Public Health Association
AUSTRALIA

Submission on targeted consultation on further details of proposed reforms to the regulation of vapes in Australia

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Contents

Preamble

The Public Health Association of Australia

The Public Health Association of Australia (PHAA) is recognised as the principal non-government organisation for public health in Australia working to promote the health and well-being of all Australians. It is the pre-eminent voice for the public's health in Australia.

The PHAA works to ensure that the public's health is improved through sustained and determined efforts of the Board, the National Office, the State and Territory Branches, the Special Interest Groups and members.

The efforts of the PHAA are enhanced by our vision for a healthy Australia and by engaging with like-minded stakeholders in order to build coalitions of interest that influence public opinion, the media, political parties and governments.

Health is a human right, a vital resource for everyday life, and key factor in sustainability. Health equity and inequity do not exist in isolation from the conditions that underpin people's health. The health status of all people is impacted by the social, cultural, political, environmental and economic determinants of health. Specific focus on these determinants is necessary to reduce the unfair and unjust effects of conditions of living that cause poor health and disease. These determinants underpin the strategic direction of the Association.

All members of the Association are committed to better health outcomes based on these principles.

Vision for a healthy population

A healthy region, a healthy nation, healthy people: living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health for all.

The reduction of social and health inequities should be an over-arching goal of national policy and recognised as a key measure of our progress as a society. All public health activities and related government policy should be directed towards reducing social and health inequity nationally and, where possible, internationally.

Mission for the Public Health Association of Australia

As the leading national peak body for public health representation and advocacy, to drive better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health.

Introduction

PHAA welcomes the opportunity to provide input to this consultation. We have entered a response into your online survey portal. However, that portal did not provide space for us to enter supporting commentary explaining our positions. This document therefore provides further text intended to form part of that survey response. Please accept this as an attachment to that response, and apply all your proper protocols regarding publication as you think appropriate.

For brevity all questions which merited a 'not applicable' response in the survey have been omitted from this document.

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

Question 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?

Yes. The PHAA supports the proposed approach to ban disposable single use vapes absolutely, and all other vaping products except those for legitimate smoking cessation use, overseen through the Therapeutic Goods Act.

The recent evidence from National Centre for Epidemiology and Population Health (ANU) and other sources makes very clear that vaping products are harmful products. The arguments have been extensively canvassed previously. PHAA strongly supports the reforms adopted by the Australian Government in tandem with all state and territory governments.

We would also emphasise that the matters under consultation here from part of a wider comprehensive approach to all aspects of nicotine products, including tobacco, vaping and other novel nicotine products.

We are also pleased to note the TGA's clear precautions against the inevitable efforts of the tobacco/vaping industries and allies to undermine and circumvent the policy framework being developed.

It is highly important that the overall policy approach, by all governments, be as comprehensive, integrated and well-coordinated as possible. The framework therefore needs to be complemented by strong implementation and enforcement, and strong and effectively implemented controls on advertising.

Regarding the specific mention of 'disposable' products, in addition to the very problematic role of disposable vapes in marketing to children and other new users, these products raise significant environmental concerns. Merely being termed 'disposable' does not imply that after use these products vanish after use without cost; in fact serious issues of environmental waste management are associated with these products.

Finally, we again express our concerns with the use of the adjective 'therapeutic' in respect of any vaping products, including those which would remain permissible as part of the cessation-under-medical-supervision exemption model. Neither vaping products generally, nor any specific vaping product, have ever been assessed by TGA as satisfying therapeutic definitions (indeed, none have ever been submitted in Australia for such assessment).

Use of the expression 'therapeutic vapes' in official documents – including the current consultation paper – is misleading to stakeholders and to the general public. The textual implication that vaping products have

such a character may expose the Commonwealth to legal complications should there be litigation between the nicotine industry or related stakeholders and governments. Official documentation should therefore merely refer to "vaping products" without adjectival addition, even where they are being discussed as part of the medical exemption model.

More broadly, there is a significant risk that such descriptions could be misinterpreted by the general public, or deliberately misused by product promoters.

With this in mind, it would be appropriate that labelling requirements (see Q.19) should include a requirement that vaping products be labelled "this is not an approved therapeutic product" or similar message.

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

During consideration of this package, we expect the industry to oppose adoption of this regulatory package by any means it can invent, including through lobbying to water down the package during adoption, and by inventing new ways to circumvent its intentions once it is adopted.

After adoption, we would hope that all industries and retail sectors will comply with the new law. Needless to say, governments will have an enforcement challenge dealing with those prepared to defy the law for profit.

Anticipating that industry will seek any possible means of advertising and promotion of its products to a mass audience, strong and effective advertising controls must be legislated and enforced, including through social media platforms.

Consumers will react in various ways, but we would expect that the clear signal sent by general prohibition of e-cigarettes will have a significant effect in reducing vaping uptake and continuation, working in tandem with other policies. Emphasis should be placed on there being every effort to maximise the key category of people who *do not become* 'consumers' in the first place, as a result of the Government's policies.

In Australia, as elsewhere, there is substantial community concern about vaping by children and young people. Further, nearly three quarters. Nearly three quarters (73%) of those aware of vapes/e-cigarettes agreed that they are unsafe to use, including 50% who strongly agreed with this. These proportions are significantly higher than in 2019 (60% and 36% respectively) or 2017 (46% and 25% respectively). Two-thirds (65%) of those aware of vapes/e-cigarettes also agreed that they are unsafe to use around others. (https://www.cancer.nsw.gov.au/about-cancer/document-library/nsw-smoking-health-survey-2021).

Question 3. Do you support the proposal to remove the personal importation scheme exception for vapes? If not, what would be the impact on you?

The medical cessation model having been accepted, we would support simplification of the clearly complex multiple regimes by which those accessing vaping products under medical supervision come into possession of them. A system where all supply of products occurs through pharmacies, on medical prescription, for regulated products lines, would be a welcome result from the Government's new policy settings. To that end, the multiple systems for individual importation should be consolidated and simplified to the greatest extend possible.

Specifically, we support the proposal to remove the personal importation scheme exception for vaping products.

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

Yes. If a person who is obtaining vaping products under medical supervision under the emerging policy happens to travel, their ability to access and carry permitted products should not be additionally constrained. Policy settings should be designed to allow the prescription model to work smoothly.

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

Yes. There should be no exceptions. The only parties who need to receive any product information about specific products are prescribing doctors and pharmacists, and it is from those sources that prescription-model patients should in turn receive product information. Ordinary 'advertising' to a 'consumer' market has no place in the emerging policy framework, including for the cessation-oriented prescription model.

In addition, promotion and 'advertising' by manufacturers or distributors of vaping products to medical and pharmacist professionals should also be prohibited.

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

2.1 Pre-market notification of TGO 110 compliance

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

Yes, we see this new proposal as an advance on the proposals put forward by the TGA in December 2022, for these reasons:

- It avoids an inappropriate proposal which, through requiring the TGA to issue a public assessment, had the risk of creating unfounded public impression that the products had been proven after official examination to be 'therapeutic 'in nature
- It is a simpler model, placing the onus of proving compliance with regulatory standards on product manufacturers/distributors, with a workable system of accountability,
- It will be significantly less demanding on the resources of the TGA, noting the possibility of the demands on the TGA to administer these reforms being substantial.

2.3 Regulation of device components

Question 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?

Yes. The key policy decisions having been decided, the law and regulations should be made as precise and simple as possible, for the convenience of the TGA as administrator, medical advisors to patients, patients themselves, researchers, and all other observers and commentators.

Our additional comment

(1) The wording of the requirement about nicotine content could be clarified, given the range of different forms that the nicotine component can take. The concentration of the nicotine component (base) of the e-liquid should not exceed 20mg/mL, regardless of whether it is in freebase, salt or any other form.

(2) As TGA is of course well aware, liquid nicotine is highly toxic, and that poisonings have occurred (Banks at al, *Electronic cigarettes and health outcomes: systematic review of global evidence*. Report for the Australian Department of Health. February 2022). This being so, all containers of such liquids should feature appropriate safety warning labelling – particularly focused on young people – that the liquid is poisonous, and specifically that it should never be directly drunk.

Proposal 3 – Improving quality standards for unapproved (unregistered) vapes

3.1 Enhanced requirements for e-liquid components

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

We have concerns about the mint flavour proposal in principle. This is a 'concession' without a health-related basis. No scientific health-promoting rationale for specifying any flavours, or for making a menthol/mint exception has been provided.

If TGA does adopt this proposal, then as in all regulations, definitions should be kept as simple and scientifically accurate as possible, and should ensure that there is no use of flavours for marketing purposes.

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

As per our answer to Q.16, we do not support the inclusion of any menthol in vapes.

If the Government adopts the menthol proposal, then the upper limit setting should ideally be based on actual evidence of efficacy, noting that no such evidence would seem to exist at present.

Question 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?

Yes. If the policy framework is that vaping products are only to be legal in the context of a prescription model, then all packaging requirements should be set to reinforce the impression on users that they are making use of a pharmaceutical intervention. The products should be packaged accordingly, and should be free of any irrelevant 'consumer appeal' visual packaging forms.

Research-based warning labels should certainly form part of the packaging restrictions.

It would also be appropriate that labelling requirements should include a requirement that vaping products be labelled "this is not an approved therapeutic product" or similar message.

Question 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?

In principle, as a prescription medical product supplied for a specific medical goal, the whole content of the products should be regulated.

We note that the transition from the current highly unregulated reality of vaping products may be complex, and the restrictive settings on product contents which may be determined at the start of this new regime may need to be revised as TGA comes into possession of better information about specific products contents and their health impacts. This implies that specific restrictions should be revisable by ministerial instruments, not set too specifically in the head legislation.

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

The reasons for capturing non-nicotine vapes in the one regime with nicotine vapes include that:

- The two kinds of products are at present entirely intermingled in the 'unregulated' distribution system. It has become clear that regulation of nicotine vaping products cannot be carried into effect without also prohibiting/regulating non-nicotine products.
- Currently there is clearly a very extensive practice of false and dishonest packaging and selling of *nicotine* products as being *non-nicotine* products, such that the honesty and integrity of manufacturers, packagers and retailers simply cannot be taken at face value.
- There are now, and would be under the new regime, severe enforcement burdens on regulators so long as the distinction between nicotine and non-nicotine products as two different classes of products is maintained.
- Non-nicotine products themselves still have adverse health consequences, and it is convenient to regulate them also in their own right, even in the absence of nicotine.

It follows that all vape products should be regulated as one products class, not as two separate classes.

Proposal 4 – Strengthening domestic compliance and enforcement mechanisms

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

We are aware of suggestions that vaping products should be available for supply from pharmacists alone, in the absence of supervision by a medical practitioner and appropriate prescription. This cannot be supported. The whole rationale for the exemption is one of medically supported efforts at smoking cessation, and there is clear evidence that the efficacy of various quit options depends highly on professional support given to the patient regarding their behavioural drivers and motivations. A model where vaping products are generally available from pharmacies without prescription creates a range of further concerns, downplaying the important role of GPs and risking access through pharmacies simply becoming a form of open retailing of these products.

Please do not hesitate to contact us should you require additional information or have any queries in relation to this submission.

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