Response ID ANON-EJTE-W31W-T

Submitted to Proposed reforms to the regulation of vapes
Submitted on 2023-09-15 11:31:57

Survey contents

Privacy and your personal information

I consent to the TGA collecting the information requested in this survey about me, including any sensitive information, for the purposes indicated above.

Agree:
Yes

Acknowledgement

I agree.

Yes.:
Yes

Introduction

1 What is your name?

Name:
Dr Colin Paul Mendelsohn

2 What is your email address?

Email:
mendel@bigpond.net.au

3 What is your organisation name?

Organisation name or N/A:
N/A

4 Please choose a stakeholder group that best describes you or your organisation.

University, researchers and experts

*If other, please specify::

5 Which best describes your response?

I am responding as an individual.

6 Are you an authorised prescriber?

No (please go to next page

Conflicts of interest (actual or perceived)

1 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.

No

If you have selected yes, please provide details here. Otherwise, please state 'Not Applicable'::

Not Applicable

2 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 'Not Applicable':

I participate in research, teaching, academic writing and advocacy for tobacco harm reduction based on the growing evidence that it creates a substantial net public health benefit. My advocacy indirectly supports the e-cigarette industry which manufactures and sells tobacco harm reduction products.

Proposal 1 -Restrictions on importation, manufacture and supply of all vapes .

1 Do you support the proposed approach to ban disposable single use vapes absolutely and all other vapes, except those for legitimate therapeutic use in compliance with the TG Act?

No

2 How would you anticipate industry and consumers to respond to a ban on the importation, manufacture and supply of non-therapeutic vapes?

* Please provide answer here. :

The definition of 'therapeutic' use in this document is too narrow (cessation or treatment of nicotine addiction). People use nicotine for other benefits, such as to improve attention, working memory and cognitive function. It also reduces anxiety and relieves depression and helps to control weight. It is beneficial for ADHD and schizophrenia. These benefits are therapeutic and adults should have access with informed consent.

The vast majority of adult vaping is therapeutic, either as a short-term quitting aid or as a long-term safer alternative to smoking. While only short-term use is recommended, research suggests that vaping may play an important role in preventing relapse.

Non-therapeutic use is rare. Less than 1% adult never-smokers vape, in international studies. Some of these users would have taken up smoking if vaping was not available.

This proposal is highly unlikely to be successful for non-therapeutic and therapeutic vaping.

Vapes are a highly popular consumer product, being used by an estimated 1.3 million Australian adults. Even after 18 months of the currently laws, over 90% of use is illegal. If access is made more difficult, people will continue to access them illegally.

The long history of prohibition of illicit drugs shows that it leads to very little impact on supply by the black market and virtually no impact on long-term use. This is consistent with the law of supply and demand. For example, in the Australian Drug Trends report (IDRS 2022) 87% of drug users said that heroin was easy or very easy to access, despite being banned since 1953.

Under the current regulations, massive quantities of illicit vaping products are being imported by the same organised criminal networks and outlaw motorcycle gangs that import illicit tobacco. The Chief of the ABF has admitted that they are unable to intercept significant numbers of these products and are rightly prioritising dangerous drugs, weapons etc.

The predictable outcome will be
• Some vapers will return to smoking. Smokers will find it more difficult to switch to vaping
• The black market will continue to thrive and will go underground, supplying high-nicotine, mis-labelled products to teens
• There will be no regulation over quality or safety of most products
• Loss of government revenue
• Substantial costs of enforcement, policing, justice and prison systems
• Closure of legal, legitimate vape businesses
• Increased criminal gang activity includes standover tactics, extortion and intimidation, fire-bombings of tobacco and vape shops, corruption of officials, gang turf wars

3 Do you support removal of the personal importation scheme exception for vapes? If not, what would be the impact on you?

No (* if not, what would be the impact on you?)

* What would be the impact on you?:

Removal of the PIS will lead to
• Some vapers will return to smoking
• Smokers will find it more difficult to access the safer alternative should they wish to do so
• The black market will step up to provide illegal, unregulated products
• Purchase of unsafe products from the black market
• More dangerous home mixing

4 Do you agree with the proposal to retain a traveller's exemption, including the proposed limits?

Yes

5 Do you support the proposed approach to prohibiting the advertisement of all vapes (subject to limited exceptions)?

No

6 [If applicable] Suppliers, what part of supply chain do you occupy?

Not applicable

* Other -specify your role in supply chain.:

6 (a) What proportion of your sales volumes is attributable to vape sales [i.e. quantity of vapes sold]?

Please provide details here: (or mark Not applicable).:
Not applicable

6 (b) What proportion of your sales revenue is attributable to vape sales [i.e. revenue earned from sales]?

Please provide details here: (or mark Not applicable).:
Not applicable

6 (c) What impact would the proposed measures have on your sales volumes?

Please provide details here: (or mark Not applicable).:

Not applicable

6 (d) What impact would the proposed measures have on your sales revenues?

Please provide details here: (or mark Not applicable).:
Not applicable

6 (e) What proportion of your vapes sales is attributable to disposable single use vapes versus refillable products?

Please provide details here: (or mark Not applicable).:

Not applicable

6 (f) How would restricting the importation, manufacture and supply of disposable single use, and non-therapeutic, vapes in Australia impact you?

Please provide details here: (or mark Not applicable).:

Not applicable

6 (g) How much stock do you have in Australia currently and how long would it take to sell that stock?

Please provide details here: (or mark Not applicable).:

Not applicable

6 (h) What would be the cost to you if you were required to dispose or otherwise move on existing stock?

Please provide details here: (or mark Not applicable).:

Not applicable

Proposal 2 -Changes to market accessibility requirements, including better regulation of device components.

7 Do you support the approach to require a pre-market notification of compliance with TGO 110?

Yes

8 [If applicable] For suppliers of therapeutic vapes, what impact would the proposed notification system have on your supply model and what transition period would you require to comply with the new notification requirement?

Please provide details here: (or mark Not applicable).:

Not applicable

9 Do you support the proposed access to vapes under the SAS C notification system?

Yes

9 (a) What impact would this pathway have on facilitating patient access to therapeutic vapes?

Please provide details here: (or mark Not applicable).:

This would reduce one barrier for doctors to prescribe nicotine vapes. However, if the doctor is required to notify the TGA after every individual prescription, the time and administrative burden would be excessive and unworkable. A 6-monthly notification as for the current AS scheme would be sufficient.

However, doctors in Australia are poorly informed about vaping, are exposed to constant negative messaging and have medico-legal concerns about nicotine prescriptions. As a result, the vast majority would still be unwilling to write nicotine prescriptions and legal access would still be greatly restricted.

Instead vapes should be regulated as adult consumer products, sold from licensed retail outlets with strict age verification, like alcohol and tobacco, as they are in all other western countries. They should be regulated by the Australian Competition and Consumer Commission, not the TGA. Nicotine vaporisers are consumer products used almost exclusively as a less harmful substitute by smokers who can't or won't quit smoking or consuming nicotine.

10 [If applicable] For prescribers, would the proposed new pathway likely change your approach to prescribing therapeutic vapes? How?

Not a prescriber of vapes

* How new pathway will change your approach to prescribing ttherapeutic vapes?:

11 [If applicable] For prescribers, which access pathway (SAS B, SAS C, or AP) would you envisage using to prescribe therapeutic vapes? Why?

Not a prescriber of vapes

Please tell us why:

12 [If applicable] For prescribers, would integration of SAS or AP applications or notifications into existing clinical software systems ease the administrative burden and/or encourage you to use the new pathway?

Not a prescriber of vapes

13 Do you agree with the proposal to regulate both e-liquid and device components of unapproved vapes under the same part of the TG Act for simplicity?

No

14 Will these changes have direct or indirect impact on you? Please provide details.

No

Please provide details here::

15 Do you require time to adjust to these requirements? If yes, how long?

No

15 (a) How long do you require to adjust to these requirements?

Not Answered

Proposal 3 - Improving quality standard for unapproved (unregistered) vapes)

16 Are the definitions of tobacco and mint flavours appropriate? If not, please provide reasons.

Yes

* Please provide reason here.:

17 Do you agree with the proposed upper limit on the concentration of menthol in vapes? If not, please provide reasons.

No (* please provide reason below)

* Please provide reason here:

There is no evidence that reducing the strength of menthol will reduce vaping by young people.

Furthermore, there is no evidence of any clinical relevance for the claim that "Menthol reduces nicotine breakdown within the body and potentially masks the early warning symptoms of respiratory problems. The link provided in the document #18 is broken.

To the contrary, restricting or weakening flavours generally will have little effect on youth vaping but will reduce the appeal of vaping to adult smokers and increase smoking.

The very weak menthol limit proposed is too low and is likely to be of limited benefit in supporting quit attempts.

Flavours are not the primary reason for youth experimentation with vaping. The main reasons kids give for vaping are curiosity and peer pressure, followed by liking the flavours.

Restrictions on flavours may even increase youth smoking. A study in San Francisco found that a ban on flavours led to increased smoking by high school students, suggesting that vaping flavours was diverting young people from smoking. Other studies have found that bans have no effect on youth vaping and users simply switch to other available options or devices.

Furthermore, the evidence suggests that a flavour ban would increase smoking overall in the population and have a net harmful effect on population health, especially for low socio-economic groups. While there may be some reduction in vaping, some adults would switch to smoking, a far more harmful alternative.

Flavours are an integral part of the appeal of vaping for adult smokers and play an important role in the initiation of vaping for current smoker. Restricting or diminishing flavours would undermine the interest in vaping and lead to more smoking.

Flavoured e-liquids are associated with increased quit rates compared to non-flavoured or tobacco flavours and reduce the rate of relapse. Those who vape with flavours also have higher odds of making a quit attempt.

Flavour restrictions would also lead to increased black-market supplies and home mixing. In one study, 50% of vapers said they would find a way to buy their preferred flavour if it was banned.

18 [If applicable] Importers, manufacturers and suppliers, would the restrictions on flavour proposed above impact you?

Not applicable

19 Do you agree with the proposal to require pharmaceutical-like packaging and presentation for vapes, e.g., vapes manufactured in black, white or grey coloured materials, predominantly white background on packaging, clear warning statements and other restrictions on labels in addition to other selective TGO 91 requirements for vapes?

No (* please provide reason below)

20 [If applicable] What impact will the labelling and packaging changes have on you?

* Please provide detail here.:

Plain/standardised packaging is inappropriate for vaping products and is disproportionate to the risk. Vaping is at least 95% less harmful than smoking. Plain packaging sends a message to smokers that vaping is harmful like smoking and may discourage adult smokers from switching to the far safer product.

Health warnings comparing the risks of vaping to smoking, are more appropriate, for example

• 'This product may be addictive but is a far less harmful alternative for adult smokers'.
• 'If you are a smoker, switching completely to vaping is a much less harmful option'.

The following are appropriate

• Warnings to keep out of the reach of children and avoid contact with eyes and skin
• Removal of images that appeal to youth, for example, cartoons, appealing characters
• An ingredient lists, including nicotine content, PG/VG ratio, expiry date and batch number, as well as contact details for the sponsor, bar codes for tracing

20 (a) How long would you need to transition your product to comply with the proposed requirements?

More than 12 months

21 Do you agree with our approach to allow only permitted ingredients in vapes, instead of trying to prohibit individual chemical entities from use in e-liquids?

No

22 [If applicable] Importers, manufacturers and suppliers, will your therapeutic vapes need any re-formulation or other changes to comply with the permitted ingredients and ingredient quality requirements?

Not applicable

22 (a) If product re-formulation is required, how long will you need to make these changes?

Not Answered

22 (b) If product re-formulation is required, what financial or business impacts would be associated with them?

Provide detail here or put 'Not Applicable':

Not applicable

23 Do you support applying the same regulatory controls to zero-nicotine therapeutic vapes, as for NVPs?

Yes

24 What is the overall business cost on you to comply with a strengthened TGO 110?

Please provide details here: (or mark Not applicable).:

Not applicable

25 Do you agree with the proposed requirements under TGO 110 that will apply to unapproved device components of vapes?

No

26 [If applicable] Suppliers, do you intend to register any vaping device on the register as an approved medical device?

No (if no, why not?)

If no, why not?:

Not applicable

27 [If applicable] Importers, manufacturers and suppliers, are you familiar with relevant US FDA, or MHRA guidance and/or EU standards covering vaping devices?

Not applicable

27 (a) Do your vapes currently comply with relevant US FDA, or MHRA guidance and/or EU standards covering vaping devices?

Not applicable

27 (b) If not, what requirements do you meet?

What requirements you currently comply with?:

Not applicable

27 (c) How long would it take to achieve compliance with relevant standards?

More than 12 months

28 [If applicable] Importers, manufacturers and suppliers, are your vapes manufactured at facilities that hold relevant international standards for Quality Management Systems, such as ISO9001 or ISO 13485?

Not applicable

Proposal 4 - Strengthening domestic compliance and enforcement mechanisms

29 Do you have any other comments in relation to this proposal?

Yes (* provide your comments below)

Comments:

As mentioned previously, this proposal amounts to ‘de facto’ prohibition and will not be effective. In fact, it will make the current regulatory failure worse. Doubling down on a failed model is incredibly poor policy.

Surveys have shown that very few consumers are willing to go to a doctor and then a pharmacist to access vapes legally. Currently only 2% of vapes are purchased through this pathway.

The demand for nicotine vapes will not diminish. Most vapers will continue to purchase products through illegal channels.

We cannot stop the importation of heroin, cocaine and ice, and we will not be able to stop the importation of illegal vapes. The vast majority of illegal imports will not be intercepted at the border. An estimated 90-100 million vapes are imported illegally into Australia each year. Of the 8 million containers arriving in Australia every year, only 1-1.5% are scanned.

The black market will continue to operate but will go further underground. The war on nicotine will have the same predictable consequences seen for decades in the war on drugs:

• Control by criminal networks, with money laundering, profits used for dangerous crimes, gang and turf wars, murders, corruption of officials, extortion, intimidation and fire-bombing of tobacco and vape outlets
• Dangerous, unregulated drug supply
• Continuing black market and sale to underage users
• Huge costs for policing and enforcement, the justice system and prisons
• Diversion of the authorities and Border Force from far more important activities
• The Australian vape industry will be decimated, with job losses, bankruptcies and loss of government revenue
• No taxation will be collected to the vast majority of vapes sold
• Reduced access to vapes will result in more smoking and more smoking-related death and disease
• The human right of smokers to readily access a far safer product to improve his/her health will be largely denied

Supplementary questions

30 [If applicable] Suppliers, please confirm if you intend to continue to supply therapeutic vapes under the proposed reforms described?

Not applicable

* Product range :

30 (a) How long would it take to meet the new requirements?

Not Answered

31 [If applicable] Suppliers, please confirm if you intend to register your therapeutic vapes in the next 2 years?

Not applicable

What guidance and/or clarity of supporting data requirements do you need from TGA:

Publication of submissions

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.

I request the TGA to consider redacting sensitive commercial information from my response before publication:
No

Please specify sensitive commercial inforation you want redatced :