Public Health Association
AUSTRALIA

Public Health Association of Australia submission on proposed TGA 110 – Standard for vaporiser nicotine

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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 our Board, National Office, State and Territory Branches, Special Interest Groups and members.

We believe that health is a human right, a vital resource for everyday life, and a 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.

Our mission as the leading national organisation for public health representation, policy and advocacy, is to promote better health outcomes through increased knowledge, better access and equity, evidence informed policy and effective population-based practice in public health. Members of the Association are committed to better health outcomes based on these principles.

Our vision is for a healthy population, a healthy nation and a healthy world, with all people living in an equitable society underpinned by a well-functioning ecosystem and a healthy environment, improving and promoting health and wellbeing for all.

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

Introduction

> "*The Therapeutic Goods Administration (TGA) is seeking comments on a proposed standard for vaporiser nicotine products*." (TGA Consultation paper, p.6)

The exercise of creating this standard is not happening in isolation. It is fundamentally important to recall that as of October 2021, in accordance with the unified policies and enacted legislation of the Commonwealth Government and of all of Australia's States and Territories, the only legal application of vaporiser nicotine products in Australia (including in regard to personal use, but also in regard to trade, sale and distribution) will be as an aid to smoking cessation, supervised by medical expertise and using those products only on prescription.

> "*The TGA recently announced a decision that, from 1 October 2021, consumers will require a doctor's prescription to import vaporiser nicotine into Australia, regardless of whether the product is for therapeutic or other use (Scheduling decision). This aligns with current State and Territory laws, which prohibit the supply of nicotine-containing e-cigarettes without a valid doctor's prescription*.
>
> *The Scheduling decision balances the importance of needing to prevent youth and non-nicotine users from taking up use of vaporiser nicotine while allowing current smokers to access these products for smoking cessation on their doctor's advice."* (TGA paper, p.9)

There is insufficient evidence that medically supervised vaporiser nicotine products assist smokers in quitting. There is further evidence that such a role is in fact NOT effective at a population level, may be associated with unacceptable adverse collateral consequences, and may serve to promote use of tobacco products among the young.[1]

It is therefore not at all surprising that this proposed Order deals only with 'unapproved' products and their usage – because no therapeutic usage has yet been identified. "*There are currently no TGA-approved vaporiser nicotine products registered in the ARTG*." (TGA paper, p.9). As far as is publicly known, no such product has even been yet submitted to TGA for evaluation as therapeutic. We are dealing here entirely with unapproved product usages which, by law, will need to be undertaken by one of the four "*access pathways for unapproved medicines*" mentioned on page 9 of the TGA paper. (Noting in passing that even the use here of the term "*medicines*" is potentially confusing.)

Note also that by law, unapproved products cannot make claims of therapeutic benefits, and the Order should be drafted to preclude permitting any such claims, whether deliberate or inadvertent.

Overall, while some regulatory details of the proposed Order might be of benefit to the health of specific prescribed users of vaporiser nicotine products, the Order must not do anything to create an impression that such products have achieved TGA approval.

Wider policy issues are important and deserve to be briefly noted. There is clear evidence that the policy decisions that allow vaporiser nicotine products to be available either on prescription, on an open market, or through illegal markets (which inevitably persist regardless of policy intentions, and even in the face of legislation and regulation), have the real-world impact of resulting in widespread and increasing nicotine addiction – especially among young people – and serious harm.

[1] https://openresearch-repository.anu.edu.au/bitstream/1885/211618/3/E-cigarettes%20smoking%20behaviour%20summary%20report%20final%20200924.pdf

Indeed, it is PHAA's position that the Personal Importation Scheme should be reviewed, and a prohibition on personal importation of nicotine liquid should be reinstated.

We also see it as important that the current proposal for a TGO standard be seen in the overall context of measures aimed at reducing smoking in Australia. PHAA is concerned at the reality that discussions about e-cigarettes and other novel nicotine products have served to distract attention from proven, evidence-based measures that will reduce smoking in all sectors of the community. It is critically important that the Government ensures the implementation of a comprehensive approach to smoking in Australia, including sustained and adequately funded national public education programs – which have been in abeyance for almost a decade – new policies relating to pricing, product regulation, smoke-free measures, and broad smoking cessation support activities.

Vaping as an (unproven) aid to smoking cessation will not provide a comprehensive answer to the disastrous level of harms caused by smoking and nicotine addiction in Australia, and should not be presented or marketed as having such a capability. Further, any moves to normalise access to vaporiser nicotine must be accompanied by very firm and strongly implemented curbs on any forms of direct and indirect promotion of such products by the commercial sector.

There is also the ethical public policy issue that nicotine industry planners are perfectly well aware of the practical enforceability limits of partly-regulated markets, and are skilled at promoting their products, especially to the young, in defiance of the health evidence and advice, the law and government policy. Such realities, together with ordinary public health precautionary principles, make a powerful case against any weakness in our regulatory policy regarding nicotine.

Noting the above policy considerations, the unified policy position of Australia's governments, and the impending settlement of the 'prescription-only' use of vaporiser nicotine products from October 2021, we proceed to offer answers to the detailed questions which TGA now posed regarding labelling, packaging, ingredient and so on of vaporiser nicotine products.

The best overall guidance on the TGA's questions is that the only standards which should be set are standards which support, and do not in any way contradict, the now clearly stated overall policy and legislative position that in Australia vaporiser nicotine products are only available on prescription. Reference should therefore only be had to the product contents relevant to aiding cessation, and the product information needed by users, GPs, and pharmacists in undertaking the prescription-based approach.

Specifically, TGA should be very clear that it is NOT setting standards for an open consumer market. No part of the regulatory questions the TGA asks should be answered by reference to a far broader conception of issues of labelling, ingredients, etc. that imagines a different regulatory scheme, in which these products are available on an open market. That scenario has already been expressly ruled out by force of law in all Australian jurisdictions.

With these considerations in mind, PHAA makes suggestions below in answer to the various questions which the TGA poses.

Overall, we find that the TGA's initial draft of TGO 110, and preferred options of detail, are sound on some points, but on other points fall short of the optimal approaches that support the prescription-only regulatory model. We propose significant tightening of the Order, or selection of tighter options than the TGA initially prefers, to achieve an appropriate design.

We also recommend that TGA takes heed of the advice which may be provided from other expert health organisations close to the coalface of nicotine policy, including Cancer Council, ACOSH, the AMA, and other health organisations.

Finally, we remind the Minister and/or his decision-making delegates, and all government officials involved in this consultation, of the Government's obligations under the WHO Framework Convention on Tobacco Control to ensure that no influence in this policy design is exercised by any tobacco/nicotine industry business, including any associated representative entity or paid lobbyist. Noting recent media reports of the operating style of such entities, we counsel TGA and the Minister/delegate to verify for themselves the identity and backers of any submitter to this consultation which might be conflicted by such interests.

PHAA, Australia's peak body for public health, believes that in dealing with nicotine, all options carry public health risk, including public health protections for all Australians. There will be an ongoing need for evidence-based programs and policies that consider such risks. The proposed Order should remain under regular review.

Answers to TGA questions

Part 1: Proposed scope of TGO 110

Q1. Do you think that export only vaporiser nicotine should be required to comply with TGO 110? Why or why not?

Option 3 is preferred, for the reasons given below (but see also our response to question 3).

Export-only products should be fully compliant with standards adopted for Australian products through the Order. For Australia to allow the manufacture and export of products not seen as safe for consumption here raises ethical and other issues, including reputational risks related to our trade and health policy image to other nations. It also conflicts with the WHO Framework Convention on Tobacco Control in regard to international cooperation to reduce the harm flowing from nicotine products. For these reasons, we therefore support Option 3 in the TGA's list of options.

PHAA frequently argues that many public health issues are border-transcendent (and indeed, that can hardly be doubted with a global pandemic raging), and that as a result cooperation and consistency between nations is an international public policy goal. Australia will inevitably have future occasions in which it finds itself arguing for either international policy decisions, or decisions that defend Australia's health priorities. At such moments our international reputation for health and safety policies will matter. To allow export of products we consider unsafe for Australian consumption would undermine that position.

Q2. Do you think clinical trial products should be required to comply with TGO 110? Why or why not?

PHAA agrees with TGA that unapproved vaporiser nicotine products that are imported or supplied for the purpose of clinical trials must comply with the Order. The alternative lacks consistency in regard to the potential outputs from such trials. We therefore oppose Option 2 in the TGA's list of options.

Q3. Do you think products that are the subject of an FDA PMTA marketing order, or that are supplied in the UK, EU, Canada, NZ and/or another country in accordance with the relevant requirements of that country, should be deemed to comply with TGO 110 (in whole or in part)? Why or why not?

This is a question about the extent to which Australian regulators can rely on taking at face value the regulatory processes and findings of other nations. The TGA position is essentially that – at least at present – the findings of the US FDA may be relied upon, but that those of the other named nations cannot.

PHAA believes that in this case, cross-jurisdictional 'deeming' approaches should be rejected. The regulatory regimes across all the nations concerned clearly differ at present, and we are unable to feel safe that any other system may be taken at face value by our TGA.

In addition, we cannot overlook the reality that nicotine policy is often politicised, and has many commercial interests at play. Blanket 'deeming' recognition of overseas regulatory regimes, and their day-to-day administration under various pressures, including political and commercial pressures – which clearly exist in regard to the nicotine industries – is not an appropriate position to set down in the proposed Order.

Moreover, we are concerned about the framing of FDA's decision factors on this matter. Factors that the TGA paper cites (pp.10-11) as relevant to FDA decision-making include the following:

- The provision of "scientific evidence demonstrating the product is appropriate for the protection of public health."
- "Whether users of any tobacco product(s) would be more or less likely to stop using such products if the proposed new product was available."
- "Whether non-users of any tobacco product(s) would be more or less likely to begin using tobacco products if the new product were available."

We have already seen the concept of 'protecting health', and the evaluation of questions such as those above, be made the subject of unscientific political pressure here in Australia. We cannot feel confident that future political pressure on US regulators will not occur, while also acknowledging that the US is not a Party to the WHO Framework Convention on Tobacco Control.

Taking a 'no deeming' position does not in any way prevent TGA from taking into account any position, data or evidence which may be obtained from oversees regulators. We understand that taking overseas data into account is a common TGA practice on many regulatory decisions.

Q4. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Q5. Do you have any other comments about the products covered by or excluded from draft TGO 110?

We have briefly commented above on the wider policies at work in regard to the prescription-based approach to permission of vaporiser nicotine products (which remain a fundamentally harmful substance to consume), and similarly the situation of proposing standards for unapproved products that cannot claim any therapeutic benefit. However, we do acknowledge that the TGA appears to be attempting to achieve some protection of the public (or at least, users of vaporiser nicotine products) through this proposed Order.

We again advise the TGA, and the decision-making delegates, to keep the ironies of the situation in mind, and ensure that the final form of the Order does not inadvertently create any impressions or expectations which can be exploited to do public harm.

It should not be forgotten that the substantial majority of smokers quit smoking unaided, and there are currently other evidence-based and tested TGA-approved products for smoking cessation available and widely used in Australia. The promotion and use of these recognised products should not be compromised by the details of the approach to regulating vaporiser nicotine products.

Part 2: Potential requirements for unapproved vaporiser nicotine products

Labelling – ingredient lists

Q1. Which option (whether listed above or not) do you prefer? Why?

Option 1, which includes information on flavours, is strongly preferred. In short, flavour ingredients should not be exempted from content information rules.

Recall once again that the product usage under discussion involves not consumer choice in an open market, but prescription of the product by medical advisors. There is no logical reason why the identity of and information about flavours – which may contain substances relevant to the health of specific individuals – should be left out.

This will also facilitate examination of the combination effects of flavours with other components of any nicotine products. Further, evidence on the health effects of heating, burning and then inhaling flavours may well differ significantly from simply ingesting flavours, and such information may be significant for human health.

Flavours are already the subject or large-scale chemical examination in Australia and overseas. It can be anticipated that most vaporiser nicotine products to be used in Australia under the adopted regulatory model will in fact be of overseas origin. Data and clinical evidence on the content and consequences of flavour chemicals may be readily available. But if it is not so, then there may be an even stronger case to ensure that flavour information is made available, to support examination of the health impacts of any specific flavour chemical.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options

Labelling – nicotine concentration

Q1. Which option (whether listed above or not) do you prefer? Why?

In acknowledging that the only legal usage of the nicotine in products in question will be as an aid to smoking cessation, the relevant information should be that which best assists doctors, pharmacists and users in selecting and monitoring dosage.

The information should be sufficient to avoid confounding of the attempts at cessation, and avoid adverse events such as drug reactions. Labelling should align with clinical knowledge possessed by medical advisers.

Labelling should include not only concentration per dose, but total concentration per whole package, to provide guidance in responding to accidental poisoning events (e.g. by children and others accessing packages).

The prospect of using nicotine salts raises concerns relating to toxicity and blood absorption. A separate technical decision should be investigated as to whether nicotine salts should be an acceptable form of product. If they are permitted, the same minimum principles as above apply, but there may be a need for additional labelling/information relating to nicotine salt products to be mandatory.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Labelling – warning statements

Q1. Which option (whether listed above or not) do you prefer? Why?

Option 2 is preferred, although the term 'only' is not needed or appropriate.

The comment in the consultation paper (TGA, p.19) that "*warning statements may undermine an individual's smoking cessation treatment by discouraging continuation with the treatment recommended by their doctor*" is speculative, not based on reliable evidence, and is not supported. Nicotine is addictive, and warnings about that fact should never be left out of product labelling. The full range of addictiveness issues

from smoking and from products uses for smoking cessation efforts should be explained to every user. Regulatory design should not be such as to suggest that nicotine in vaporiser form is not addictive.

Option 3 as stated is not adequate. Differences may exist, or may emerge, between jurisdictional requirements. Since the new TGA scheduling regime (from October 2021) will clarify the regulatory system in Australia under national policy, the opportunity should be taken to set in place a uniform, evidence-based approach to warning labelling. It is important that, as with cigarette labelling, any labelling in this area is based on independent, expert research.

Of the other two options, it makes most sense for warnings to be included on packages and also in information sheets as part of an informed consent process, the latter information sheet being a desirable extra aid to informing users and their medical advisers.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Ingredients – prohibiting certain ingredients

Q1. Which option (whether listed above or not) do you prefer? Why?

All 'ingredients' that are (or may be) harmful to health and that are not relevant to the aim of assisting users to reach smoking cessation should be excluded from vaporiser nicotine products permitted under this regulatory scheme.

Option 1, the most comprehensive of the options, is therefore clearly the best option.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Ingredients - Flavours

Q1. Which option (whether listed above or not) do you prefer? Why?

Flavours, like other ingredient additives, may contain harmful substances. Users and their medical advisers under this regulatory regime are entitled to have assurance that harmful flavourings have been excluded.

Flavourings are, quite simply, a marketing device to make products competitively attractive in an open consumer market. That is not the type regime being considered here. An unlimited approach to flavours is not consistent with the overall scheme that vaporiser nicotine products are only permitted as an aide to smoking cessation. There is compelling evidence on the role and use of flavours in encouraging and promoting use of these products (as well as other tobacco products), and on their role in encouraging and promoting use of e-cigarettes and other novel products by children and young people.

Option 3 – no limits on flavours – preferred by the TGA (TGA consultation paper, p.23), is therefore clearly not appropriate, and might indeed play a role in promoting use of these products by children and young people.

The arguments presented in support of flavourings are weak, based on very limited evidence, and are certainly not adequate to justify a diverse and changing range of product flavourings being permitted.

The issue of flavours rendering products attractive to youth is very real, and provides a powerful argument against an 'open market' for vaping products. While in theory this problem should be limited to the proposed prescription-only regulatory regime, the reality (and experience elsewhere, as well as over time with tobacco products) is that this limitation is only theoretical. Noting the potential for illegal access to products to continue, the use of flavours specifically designed to be attractive to children, and any associated packaging promoting such flavours, should be specifically prohibited, in practice as an exercise of Option 2.

As between Options 1 and 2, the difference really lies in when the TGA will be asked to exercise a judgement to permit-or-prohibit a specific flavour. In either case, product manufacturers should be expected to provide evidence that a flavour is not harmful. Option 1, the 'allowing' option, is the most thorough, but may require more TGA resources up front. A combination of Options 1 and 2 may be appropriate, allowing TGA flexibility.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Packaging – child-resistant packaging

Q1. Which option (whether listed above or not) do you prefer? Why?

The overriding goal in regard to this issue is to prevent accidental poisonings. TGA's preferred Option 2 seems more comprehensive than Option 1 alone, and therefore the TGA's position is supported.

Option 3 does not propose a specific outcome.

Option 4 is not adequate. Differences may exist, or may emerge, between jurisdictional requirements. Since the new TGA scheduling regime (from October 2021) will clarify the regulatory system in Australia under national policy, the opportunity should be taken to set in place a uniform approach to child-resistant packaging.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Packaging – tamper-proof/evident packaging

Q1. Which option (whether listed above or not) do you prefer? Why?

Option 1 is strongly preferred over the non-requirement represented by Option 2.

Given the availability of tamper-proof/-evident packaging requirements from the start of the new regulatory scheme, there seems to be no reasons not to make use of this option to further protect the community from serious inadvertent harm.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Nicotine concentration

Q1. Which option (whether listed above or not) do you prefer? Why?

Option 1 is strongly preferred. Medical advisers and prescribers will be able to dispense products in the quantities they believe appropriate for each user to assist their effort to cease smoking.

However, the risk of product misuse, circulation on illegal markets, and accidental consumption (especially by children) remains real. Given these risks, the lower the concentration of nicotine in each package, the better. To facilitate such controls, the Order should make provision for a maximum concentration.

The specific maximum concentration level should be monitored and reviewed over time according to evidence of accidental consumption or other misuse.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Volume

Q1. Which option (whether listed above or not) do you prefer? Why?

As with our comments in regard to nicotine concentration (above), and for the same reasons, we recommend that some maximum volume be set. Maximum volumes are a common limit in the supply of many pharmaceuticals with potential dangerous for over-use, or for accidental consumption (e.g. by children).

Option 1 is therefore preferred.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Other questions/ comments

Q1. Are there any other potential minimum requirements for unapproved vaporiser nicotine products the TGA should consider including in TGO 110?

No.

Q2. Would you like to be consulted on any draft guidance prepared for TGO 110?

Yes. PHAA has a long and consistent track record of assisting governments and health agencies to make evidence-informed policy in this area, and we will continue to contribute strongly.

Part 3: Related matters

Default standards and nicotine purity

Q1. Which option (whether listed above or not) do you prefer? Why?

There is a strong case for ongoing adherence to pharmacopoeial quality standards and 'monographs', and therefore Option 1 is the most appropriate setting.

Q2. Would any of these options, particularly the TGA's proposed option, have an impact on you? How?

PHAA as an organisation is not directly impacted by the options.

Compounding

Q1. Do you have any comments on the application of TGO 110 to compounded vaporiser nicotine products?

Application of the Order to compounding seems to be appropriate.

Conclusion

Over many years of sustained effort Australia has achieved encouraging outcomes in terms of a decline in smoking. While much more action is needed, there is clear evidence to support measures that will continue these encouraging trends. Consistent with the WHO Framework Convention on Tobacco Control, there should be a strong governmental focus on these measures, and on ensuring that the promotion of novel nicotine products is not allowed to distract attention from the evidence-based action that is needed.

In this context, PHAA supports the unanimous position of Australia's governments that nicotine liquid should be accessible on (and only on) the basis of medical prescription.

As noted elsewhere in this response, we see it as critical that any action in this area should also be in the context of:

(a) a strong and continuing comprehensive approach to reducing smoking, with implementation of evidence-based policies known to reduce smoking
(b) a return to sustained, adequately funded, evidence-based mass media programs promoting quitting
(c) the Australian Government's commitment to the WHO Framework Convention for Tobacco Control, including Article 5.3, which precludes any influence on tobacco policy by tobacco companies and related interests
(d) clear policies and commitments (including funding) for implementation and monitoring
(e) strong and well implemented controls to prevent any commercial marketing of products in the areas under consideration
(f) the need for any labelling, warnings or product information to be based on independent, expert research.

The PHAA appreciates the opportunity to make this submission. 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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