Public Health Association
AUSTRALIA

Submission to the TGA on potential reforms to the regulation of nicotine vaping products

Contact for recipient:
Therapeutic Goods Administration
via TGA Consultation Hub
https://consultations.tga.gov.au/medicines-regulation-division/proposed-reforms-to-the-regulation-of-nicotine-vap.

Contact for PHAA:
Terry Slevin – Chief Executive Officer
A: 20 Napier Close, Deakin ACT 2600
E: phaa@phaa.net.au **T:** (02) 6285 2373

16 January 2023

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 the Therapeutic Goods Administration's consultation paper ***Potential reforms to the regulation of nicotine vaping products*** (November 2022).

The scourge of nicotine addiction through nicotine vaping products (NVPs), largely affecting young people, is one of Australia's most critical current public health challenges.

PHAA supports a comprehensive, evidence-based approach to tobacco control – including e-cigarettes and any other novel nicotine products – that encompasses regulation of supply and demand drivers, public education, regulation, taxation, smoke-free measures, cessation support, and special programs for disadvantaged priority population groups including Aboriginal and Torres Strait Islander people.

Our full policy position statement on e-cigarettes is available here. Key points include the following:

1. As with other products for which therapeutic claims are made, manufacturers of e-cigarettes and other novel tobacco products should submit these products to the Therapeutic Goods Administration with evidence of safety and efficacy. It should then be left to the TGA to make appropriate determinations as to whether they may be sold, and if so under what conditions.
2. The sale of alternative nicotine and non-nicotine delivery systems including e-cigarettes should be prohibited unless they have received TGA approval.
3. Advertising and promotion of e-cigarettes and other novel tobacco products should be prohibited and consistent with tobacco advertising prohibitions.
4. PHAA strongly supports the WHO Framework Convention on Tobacco Control (FCTC), which has been ratified by the Australian Government and 180 other governments, and specifies that "in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law".

Scientific evidence is building on the health harms of e-cigarettes and other novel tobacco products. NVPs play a role in increasing smoking uptake, particularly among young people. There are indications that e-cigarette use may depress overall smoking cessation rates.

Neither the safety of NVP products nor any claimed superior efficacy in smoking cessation have been definitively demonstrated. Studies that tend towards any positive conclusions are still preliminary (inevitably, due to the short history of these products), and many are limited to behavioural therapy and do not examine broader physiological issues. There is by contrast increasing evidence that at a population level e-cigarettes maintain nicotine addiction and increase the risk of relapse to smoking. In Australia the therapeutic value of NVPs, together with any adverse health effects, have not been assessed under therapeutic goods laws.

The promotion of these products as a cessation aid creates false impressions of product safety in users, a concern which must be addressed carefully by the TGA given the agency's role in influencing community perceptions.

The wider policy picture is also very important. It should not be forgotten that the larger critical health issue is the need to reduce smoking rates and nicotine addiction overall. The rapidly increasing promotion of e-cigarettes by industry, and debates over their proper regulation, threaten to distract the attention of governments from the continuing need for measures to reduce smoking.

A range of further novel tobacco products have been developed and are being promoted, primarily by tobacco companies which are prominent in the global e-cigarette market. The industry uses e-cigarettes

and other novel products to promote their own commercial interests, advertise and promote these products in ways that will normalise (or re-normalise) smoking behaviour, seek new forms of involvement in policy-making processes, and undermine existing tobacco control initiatives. Their strategies are particularly targeted at young people.

It is revealing that unlike all other manufacturers of therapeutic products, vaping product developers have made no attempt to demonstrate the safety and efficacy normally required through randomised controlled trials and other standard procedures to obtain product regulatory approval through TGA and Pharmaceutical Benefits Advisory Committee (PBAC).

PHAA strongly supports the commitment of all Australian governments to maintaining a precautionary approach to e-cigarettes.[1] PHAA also shares the concerns expressed in the TGA's consultation paper, which echo international WHO concerns, that existing requirements for nicotine vaping products are not meeting the governments' aim of preventing children and adolescents from accessing NVPs.[2] Instead, it is estimated that there are nearly one million regular vapers in Australia (4.7% of men, 2.9% of women) which has doubled since 2019-20. In 16-24 year olds the rate is 11%.

The key findings of a recent report by the ANU National Centre for Epidemiology and Population Health include the following:

- "e-cigarettes are likely to be harmful when used for purposes other than smoking cessation, including use by non-smokers
- they are likely to be particularly harmful for adolescents and young adults, largely due to their effects on addiction, the developing brain and increased uptake of combustible tobacco smoking
- 89% of the Australian population aged 14 and over are not current daily smokers
- tobacco smoking is exceptionally harmful and quitting brings large benefits
- at a population level, while smoking cessation remains important, avoidance of uptake of smoking in youth is currently the main driver of declining smoking prevalence in Australia
- e-cigarettes may benefit smokers who use them to quit completely and promptly, bearing in mind uncertainties regarding their effects on major clinical conditions
- most smokers quitting successfully do so unaided, with only a minority seeking medical support for quitting
- among those who need support to quit, multiple approved smoking cessation products are available
- most smokers who use e-cigarettes continue to smoke."[3]

It is vital that regulation of e-cigarette products not be determined in isolation, but forms part of an ongoing effort by governments to control the 'nicotine industry' as a whole, especially as it seeks to develop new product classes while also maintaining traditional smoking products. As the ANU findings above indicate, reducing the rate of smoking remains the critical national goal. Whatever their claimed origins, vaping products have been promoted in such a way as to introduce new users (often young people) to nicotine, in turn drawing some users into traditional smoking. The regulation of NVPs must be framed in the light of this reality.

The cost-benefit rationale for regulating NVPs is very strong. Future costs to the health system driven by NVP usage is a major emerging national health issue, and the rapid expansion of usage seen in recent years creates an urgent need to reassess future health cost estimations. PHAA is aware of a forthcoming paper on the national costs of new uptake in e-cigarette use, the finding of which will include estimates of significant additional healthcare costs to governments and to the economy attributable to e-cigarette-initiated smoking, and specifically attributable to additional prevalence of malignant cancer, heart disease and respiratory diseases.

In addition, the environmental costs of vaping use and disposal of equipment are emerging. Vaping products contain an array of plastics and chemicals that are harmful to the environment and difficult to effectively manage after disposal. Vaping device batteries also have a fire hazard potential when present in landfill and other places.

The current circumstances are good for effective policy-making. The nation's governments are in agreement about the nature of the vaping problem, and united in their policy goals. Australian Minister for Health Mark Butler has recently given clear direction about the Government's goal for enhancing Australia's reputation on combating the harms of all nicotine products, commenting that "Australia needs to reclaim its position as a world leader on tobacco control. Because, quite frankly, lives are at stake." The TGA's consultation paper is similarly frank about the nature of the challenge.

In summary, **our preferred responses** to the consultation paper's four issues are as follows:

1. *Changes to border controls for NVPs – Option 4*
2. *Pre-market TGA assessment of NVPs against a product standard – Option 1, based on the need to avoid creating unjustified social license through a special approval process for NVPs; if that is not favoured, then Option 3*
3. *Strengthening of the product standard regarding minimum quality and safety – All of Options 2 through 6*
4. *Clarifying the status of NVPs as 'therapeutic goods' – Yes.*

Finally, we note that Australia is a party to the WHO Framework Convention on Tobacco Control (FCTC), Article 5.3 of which requires public institutions and officials to protect public health policies in relation to tobacco control "from commercial or other vested interests of the tobacco industry". This obligation extends to the regulation of e-cigarettes and to the industries or retail sectors which promote their use. We urge the TGA to ensure very strict observance of these obligations.

Changes to border controls for NVPs

The consultation paper asks respondents to comment on the following four options:

Option 1 – No legislative changes, but increase enforcement at the border

Option 2 – Remove Personal Importation Scheme exemption for NVPs

Option 3 – Impose tighter controls on the importation of NVPs by requiring an import permit

Option 4 – Introduce controls on the importation of all vaping products through the Customs Regulations to assist with the enforcement of the controls on NVPs

PHAA supports controls on the importation of all vaping products. Each of options 2 and 4 have value, but **implementing option 4 – strong border controls – is clearly the most important and urgent objective**. The critical situation to be addressed is the massive quantity of NVP products circulating illegally in Australia. Stronger regulations, and resourcing of effective enforcement, should be put in place urgently to dramatically reduce the illegal availability of NVPs. This is the most important proposal in the TGA's paper.

The regulations should limit product importation into Australia only to that needed to accommodate the limited use that is legal – that is, the cessation-aid prescription use (noting that the health care rationale even for this use is not without controversy and remains under active study).

Enforcement practicalities also need to be considered. The border control staff and other resource implications will not be trivial to do this properly. Such resource needs can be justified in the context of the large future economic costs, and future health care cost pressures caused by vaping, that would be averted by investment in protective policies.

As to option 2, concerning the Personal Importation Scheme exemption, there is evidence that this pathway is being abused for individual-level importers to obtain quantities of NVPs then resold (illegally) to other users.[4]

Since the only legal use of NVPs in Australia is the cessation-prescription usage, importation should only be occurring to an extent that supplies products to doctors and pharmacies for that usage alone. If an individual importation exemption scheme cannot operate without widespread abuse – as is clearly the case at present – then it should be eliminated, and prescription-usage supplies should be imported in line with other controlled pharmaceutical product importations.

Option 3 is only a useful option to the extent that import permits for cessation-usage related supply chains are effectively regulated. Option 3 should *not* be regarded as a suitable option as it provides for the continued existence of pathways of supply that can be abused for illegal end-outcomes.

Non-nicotine vaping products are not harm-free and should also be controlled. It is important to capture all imported vaping products in such control, given the evidence that nicotine content labelling of products are frequently false. The scale of mislabelling of products currently seen, with vaping products labelled as 'non-nicotine', or not labelled as to nicotine content, is extraordinary.[5] To effectively address this situation and enforce current law, all vaping products should be intercepted on the presumption that they contain nicotine until individual supply chains can prove otherwise.

PHAA has argued that non-nicotine vaping products should themselves be prohibited, as a necessary adjunct to the vital policy objective of eliminating nicotine vaping products from general circulation.

Pre-market TGA assessment of NVPs against a product standard

The consultation paper asks respondents to comment on the following three options:

Option 1 – Make no changes

Option 2 – Regulate by requiring pre-market assessment of NVPs by the TGA

Option 3 – Regulate by requiring registration in the ARTG

PHAA supports Option 1, based on the critical need to avoid creating an unjustified social license for NVPs. If Option 1 is not favoured, then Option 3 is next preferred.

The proposed Option 2 presented in this question raises squarely the issue of ***whether it is appropriate to allow any public impression to be created that NVPs are a safe product***.

The therapeutic value of NVPs, together with any adverse health effects, have never been assessed under our therapeutic goods laws. In the absence of such rigorous assessment (not merely of individual product brands, but of NVPs as a whole) it would be contrary to the direction of national policy to allow a less rigorous form of assessment, based only on a product standard (such as a revised version of TGO 110), rather than on a comprehensive assessment of therapeutic value, to in any way endorse specific products as safe for use. To do so would allow and encourage the promoters of products to make unjustified use of claims that their products are officially "assessed" and "approved" to be "safe". This is likely to increase public confusion and potentially undermine parents' and teachers' messaging about e-cigarette use to non-smokers, particularly children, adolescents and young adults.[6 7 8]

Adopting the Option 2 approach would put pressure on the TGA to issue a product standard specifically designed to permit some products to meet that standard, since to issue a standard which *no* product could meet – even if the terms of such a standard align with health evidence – would be pointless. This raises a clear risk that the integrity of the TGA's processes will be compromised.

Proponents whose products were approved by TGA against such a standard would inevitably make simplified public marketing claims that their products are "approved", "safe", and so on, when in fact no comprehensive therapeutic assessment would have been carried out. Controlling public information in such circumstances would be highly problematic, as the capacity of marketers to make claims would far exceed the capacity of regulators to communicate to the public quality information about such claims. The result would be directly contrary to the policy goals stated by the Minister and by the cross-jurisdictional agreement of all governments.

An additional barrier to the adoption of either of options 2 or 3 is that, by creating a less stringent form of health regulation specifically to accommodate products of the tobacco industry, Australia might be in breach of its obligations under the FCTC, which rule out allowing the industry to influence the making of policy in signatory nations. In addition to the desirability of taking a strong Australian position on strict adherence to the FCTC, were Australia to set a precedent on this point other FCTC member nations might have good grounds to criticise our policy.

For these reasons, PHAA's strongly preferred response is Option 1: do not create any form of low-rigour regulatory process which can be (and inevitably, will be) abused.

Out of the non-preferred Options 2 and 3, Option 3 seems likely to do the least damage, and/or minimise risk. A registration scheme (Option 3) would at least capture data about some of the products in circulation, which would be useful. However, we stress that ARTG is still, by name, a register of "therapeutic goods",

and it would be false and misleading to allow NVPs to be listed on any register so named. The TGA would need to give careful consideration of the processes and language used, especially terms such as "approved", "approval" and "safety". The better approach would be to establish a separate sub-register which does not carry any suggestion that items listed in it have been found to be therapeutic.

Finally, we note that given the extraordinary willingness of the vaping products industry to circumvent existing law and government policy, the practical capacity of the TGA and other regulators to enforce such a product registration scheme is highly questionable. It is not in the interests of the TGA to bear a registration responsibility which it could not credibly implement.

Strengthening of the product standard regarding minimum quality and safety

The consultation paper asks respondents to comment on the following six options:

Option 1 – Make no changes to minimum safety and quality requirements

Option 2 – Prohibit all flavours (except tobacco) and additional ingredients

Option 3 – Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging and/or additional warning statements

Option 4 – Reduce the maximum nicotine concentration for both freebase nicotine and nicotine salt products to 20 mg/mL (base form or base form equivalent)

Option 5 – Limit the maximum volume of liquid NVPs

Option 6 – Remove access to disposable NVPs

1. *Do you support restricting or prohibiting the inclusion of flavours in NVPs? If so, which flavours would you like to see restricted? Should all flavours be prohibited or should tobacco flavour still be permitted?*
2. *Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients? Why?*
3. *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?*
4. *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 prescription-only medicines?*
5. *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?*
6. *Do you support limiting the maximum volume of liquid NVPs? If so, what maximum volume should be specified?*
7. *Do you support preventing access to disposable NVPs?*
8. *Would any of these options have an impact on you? How?*

9. *If new restrictions were to be introduced 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?*
10. *Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?*

PHAA generally supports the rapid implementation of all of Options 2 through 6. Each of these measures could make a contribution to increasing consumer awareness about the nature of the NVPs they encounter, and/or reducing the harms resulting from NVP use.

It is critical to note, however, that taking any or all of these measures should not be allowed to contribute to the normalization of NVPs in the public mind. Product supply of NVPs to the Australian community outside of the prescription model is already illegal. NVPs should clearly remain illegal products in Australia for all purposes outside the cessation-prescription model, and strong end effective importation and supply measures should be taken with the goal of dramatically reducing – ideally, eliminating – illegal NVP supply.

Flavours are not used in other therapeutic products such as puffers for asthma patients – used by children and adults – presumably because of potential harms. Used in NVPs, the range of flavours – including "gummy bear", "nacho cheese" and "fairy floss" – are simply a marketing device to render these products attractive to users, and especially to new users. They are simply one part of a deliberate product presentation strategy which draws users towards nicotine addiction. Flavours may also in themselves, used through NVP devices, have harmful impacts. Evidence indicates no clear association of flavours with usage for smoking cessation. Prohibiting them is appropriate.

Plain packaging has been well demonstrated to work in regard to tobacco products over the past decade.[9] [10] [11] However it is important to note that since the only usage of NVPs which remains legal in Australia is the cessation-prescription usage, labelling should not merely be 'plain' but should clearly draw the observers attention to the fact that the products contained are illegal for sale and use outside of that prescription pathway. Packaging designs and labels should not allow the impression that the product is legal for general sale, or indeed be misleading in any other way. Labelling of health and safety warnings should be research based and should be chosen for effectiveness in achieving desired user responses.

Limitations to the nicotine volume and total content, likewise, should be based on quantities which align with the limited cessation-prescription usage which remains legal.

The industry has developed so-called **"disposable" forms of NVP**, but *all* NVP devices end up being disposed of, and often not in a way that is environmentally safe. To start with, e-cigarettes that require users to dilute and mix their own liquid nicotine have immediate environmental health risks, including poisoning. There is also growing evidence of NVP products – whether described as 'disposable' or otherwise – have significant environmental impacts, including enduring plastics, hazardous chemicals, and battery-caused risks of fire. The environmental damage aspects of NVP proliferation are an issue in their own right. Product design for effective disposal should be mandated, noting once again that such regulation should align with cessation-prescription usage being the only legal usage in Australia.

In regard to **implementation timing** mentioned in question 9, we note that this is a discussion about improving the regulation of what are already illegal products. Conceding implementation periods to allow importers to "organise procurement of compliant products" is perverse. No suggestion has been raised that there are supply chain difficulties in meeting the very limited demand for legal cessation-prescription usage. Implementation should be as rapid as possible.

In regard to "unregistered NVPs" mentioned in question 10, any product not registered should be prohibited, and as such there should be no suggestion of specific requirements for unregistered products.

Clarifying the status of NVPs as 'therapeutic goods'

The consultation paper asks respondents to comment on the following:

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

Yes, it is appropriate to use the existing TGA regulatory framework to control NVPs.

One of the primary challenges with enforcement is the current legal sale of *non*-nicotine vaping products. These products have harms from both the 'hidden' nicotine and from favours. One of the immediate regulatory challenges is applying the current law to the large supply of NVPs that *do* contain nicotine but are *not* labelled as doing so. Many such products masquerade as legal non-nicotine vaping products, and the existence of this apparently legal product class provide a powerful mechanism for illegal products to be widely available for sale.

In any case, non-nicotine vaping products are not harm-free, as there are known carcinogens in e-liquids and aerosols. E-cigarette liquids and aerosols contain definite and probable oncogens including nicotine derivatives like nitrosamines (nitrosonornicotine NNN, nitrosamine ketone NNK), polycyclic aromatic hydrocarbons, heavy metals (inc organometal compounds), and aldehydes/other complex organic compounds. It is also important to note that non-nicotine products have the actual effect of inducing new users – typically young users – into ongoing nicotine product use and addiction.

It is problematic that vaping products are one of the most unregulated consumer goods, which comes about because they belong to no regulated class of goods, being neither a food nor a medical or therapeutic product. Proponents have (with great irony) avoided ever submitting their products for therapeutic merit assessment under the Therapeutic Goods Act. Allowing this whole class of goods to be brought under the scrutiny of the TGA by making a declaration under section 7 of the Act is a sensible regulatory option.

However, the TGA needs to exercise care in its public language and processes that this regulatory control declaration does not promote the impression that NVPs have been demonstrated to be a product with "therapeutic" value. This has never been established as a fact through any rigorous technical evaluation.

Conclusion

PHAA strongly supports the strong and clear direction of all Australian governments, and we also actively support the efforts of the TGA to strengthen regulation of NVPs.

Australia's regulatory efforts relating to vaping lagged badly for the first decade or more of the development and promotion of these unhealthy products, but governments are more recently moving to recover our policy leadership. We commend government efforts to foster the health and wellbeing of all Australians.

We strongly support a comprehensive, evidence-based approach to tobacco control, encompassing supply and demand reduction measures consistent with the WHO FCTC. This includes but is not limited to regulation, cessation supports, public education, taxation, smoke-free measures and targeted programs for priority groups, including Aboriginal and Torres Strait Islander peoples. Strong and effective importation and supply measures should be taken with the goal of dramatically reducing the circulation of NVPs in Australia.

Finally, we wish to once more emphasise that taking any or all of the measures proposed by TGA must not be allowed to further normalise NVPs. Product supply of NVPs to the Australian community outside of the prescription model is already illegal. NVPs should remain illegal products in Australia for all purposes outside the cessation-prescription usage (the merits of which remain under examination).

The PHAA appreciates the opportunity to make this submission. Please do not hesitate to contact me should you require additional information or have any queries.

Terry Slevin
Chief Executive Officer
Public Health Association of Australia

16 January 2023

References

1 See Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia | Australian Government Department of Health and Aged Care.

2 TGA, *Potential reforms to the regulation of nicotine vaping products* consultation paper, 2022

3 Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, G. J. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. Canberra: National Centre for Epidemiology and Population Health, 2022.

4 Watts, C., Egger, S., Dessaix, A., Brooks, A., Jenkinson, E., Grogan, P., & Freeman, B. (2022). Vaping product access and use among 14–17-year-olds in New South Wales: a cross-sectional study. Australian and New Zealand Journal of Public Health, 46(6), 814–820. https://doi.org/10.1111/1753-6405.13316

5 Associate Professor Alexander Larcombe, https://www.telethonkids.org.au/news--events/news-and-events-nav/2019/impact/rapid-response-to-e-cigarette-findings/

6 Watts, C., Egger, S., Dessaix, A., Brooks, A., Jenkinson, E., Grogan, P. and Freeman, B. (2022), Vaping product access and use among 14–17-year-olds in New South Wales: a cross-sectional study. Australian and New Zealand Journal of Public Health, 46: 814-820. https://doi.org/10.1111/1753-6405.13316

7 Hansen J. Vape Detectors Installed in NSW Schools to Combat Rise in Students Vaping. The Daily Telegraph [Internet]. 2021 [cited 2021 Dec 10] Jul;1. Available from: https://www.dailytelegraph.com.au/news/nsw/vape-detectors-installed-in-nsw-schools-to-combat-rise-in-students-vaping/news-story/94e3a2a4d73913cebdcca7eac5d6b1fd

8 Chrysanthos N, Bagshaw E. From Bootcamps in China to Australian Schools: How Vapes Hook Children on Nicotine. The Sydney Morning Herald [Internet]. 2021 [cited 2021 Dec 10] Sep;2. Available from: https://www.smh.com.au/world/asia/from-bootcamps-in-china-to-australian-schools-how-vapes-hook-children-on-nicotine-20210830-p58n6w.html)

9 Wakefield M, Coomber K, Zacher M, et al, Australian adult smokers' responses to plain packaging with larger graphic health warnings 1 year after implementation: results from a national cross-sectional tracking survey Tobacco Control 2015;24:ii17-ii25.

10 Maddox, Raglan, Sarah Durkin, and Ray Lovett. "Plain packaging implementation: perceptions of risk and prestige of cigarette brands among Aboriginal and Torres Strait Islander people." Australian and New Zealand journal of public health 40.3 (2016): 221-225.

11 Moodie C, Hoek J, Hammond D, et al, Plain tobacco packaging: progress, challenges, learning and opportunities, Tobacco Control 2022;31:263-271.