Parliament of Australia Senate Standing Committees on Community Affairs
Vaporised Nicotine Products Bill 2017
Comments on the draft Bill

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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 provides 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 overstretching legilations 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	**Interstate Road Transport Regulations 1986** At the end of regulation 51B add: For the purposes of section, ***smoking*** means smoking a tobacco product using a combustion process.
None	**Air Navigation Regulations** At the end of regulation 37 add: For the purposes of section, ***smoking*** means smoking a tobacco product using a combustion process.

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 7[3]. 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)b[4] in 2014. However, it has no basis in science or risk management and attracted criticism from the scientific expert community[5] based on widespread misunderstanding of the risk posed by nicotine[6].

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/ml[7]. 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

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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/ml[8]

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 unsatisfying[9]:

   > *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.

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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
Therapeutic Goods Act 1989 **3 After section 52E** Insert: **52EAAA Certain products to be treated in the same way as tobacco** (1) The Secretary must ensure that the current Poisons Standard applies in relation to: (a) nicotine in electronic nicotine delivery systems in concentrations no greater than 20 mg/mL; and (b) nicotine in tobacco prepared and packed for heating; in the same way as it applies in relation to nicotine in tobacco prepared and packed for smoking.	***Therapeutic Goods Act 1989*** **3 After section 52E** Insert: **52EAAA Certain products to be exempted from the Poisons Standard Schedule 7** (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: (a) nicotine in tobacco prepared and packed for smoking; (b) nicotine in tobacco prepared and packed for heating; (c) nicotine in smokeless tobacco prepared and packed for sucking or chewing; (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

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 Standard[11] (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 Law[12] 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	After section 2 of the draft Bill insert a new section: 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. (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.

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 1992[16] 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 law[19]. The system also functions with industry-specific codes. The ABAC Responsible Alcohol Marketing Code[20] 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.

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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

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 Poison 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.

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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 rescheduling of nicotine to lift the *de facto* prohibition

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