Response ID ANON-BVEN-CX5K-6

Submitted to Proposed reforms to the regulation of nicotine vaping products
Submitted on 2022-12-23 02:40:38

Survey contents

Privacy and your personal information

Introduction

1 What is your name?

Name:
Richard Pruen

2 What is your email address?

Email:
richard@pruen.co.uk

3 Which best describes your response?

I am responding as an individual

4 If you are from an organisation, is your organisation a:

Not applicable

If other, please specify::

5 What is your position in the organisation?

Please provide details here: (leave blank if not applicable):

6 Which best describes you?

None of the above/personal interest (go to next page)

7 Please specify what type of health care professional are you?

Other (go to next page)

8 Are you an authorised prescriber?

No (go to next page)

Conflicts of interest (actual or perceived)

9 Have you or your organisation ever received services, assistance or support (whether monetary or non-monetary in nature) from the tobacco industry and/or e-cigarette industry? If this scenario applies to you or your organisation, please provide relevant details in the textbox.

Yes

If you have selected 'yes', please provide details here. Otherwise, please state 'no input'::

I owned a company testing electronic cigarettes for compliance with UK and other standards, as well as carried out investigations of failures including battery failure. I also worked on R&D and provided consulting services on for example battery protection circuits, chargers etc. Payment was from user fees for testing, government agencies, trade associations, and sometimes individuals or companies carrying out due diligence testing or failure mode analysis.

10 Have you or your organisation ever provided services, assistance or support (whether monetary or non-monetary in nature) to the tobacco industry and/or the e-cigarette industry? If this scenario applies to you or your organisation, please provide further information in the textbox.

Yes

If you have selected 'yes', please provide details here. Otherwise, please state 'no input'::

I assisted in writing standards for UK vaping products (PAS 54115 A guide for the importation and sale of electronic cigarettes and directly related products, with product safety testing methods) and proposed an IEEE standard project number P2800. Several sampling machines were supplied to others testing electronic cigarettes, and other custom test equipment, the supplied equipment presumably used to carry out tests on electronic cigarettes as designed. As academic and test houses purchased this equipment it is assumed this was paid for by test fees, or grants to carry out tests on electronic cigarettes, again possibly linked to taxes etc from tobacco and or electronic cigarette sales. The same funding source as government agencies, politicians and others working in the field.

11 If you select continue, you can answer the questions in the consultation paper online. Alternatively, you can upload your submission as a standalone document if you would prefer. Do you wish to upload your submission as a separate document?

No

Options for border control

12 Which border control option for regulating NVPs is preferred by you? Why?

6. Any other option (please explain).

Please provide details here::

Firstly please ignore the previously saved but incomplete response, I have been unable to access it via the token to complete it, this response should be substituted instead, thanks.

Given that vaping products are small and several years of nicotine supply for one user can be contained in a one-litre bottle. Enforcement will be extremely difficult as has already been found with disposables.

I suggest a new approach, which would be to have legally regulated and tested vaping devices available and to allow imports of these. This would require standards for the quality and environmental impact (recycling should be built in for especially disposable products). I believe this to be the best chance to stop the flow of black market products, by rendering smuggling etc uneconomical.

Allowance should be made for travellers, or those visiting Australia from countries that allow vaping to bring their normal device with them, as well as a supply of liquid and consumables for personal use. If any paperwork is required it should be quick and easy to obtain at minimum cost.

13 Would any of these options have an impact on you? How?

Yes

Please provide details here::

I have relatives in Australia and would like to visit, but would not wish to be forced to return to smoking for the duration of my visit.

14 If the border control regulations are changed, how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary, before the reforms come into effect?

Time required before reforms come into effect (in months)::
N/A

Please provide details here::

not applicable

Options for pre-market assessment of NVPs by TGA

15 Which option (for pre-market assessment of NVPs) do you prefer? Why?

5. Any other option (please explain)

Please provide details here::

A consumer pathway for standards-based approval should be available, and easily accessible for responsible vendors and shops. Requirements for age checking are reasonable and should be much easier to enforce than trying to squash black market sales to youth. Instead wide availability to those who benefit from access to the devices (adult smokers) would eliminate the incentives for a black market, and thus it will collapse.

Manufacturing within Australia should be encouraged as such businesses will be easier to regulate and contribute to the local economy while providing jobs.

An additional pathway should be available to allow products that are passed as medical devices, and thus should have to prove effective levels of nicotine are delivered to prevent cravings. Performance should be equivalent to NRT or better at helping people who smoke switch to safer nicotine.

The two pathways should be functionally separate but might include shared standards for the safe venting of batteries on the rare occasions that failure

occurs, and other physical safety issues.

16 Would any of these options have an impact on you? How?

Yes

Please provide details here::

As a probable visitor to Australia, only if purchasing locally made liquid refills or devices.

17 If changes are made to pre-market assessment of NVPs by the TGA, how much time would you require, if any, to become familiar with the reforms, and to organise procurement of compliant products as necessary before the reforms come into effect? What impact would any requirement to pay a fee have on you?

Time required before reforms come into effect (in months)::
N/A

Please provide details here (including any impact of a fee requirement)::

not applicable

Minimum quality and safety standards for NVPs

18 Which option to restrict flavours in NVPs do you prefer? Why?

Make no change to the list of currently restricted flavouring agents in NVPs

Please provide details here::

Flavouring compounds should only be excluded for safety reasons, and a blacklist of compounds that should not be used seems to work in the UK/Europe. There is every reason to adopt an already working system, it will also be easier to keep up to date if using the same sort of system.

19 Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients?

No

Please provide details here::

No further restrictions

20 Do you support introducing plain packaging requirements for NVPs? If so, should this entail packaging similar to other prescription-only medicines, or should additional measures be considered?

No

Please provide details here::

Plain packaging should not be required, at least for consumer items, indeed it may encourage adult smokers to switch. The usual standards for packaging should apply, including warning labels, child-resistant caps etc.

21 Do you support introducing additional warning statements for NVPs? If so, which warning statements should be included? How would this align with the treatment of NVPs as a prescription-only medicine?

No

Please provide details here::

A nicotine warning may be appropriate for products that contain nicotine, plus the usual recommendations to keep out of reach of children.

22 Do you support restricting nicotine concentrations in NVPs to 20mg/mL (or base form equivalent concentration for nicotine salt products)? If not, what alternative do you support?

No

Please provide details here::

I believe a realistic limit is 80mg/ml, this level provides safety advantages in that it is nearly impossible to overdose by drinking the liquid, the body will expel the liquid by vomiting before sufficient is absorbed to be life-threatening. The limit allows for heavy smokers to obtain enough nicotine to successfully switch (a problem with the UK's 20mg limit) and allows for lower power pod devices that use higher nicotine due to low output.

23 Do you support limiting the maximum volume of liquid NVPs? If so, what maximum volume should be specified?

No

Please provide details here::

Limiting volume achieved no benefits in the UK but significantly increased plastic bottle waste, on environmental grounds a bad idea and of no use from a safety point of view.

24 Do you support preventing access to disposable NVPs?

No

Comments::

Disposables should be allowed, but only if they comply with basic recycling rules, such as the removability of batteries, and the use of recyclable or biodegradable materials. There should also be a viable pathway to recycle them before they are allowed for sale. Encourage rechargeable or rechargeable/refillable disposables where possible, where the device is only disposed of after the atomiser reaches end-of-life.

25 Would any of the options set out in questions 18 to 24 have an impact on you? How?

No

Please provide details here::

not applicable

26 If changes to product quality and safety standards are made, how much time would you require, if any, to become familiar with the reforms, and to organise the procurement of compliant products as necessary, before the reforms come into effect?

Time required before reforms come into effect (in months)::
N/A

Please provide details here::

not applicable

27 Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?

Yes

Please provide details here::

As above, recyclability particularly for single/limited-use devices.

Clarifying the status of NVPs as 'therapeutic goods'

28 Do you support regulating NVPs that contain nicotine, but are not labelled as containing nicotine, under the therapeutic goods framework?

No

Please provide details here::

The question is ambiguous.

Products that contain unlabeled ingredients should be dealt with under the rules for consumer goods, and accurate labelling should be required the same as any other item.

Standalone submissions and additional documents

29 If you wish to provide a standalone submission or any other relevant documents, please upload them here.

Please attach a copy of any documents you wish to include:
No file uploaded

Publication of submissions

30 To proceed, please select from the options below how you would like the TGA to deal with your submissions:

I agree to the TGA publishing my response in full.