobacco control, induce young people to smoke, or reduce the rate that adults quit smoking. The evidence, when examined dispassionately, shows what a neutral observer would expect unless presented with evidence to the contrary: people use much safer products to reduce their health risks or quit smoking.
- ENDS are an effective tool for switching from smoking at no cost to the public purse – the individual smokers bear the costs.
- A widespread switch to ENDS would reduce exposure to second-hand tobacco smoke. E-cigarettes pose no material risk to bystanders³².
- The quality of products available from reputable manufacturers is now very high and they are on widespread sale in the European Union, North America and throughout Asia without any major problems.
- There is a growing international experience with the regulation of ENDS as consumer products, and, by changing its approach, Australia has the opportunity to take a leadership role in these developments.
- It would be better for Australia to have its own legitimate and properly regulated supply chain and to have responsible producers contributing corporate and sales taxes as appropriate, and less international internet trade in high strength liquids.
- There is no reason to protect the cigarette trade in Australia from competition from superior low-risk products or erect regulatory barriers to entry that are so severe that only tobacco companies have the resources to enter the market, if any company does.

Misrepresentation of scientific findings by some academics and the media have combined to exaggerate risks but understate the benefits of e-cigarettes. There are no precedents for banning safer products while leaving the most dangerous products widely available. On the contrary, ENDS will *support* a tobacco control agenda by giving smokers options to respond to increasing taxes and other controls on smoking. ENDS offer far safer options to smokers than coping with high taxes by switching to buying cigarettes on the black market.

³¹ Hall W, Gartner C, Forlini C. Ethical issues raised by a ban on the sale of electronic nicotine devices. *Addiction* 2015; **110**:1061–7 [[link](#)]

³² 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 [[link](#)]

Annex 2: Comment on proposal to amend the Poisons Standard entry for nicotine

f.2 The experience of users

Ministers, officials and regulators should be mindful of the human consequences of their decisions and avoid dehumanising the 2.8 million Australians who smoke. Vapers in Australia³³, the United Kingdom³⁴ and the United States³⁵ provide moving and inspiring testimony of their experience in using ENDS to quit smoking. Three examples of thousands of user testimonials are included below in their own words:

Example of experience from Australia

“It’s really hard to believe it’s been a year. Never in my wildest dreams did I think that I could really quit smoking and make it last this long. I figured my addiction would kill me one day. Now, I am in great health, have managed to slim down to what I weighed in my 20’s, and am fitter than I have been in years. I’ve tried to convert many people, but so far have only succeeded with one friend. I hope to continue to pay forward the time that the Brisbane lady gave me at the airport one year ago and will chat to anyone in the street about vaping.

Example of experience from the UK

“Vaping has probably saved my wife’s and my own life, I was a smoker for 50 years, nothing I have ever tried has had the impact of vaping, this alone was the only thing that saved me, how can governments legislate against something that is saving so many peoples lives.

Example of experience from the United States

“I had been a pack-and-a-half a day smoker for 25 years, the majority of my life. I had tried to quit for about a third of that, using methods like the gums, but without success—I could only ever quit for a few days at most. In December of 2014 I first tried vaping, exploring a variety of vaporizers and fluids. I cut my smoking down dramatically, and was a dual user for about a month and a half. On my birthday in the following January, I threw my cigarettes away by plan, and have been an EX-smoker for the many months since then.

f.3 The preferences of users

A 2014 survey of Australian vapers³⁶, an important group of notional beneficiaries of Australia’s policy approach, drew the following conclusion about attitudes to regulation:

E-cigarette users in Australia are in favour of e-cigarettes being regulated as long as those regulations do not impede their ability to obtain devices and refill solutions, which they view as important for them to remain smoke free. These views align with some aspects of appropriate policy designed to maximise the public health potential of e-cigarettes in society, but conflict with some of the proposed regulatory models. Governments should consider how future regulation of e-cigarettes will affect current consumers while helping to maximise the number of smokers who switch to e-cigarettes and minimise the possibility of non-smokers becoming addicted to nicotine.

The Secretary should reflect on the justification for state intervention to *prevent* smokers adopting vaping. There is now every reason to encourage rather than discourage these user experiences in Australia. There is no reason for any government to place obstacles in the way of smokers making the life-saving transformations described in the testimonials above and thousands of others.

³³ AussieVapers forum, Your story. [\[link\]](#)

³⁴ Counterfactual. UK vaping testimonies. [clivebates.com](#). [\[link\]](#)

³⁵ Consumer Advocates for Smoke-free Alternatives Association (CASAA), E-cigarette user testimonials. [\[link\]](#)

³⁶ Fraser D, Weier M, Keane H, *et al.* Vapers’ perspectives on electronic cigarette regulation in Australia. *Int J Drug Policy* 2015;**26**:589–94. [\[link\]](#)

**Annex 3: Response of 21 experts to Therapeutic Goods Administration –
a detailed critique of TGA reasoning for rejection of the rescheduling
proposal**

February 2017

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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Annex 3: Comments on the reasoning of the TGA in rejecting a proposal to reschedule 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.

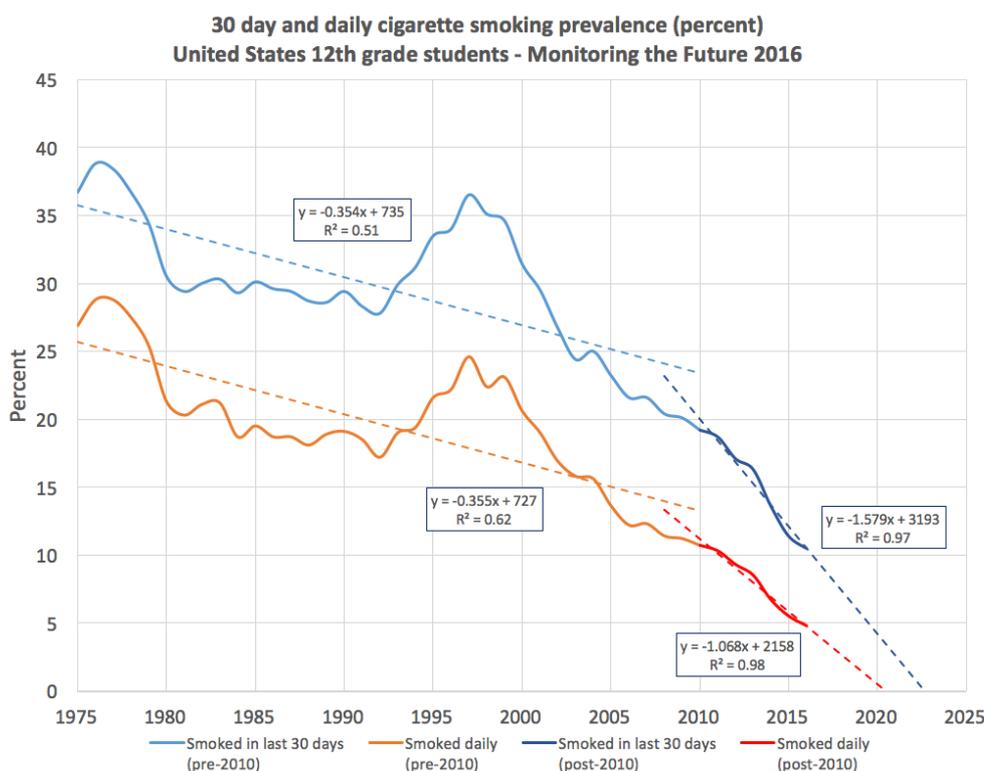
³ Farsalinos KE, Poulas K, Voudris V, Le Houezec J. Electronic cigarette use in the European Union: analysis of a representative sample of 27 460 Europeans from 28 countries. *Addiction*. 2016 Jun 24; [\[link\]](#)

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. [\[link\]](#)

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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 [\[on-line\]](#)

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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. [\[link\]](#)

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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. [\[link\]](#)

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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 [\[link\]](#)

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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; [\[link\]](#)

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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. [\[link\]](#)

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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).

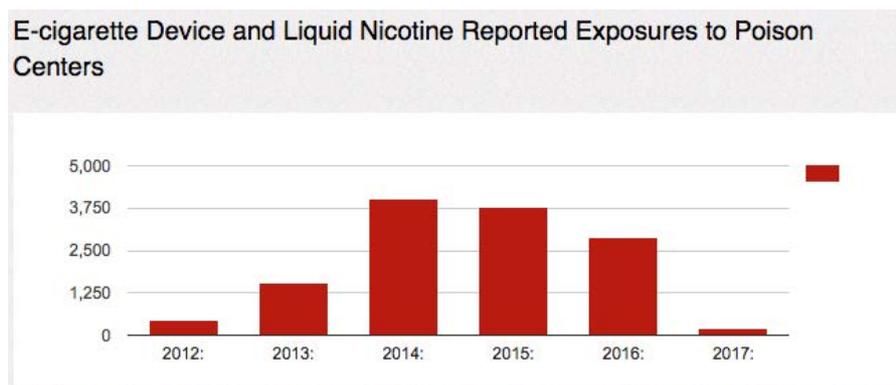
Substance (Major Generic Category)	All substances	% ^a	Single substance exposures	% ^b
Analgesics	291,062	11.29	187,329	9.73
Cosmetics/Personal Care Products	199,291	7.73	192,552	10.00
Cleaning Substances (Household)	198,018	7.68	178,973	9.29
Sedative/Hypnotics/Antipsychotics	150,715	5.85	55,653	2.89
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, [\[link\]](#)

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- 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. [\[link\]](#)

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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 [\[link\]](#)