13 January 2023

Attention: Nicotine Vaping Products Team, Therapeutic Goods Administration
Re: Submission on proposed reforms to the regulation of Nicotine Vaping Products

Thank you for the opportunity to provide a written submission on the proposed reforms to the regulation of nicotine vaping products. This consultation must result in the implementation of stronger regulation that protects the health of all Australians.

The Victorian Health Promotion Foundation (VicHealth) is an independent government authority established under the Victorian *Tobacco Act 1987* with a mandate to promote good health for all Victorians and provide evidence-based policy advice. We are a pioneer in health promotion, working with partners to discover, implement and share solutions to the health problems facing Victorians. We seek a Victoria where everyone enjoys better health and wellbeing. We work to keep people healthy, happy and well – preventing chronic disease and reducing the burden of poor health on everyday Australians. Since our inception in 1987, we have invested significantly in the work of Quit Victoria, supporting the delivery of education campaigns, cessation support, tobacco policy and research. While smoking rates have reduced in recent decades – thanks in part to the role of price increases on tobacco products, mass media campaigns and legislative changes such as plain packaging – growth in e-cigarette use presents a new and significant challenge. Over the past years, it has become increasingly clear that e-cigarettes are harmful to those that use them and the people that surround those consumers.

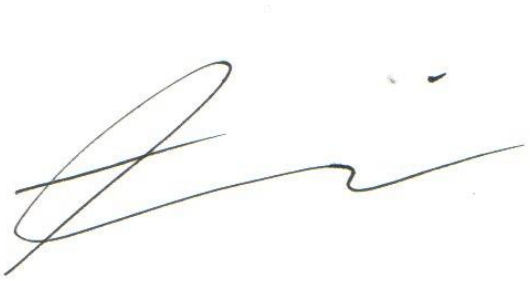
VicHealth has provided the below responses to the questions of the consultation paper '*Potential reforms to the regulation of nicotine vaping products'*. In keeping with our previous history in tobacco and nicotine control, our recommendations aim to support a high standard of regulation to keep the Australian public safe from the harms from e-cigarettes.

While partially outside the scope of the current consultation, VicHealth stands with the Cancer Council and other leading public health organisations in calling on the Australian Government to take further sensible and urgent actions to stop e-cigarette companies addicting a new generation of Australians to toxic nicotine products. This must include proactively monitoring and taking strong action against illegal advertising and promotion of any and all e-cigarettes online and via social media.

VicHealth encourages the Australian Government to take these matters into consideration. The proposed reforms to the TGA are critical and reflect a distinct interest in effecting change in this space. However, a multi-pronged approach must be utilised to protect a new generation of Australians from becoming addicted to these harmful products.

Should you wish to discuss this submission further, please contact Stephanie Kilpatrick, Policy and Government Relations Manager via skilpatrick@vichealth.vic.gov.au.

Kind regards



Dr Sandro Demaio

Chief Executive Officer

Introduction

VicHealth would like to commend the Therapeutic Goods Administration (TGA) for their reflection on the current challenges of existing nicotine regulation. VicHealth strongly supports further regulation in this space in order to protect the health of all Australians. VicHealth in particular shares the TGA's concerns regarding children and adolescents accessing Nicotine Vaping Products (NVPs) at a rapidly increasing rate. Further, as noted in the consultation paper, there is evidence a large number of adult consumers are using NVPs without a doctor's prescription or without having been through a process that ensures a NVP prescription is a smoking cessation tool of last resort. The TGA consultation must create outcomes that respond to these challenges and safeguard public health.

Use of NVPs by young Australians is increasing at an alarming rate. The consultation paper references a report by Cancer Council Victoria[i] and the Generation Vape Research Project. Whilst not a prevalence survey, the most recent data from Wave 3 of that project suggests that among a national sample of young people aged 14-17 years, 35% have ever vaped. Over half of those trying a vape for the first time are under age 16. Among young adults aged 18-24 years, nearly half have ever vaped, with 55.4% first trying vaping between ages 15-19, and 40.9% between ages 20-24.[ii] More recent unpublished data from the same survey indicated how readily young people are able to access vaping products. Over 80% said it was quite easy, easy or very easy to get e-cigarettes.[iii]

The above statistics reflect a shortcoming of previous governments to regulate e-cigarette and e-liquid imports, sales and advertising in Australia. Further delays in protecting our community from the e-cigarette industry will threaten decades of progress at decreasing smoking and nicotine addiction rates across Australia. VicHealth strongly encourages the Australian Government to undertake the additional reforms of laws and regulations, outlined below, in order to put the health and wellbeing of our community above the profitability of an industry that preys on addiction.

Legislative reform is urgently required to address deficiencies in enforcement that have contributed to this epidemic of NVP use among young people. **It is of utmost importance and urgency that all vaping products (whether or not they contain nicotine) should be**

prohibited imports under the *Customs (Prohibited Imports) Regulations 1956* (Cth) ('the Customs Regulations') unless they have been imported under existing TGA access arrangements for unapproved products. It is essential that the regulatory approach adopted at the border apply to non-nicotine as well as to nicotine vaping products. Reform options that do not adequately address the widespread mislabelling and concealment of NVPs will not be successful in stopping the flood of illegal NVPs into Australia.

NVPs are addictive and present a very real danger to our community – especially for children and young adults. But the harm of e-cigarettes is greater than just nicotine as e-cigarettes contain dozens of toxic chemicals. These include formaldehyde and heavy metals, which can cause cancer and damage the brain and lungs.

Evidence of the public health risks and health harms of e-cigarette use continues to mount. Of particular significance is the systematic review undertaken by the Australian National University for the Australian Government ('the ANU Review'). The ANU Review is the most recent study on the health effects of e-cigarettes and among the most comprehensive published in the world to date.[iv]

The ANU review confirms that NVPs carry significant harms; that *"…there is conclusive evidence that their use leads to addiction"*; that their use is increasing and widespread among children and young people; that they are harmful for non-smokers, especially youth; and that *"…there is strong evidence that non-smokers who use e-cigarettes are three times as likely to go on to smoke combustible tobacco cigarettes as non-smokers who do not use e-cigarettes, supportive of a 'gateway' effect".* The report finds conclusive evidence that the use of e-cigarettes can cause lung injury, burns and trauma from explosions, nicotine poisoning and seizures.

Standing with Cancer Council Australia, VicHealth's submission is based on the following guiding principles:

1. **Addressing the illegal importation of NVPs is the most important objective for any regulatory reform.**

Reform options that do not relate directly to ensuring optimal border control of NVPs should be considered supplementary only and should not be adopted in isolation or be allowed to distract from or delay strong action at the border.

2. **Access to NVPs for smoking cessation should only occur under medical supervision as a last resort.**

The scheduling of vaporiser nicotine as a schedule 4 (Prescription Only) medicine recognises that they should only be used under medical supervision. This ensures that NVPs are used as part of a comprehensive smoking cessation program that includes behavioural support. The RACGP's guide for health professionals on supporting smoking cessation[v] states that: "*For people who have tried to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy) but failed and are still motivated to quit smoking, NVPs may be a reasonable intervention to recommend along*

with behavioural support. However, this needs to be preceded by an evidence-informed shared-decision making process, whereby the patient is aware of the following caveats:

- *Due to the lack of available evidence, the long-term health effects of NVPs are unknown.*
- *NVPs are not registered therapeutic goods in Australia and therefore their safety, efficacy and quality have not been established.*
- *There is a lack of uniformity in vaping devices and NVPs, which increases the uncertainties associated with their use.*
- *To maximise possible benefit and minimise risk of harms, dual use should be avoided and long-term use should be minimised.*
- *It is important for the patient to return for regular review and monitoring.*"

3. **NVPs should be required to comply with measures to reduce known risks such as accidental poisoning. However, such measures must not be represented or misinterpreted as ensuring 'quality' or 'safety'.**

Nicotine is a highly addictive chemical that can be lethal in relatively small doses if ingested or absorbed through the skin. Smokers who wish to use NVPs for smoking cessation as a last resort should have access to products that accurately report nicotine content and comply with other measures to reduce attractiveness to children and minimise the risk of poisoning. Compliance with a strengthened Standard should be a condition of all import permits with the onus on the importer to demonstrate ongoing compliance. However, this should not be represented or interpreted as a guarantee of quality or safety. And as TGO-110 applies only to prescribed products, amendments to the Standard will have no impact on the products most consumers are using unless this measure is adopted *in addition to robust border controls*.

4. **Further, the TGA should not undertake pre-market assessments of products that would lower the bar for regulation of medicines in Australia, give the impression of TGA endorsement, and lead to misunderstandings about the safety and quality of the products.**

The TGA must resist proposals that would create even more exceptions for NVPs and a lowering of usual standards in relation to therapeutic products. Pre-market assessments would be a burden on the TGA and set a dangerous precedent for medicines policy in Australia. Pre-approval has the potential to give the impression that NVPs have been endorsed by the TGA and may lead to misunderstandings about the safety and quality of these products.

5. **Implementing additional reforms at Commonwealth, state and territory levels, particularly in relation to non-nicotine vaping products, should not prevent or delay the introduction of stronger border control measures.**

Addressing the problem of illegal supply of NVPs will require an inter-governmental response. It is an offence in all states and territories to supply an NVP to a consumer who

does not have a prescription. Further, it is unlawful for retail stores (e.g. convenience stores, vape shops, tobacconists) to sell NVPs. State and territory authorities are responsible for enforcing these laws.

- In all Australian jurisdictions except Western Australia, it is legal to sell non-nicotine vaping products to adults. These products are harmful because they are attractive to children, promote smoking behaviours, and serve no therapeutic purpose. Non-nicotine vaping products also greatly hamper enforcement efforts by drawing a legal distinction between nicotine and non-nicotine products, which cannot be verified without laboratory testing.
- The consultation paper notes that over the coming months the Commonwealth, in conjunction with State and Territory governments, is considering whether the regulation of non-nicotine products requires any change. Changes are urgently required but this should not prevent or delay action at the border to stop the flood of illegal imports of NVPs in the meantime.

6. Australia must adhere to its international obligations with respect to interaction with the tobacco and vaping industries.

Australia is a party to the WHO Framework Convention on Tobacco Control ('the FCTC')[vi]. Article 5.3 of the FCTC requires public 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 e-cigarettes due to the increasing integration between their manufacturers and the tobacco industry.

VicHealth is increasingly concerned by aggressive lobbying to weaken regulatory controls on NVPs by the tobacco and vaping industries and those organisations working to further their interests. Article 5.3 requires Australia to strictly ensure that industry is not permitted to interfere in a way that is intended to distract from, delay or dilute important reforms to the regulation of NVPs that are urgently required. The Guidelines to Article 5.3 also require Parties to not provide incentives or preferential treatment to the tobacco industry.[vii]

The TGA's preferred options do not address: a) the reality of how illegal NVPs are entering the country and being supplied; b) how young people are actually accessing illegal NVPs; c) the regulatory deficiencies that hamper enforcement; d) non-nicotine vaping products as a complicating issue for enforcement authorities and a means by which industry is exploiting enforcement loopholes.

Australia plays an important leadership role in tobacco control in the Western Pacific region and previously has been a world leader in this policy space. Failure to implement the strongest options available to the TGA will result in questions being asked in global fora as to why lesser measures were adopted which will also put the public health of Australians at risk.

The TGA's preferred options will not address the epidemic levels of youth vaping in this country. **The only way to reverse this public health crisis is to significantly strengthen**

border controls on the importation of *all vaping products*, as proposed in option 4 of Part 1 of the consultation paper – border controls.

Overview of response to reform options

With respect to each of the reforms outlined in the consultation paper, VicHealth, in brief, recommends the following as the only way to halt the vaping crisis in Australia.

- **Section 1: Border Controls** – Option 4
- **Section 2: Pre-market TGA Assessment of NVPs** – **Option 1** (acknowledging that Option 3 is the desired policy destination)
- **Section 3: Minimum quality and safety standards for NVPs** – Option 7 but *with* additional warning statements
- **Section 4: Clarifying the Status of NVPs as 'therapeutic goods'** – Yes.

Section 1: Border Controls

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

1. *Make no changes to the current regulatory framework.*
2. *Prevent NVPs being imported under the personal importation scheme exemption under the*

Therapeutic Goods Regulations 1990

3. *Impose tighter controls on the importation of NVPs by requiring an import permit*
4. ***Introduce controls on the importation of all vaping products through the Customs (Prohibited Imports) Regulations 1956, to assist with the enforcement of the controls on NVPs (rather than with the aim of limiting access to non-nicotine vaping products)***
5. *Options 2 and 3 together (preferred option)*
6. *Any other option (please explain).*

VicHealth strongly supports **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. Adoption of option 4 is crucial in order to reverse the public health crisis of rapidly escalating NVP use in non-smokers.

The TGA's preferred options for border control (options 2 and 3 together) fails to adequately address the flood of illegal NVPs entering Australia. Specifically, two weaknesses in the current regulatory scheme hamper enforcement at the border and weaken the capacity of state and territory governments to combat illegal supply of NVPs:

i. The need for the Australian Border Force ('ABF') to refer matters to the TGA for assessment, without having authority to immediately seize vaping products that are suspected to be unlawful. Since NVPs are not currently listed as prohibited imports under the Customs Regulations, the ABF does not currently have the power to

immediately seize vaping products which it suspects contain nicotine, without first referring them to the TGA for assessment; and

ii. The ease with which importers can evade detection of NVPs by deliberately mislabeling to conceal nicotine content. As nicotine cannot be detected by sight or smell, products must be subjected to lab analysis to determine if they contain nicotine.

Option 3 is significantly flawed in that it fails to overcome the significant enforcement problems that arise from the deliberate mislabelling of NVPs to conceal their nicotine content. **Option 3 does not include any additional controls on the importation of non-nicotine vaping products. Under this option, NVPs would continue to be imported in large volumes, concealed as non-nicotine products.**

In contrast, option 4 extends the scope of option 3 so that it applies to all vaping products, regardless of nicotine content. As outlined in the consultation paper (and above), NVPs are readily accessible across Australia by people without a prescription. This is of serious concern, and the mislabelling of NVPs is central to the problem. Non-nicotine vaping products provide an ideal vehicle for concealing illegal NVPs. They serve no constructive purpose, pose substantial safety risks and **should not be available as consumer products.** Option 4 is the only regulatory option outlined in the consultation paper which has the potential to address the very significant enforcement issues arising from the mislabelling and concealment of NVPs.

VicHealth therefore strongly recommends that the *Customs (Prohibited Imports) Regulations 1956* be amended to include all vaping products as a 'prohibited import' (regardless of whether they contain nicotine). A clear exemption to allow for importation of products being supplied through the TGA's recognised access channels for unapproved therapeutic goods would ensure those access channels remain available for individuals to access NVPs for smoking cessation purposes under medical supervision.

Although VicHealth recommends the adoption of option 4, it does not recommend the imposition of a requirement that non-nicotine vaping products be accompanied by testing results from an accredited laboratory confirming they do not contain nicotine (as suggested by way of example in the consultation paper). Just as the ABF does not have the capacity to ensure each vaping product is tested for the presence of nicotine, the ABF would also lack the capacity to verify the authenticity of each set of test results. Such a requirement would therefore not have a significant impact on the illegal importation of NVPs. In addition, it would allow manufacturers and suppliers to undertake misleading marketing claims that their products are 'tested by accredited laboratories and meet TGA requirements', providing a health halo to an inherently dangerous product, and providing false reassurance to the public.

VicHealth neither supports nor opposes option 2 (removal of the Personal Importation Scheme ('PIS'). Option 2 would require patients to have their prescriptions dispensed from an Australian pharmacy (online or physical) and importation of NVPs would occur only by air and sea cargo (not mail). This would simplify the regulatory approach and may aid enforcement to a limited extent by reducing the number of lawful importation channels. It

would also improve safety by ensuring that consumers receive advice from a pharmacist before accessing NVPs (at least where NVPs are obtained legally).

However, there is no strong evidence that the PIS is currently being exploited to facilitate the illegal supply of large volumes of NVPs. The most recent data from the Generation Vape Research study indicates that when young people aged 14-17 buy vaping products themselves, 40.1% buy from a friend or someone selling them, 38.9% buy from a retail outlet (petrol station, convenience store, tobacconist or vape store) and 14.1% buy through social media (Snapchat, Instagram or Facebook). Among young adults aged 18-24, a higher proportion (72.3%) purchase from a retail outlet, with only 10% purchasing from an online vape store[viii].

Removal of the PIS as a standalone measure (or in conjunction with option 3) would not have a significant impact on the rapidly escalating use of NVPs by young people.

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

As a body that advocates on behalf of population-level health, the impact of nicotine and vaping on the public is of paramount importance to VicHealth. Young people between the ages of 0 and 25 are a primary focus for VicHealth, and this is a particularly vulnerable group. Currently, they are not adequately protected from the harms of e-cigarettes. The current legislation and regulation in place fail to protect the most vulnerable in our communities particularly as the evidence of harm from second-hand vapour grows. These products therefore have the ability to impact both users of NVP products and those nearby who are exposed to the vapour and the toxic chemicals it contains. Until the laws are altered and Australians are protected from the harms of a tobacco industry set on addicting another generation to their lethal products, and until e-cigarettes are accessible only to those utilising them for therapeutic needs, then the impact on population health and communities will be incredibly damaging.

Section 2: Pre-market TGA Assessment of NVPs

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

1. ***Make no changes.***
2. *Establish a regulated source of quality NVPs by requiring pre-market assessment of NVPs by the TGA against a quality and safety standard (rather than requiring all the requirements for registration in the ARTG to be met), with or without an assessment fee. Any safety evaluation would relate only to the safety of the ingredients and would not involve a full safety analysis of the product. There is no evaluation of efficacy under this pathway.*
3. *Establish a regulated source of quality NVPs by requiring registration in the ARTG, following successful evaluation of quality, safety and efficacy (for smoking cessation)*
4. *Options 2 and 3 together - which would enable supplies of both unapproved NVPs that meet a quality and safety standard and of TGA-approved NVPs that have been assessed for quality, safety and efficacy (preferred option).*

5. *Any other option (please explain)*

VicHealth supports Option 1 (make no changes).

Option 3 (registration on the ARTG and importation only of registered products), is the most appropriate ultimate policy destination, offering maximum protection to public health. The routine application of TGA exemptions to support access to unapproved prescription NVPs is a departure from standard practice in Australia which ordinarily requires that prescription medicines have met the TGA's rigorous safety, quality and efficacy standards. If option 3 were adopted, prescribers could be confident that NVPs had been thoroughly assessed as safe, efficacious and of suitable quality. However, registered NVPs are not currently available so, at the present time this option would block access to legally prescribed, though unapproved products, in Australia. As detailed below, Option 2 (pre-market assessment) is not supported by VicHealth. Option 4 is therefore also not supported. This leaves Option 1— no changes at present— as the most appropriate of the options presented.

Concerns regarding Option 2
VicHealth does not support the adoption of option 2 nor, therefore, option 4, which is the TGA's preferred option.

Pre-market assessment of NVPs by the TGA would 'lower the bar' by applying a lesser standard to NVPs than is ordinarily required for prescription-only medicines. This would continue the pattern of creating exceptions for NVPs, despite the known harms they carry. Manufacturers of nicotine replacement therapy (NRT) products such as patches and gum have met the standards required to have their products listed on the ARTG. At present, neither the tobacco industry nor e-cigarette industry have chosen to submit one of their products for assessment to be included on the ARTG, despite this process being open to them. Offering a lower level of assessment for NVPs without an efficacy criterion would set a dangerous precedent in relation to prescription medicines and has the potential to erode public trust and confidence in the TGA by undermining the TGA's reputation for expertise, independence and rigour in its evaluation of therapeutic products. It would also open the TGA to questions from manufacturers of NRT products who are listed on the ARTG as to why a new lesser standard has been developed for a product that claims to have the same therapeutic outcome as theirs i.e. smoking cessation.

To our knowledge, no other prescription medicine is subjected to the lesser standard of TGA evaluation/assessment such as that contemplated by option 2. We understand that listed medicines are assessed for quality and safety, but not efficacy. These, however, are not at all comparable to NVPs because these medicines, "*are usually considered to be relatively benign…they are all unscheduled medicines with well-known low risk ingredients, usually with a long history of use, such as vitamin and mineral products or sunscreens*".[ix] This is in stark contrast to NVPs which contain a highly toxic and addictive substance.

We are concerned that pre-market assessment will lead to misunderstandings among consumers about the safety and quality of NVPs, and this would be exploited by misrepresentations from industry. **The general public would be given the false impression**

that NVPs are TGA approved or endorsed. It would be difficult, if not impossible, to correct such a misperception (despite the TGA's ability to take enforcement action against misrepresentations).

Under option 2, the TGA would carry the burden and cost of undertaking the pre-market assessments of NVPs. Given the concerns outlined above, this would not be an effective use of resources. The objectives of option 2 can be achieved without the TGA applying a lower standard of evaluation to NVPs. Controlling the illegal importation and illegal supply of NVPs (by adopting border control option 4) would help to ensure that products are only accessed through lawful channels. This would motivate the medical and pharmacy sectors to engage in processes that could set ongoing improvements in minimum standards.

The Guidelines to Article 5.3 require parties to not provide incentives or preferential treatment to the tobacco industry. The preferred TGA option (i.e. options 2 and 3 together) for the *Pre-market TGA assessment of NVPs* would result in the TGA doing just that, thereby putting Australia in breach of our FCTC Article 5.3 obligations.

Australia has long been regarded as a world-leader in tobacco control. Since NVPs became a global tobacco control concern, Australia's strong regulatory framework of prohibiting their supply except on prescription has been considered enviable by many countries. However, in the past few years, countries have become increasingly aware of Australia's lack of enforcement of our existing laws, and the unwillingness of successive governments to undertake regulatory reform to properly protect young people from the predatory practices of tobacco and vaping companies. This failure to act has resulted in a rapid increase in NVP use and nicotine addiction in young people and non-smokers. Australia's international reputation as a global tobacco control leader has been significantly eroded as a result.

Adoption of a pre-market approval process will not address the very significant enforcement problems that arise from the deliberate and flagrant mislabelling of NVPs to conceal their nicotine content. Improving and properly implementing strict border controls on all vaping products (as recommended further above) is the only way to do this, and urgent action on this front is required.

Section 3: Minimum quality and safety standards for NVPs

Options

1. Make no changes to minimum safety and quality requirements.

2. Prohibit all flavours (except tobacco) and additional ingredients.

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

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

5. Limit the maximum volume of liquid NVPs.

6. Remove access to disposable NVPs.

7. Options 2, 3, 4, 5 and 6 together – however WITH additional warning statements.

VicHealth supports the proposed amendments to strengthen the TGO 110 as per option 7, but *with* additional health warnings. However, VicHealth also strongly recommends that amendments to TGO 110 not be implemented as a standalone measure for addressing the problems with the current regulatory framework. Any amendments to TGO 110 should be made *in addition to* recommended changes to border controls for all vaping products as discussed above. Compliance with an improved TGO 110 should be a condition of any import permit, which would be used to implement border control option 4. Without adoption of the border control reforms recommended further above (option 4), any changes to TGO 110 would be rendered practically irrelevant by the continued flow of illegal NVP imports. The demand reduction measures proposed by the TGA in this section should be seen only as additional or complementary to reforms that address supply and access.

Subject to the above, we support strengthening the Standard applicable to NVPs to reduce short term harms such as nicotine toxicity and poisoning including by reducing appeal to young people and non-smokers. It is important, however, that this be accurately described as 'measures to strengthen TGO-110' rather than as comprehensive 'minimum quality and safety standards'. The reality is that products complying with a strengthened Standard could still result in use of products of lower-than-optimal feasible quality, that are unsafe for several reasons, including the following:

1. TGO-110 requires child-resistant packaging of liquids. However, relating as it does to liquids but not devices, the Standard does not ensure that open-system devices used to vape nicotine are child resistant. This is problematic if large numbers of people continue to use open systems.
2. Trauma and burns resulting from exploding devices are one of the most significant adverse effects of using these products.[x] The ANU review has found conclusive evidence that e-cigarettes can cause burns and injuries, which can be severe and can result in death. However, TGO-110 does not cover the devices and the discussion paper does not include a proposal to amend it to do so.
3. Nicotine vaping liquids need to include solvents/ carriers. While two (diethylene glycol and ethylene glycol) have already been prohibited in the current Standard, the long-term inhalation effects of others have not been established or studied.
4. Nicotine vaping devices heat e-liquids to form an aerosol. Heating leads to chemical reactions that produce new chemicals such as carbonyl compounds. These new chemicals have been demonstrated to include highly toxic aldehydes such as formaldehyde and acrolein.[xi] To meaningfully improve safety, a minimum standard would need to specify not just what was in liquids but also what was in aerosols produced when the liquid was heated in particular devices.
5. Metals leaching from device tanks or coils[xii]or contaminating the ingredients have known harmful effects and have been detected in the aerosol produced by nicotine vaping devices at concentrations comparable and higher to concentrations in tobacco smoke.[xiii] Concentration is affected by device design and power levels.[xiv] The

lowest possible shedding of metals would be a bare minimum for product 'quality' and depends on being able to test the aerosol for particular device–liquid combinations, however such testing is not contemplated in the current reforms which continue to exclude the device itself.

6. The nicotine itself poses known safety risks not just for children through skin exposure or ingestion, but also from excessive intake by users (nicotine poisoning, seizures).[xv]

VicHealth notes that the TGA's preferred option is to not require package warnings. **However, as part of a suite of reforms including border control option 4, VicHealth supports the introduction of additional warnings** including pregnancy warning, nicotine addictiveness warning, health risk to children, and unknown health risks warning. Under this proposal, VicHealth notes that those who are accessing e-cigarettes as a smoking cessation device with medical supervision will still be able to receive the balance of health information and evidence about the health risks of combustible cigarette and e-cigarette usage. Therefore, the additional health warnings should have limited impact on e-cigarette users following the prescription pathway and seeking health advice. However, these health warnings may have an important additional impact in dissuading young people and non-smokers from trying a product they see others using.

All of the measures proposed in the Consultation Paper should reduce the risk of accidental and intentional nicotine poisoning. They would do this by making products less attractive to children and young people by removing the easy-to-use products from the domestic environment of those prescribed the products (ban on *disposables*), by improving the consumer information on the product (*labelling*), and by reducing the amount of nicotine delivered (*maximum concentrations and volume limits*). Some measures might also reduce the appeal for teenagers who might seek to get hold of devices belonging to adults (*flavours, colouring agents and packaging)*. The measures are all worth pursuing for these reasons (expanded on below). However rather than being promoted as 'minimum quality and safety standards', the measures should be described in an updated TGO-110 instrument (and supporting documentation) simply as "Measures to strengthen TGO-110".

VicHealth supports option 7 (options 2, 3, 4, 5 and 6 together) and makes the following comments in relation to each option.

2. Prohibit all flavours (except tobacco) and additional ingredients

E-liquids have repeatedly been found to contain solvents, water, nicotine, flavours, coolants and contaminants. Solvents make up by far the greatest percentage of total volume. Flavourings and other chemicals added to food that are ingested cannot be assumed as safe when heated and inhaled. Chemicals identified by NICNAS in e-cigarette liquids or emissions included 42 chemicals known to have harmful effects through inhalation, 116 with unknown effects when inhaled, 8 known or suspected respiratory sensitisers and 203 other chemicals with other known or suspected health risks[xvi]. Some of the harmful chemicals detected in e-cigarette products are derived from flavours and coolants. [xvii] Toxic contaminating chemicals are produced in chemical reactions during e-liquid storage and when this mix of chemicals is

heated during use[xviii]. Numerous studies over the past ten years have demonstrated inflammatory effects of e-cigarette flavourings[xix]. It therefore makes sense to limit non-essential ingredients in e-cigarettes.

The use of these flavourings is an intentional attempt to market these products toward children and young people, and reflect industry attempts to addict a new generation to toxic and harmful products. In Australia, nicotine vaping products are intended to be accessible only to adult smokers using them for smoking cessation. Strengthening of controls at the border and vigorous enforcement of laws banning sales at retail outlets are needed to prevent access by young people. Restricting flavourings and colourings for prescribed products would likely reduce interest in these products and preventing poisonings among young children.

3. Modify labelling or packaging requirements, including to require pharmaceutical-like plain packaging

The current packaging of many NVPs being used in Australia (and elsewhere) is brightly coloured, with cartoon and other design elements intent on appealing directly to young people. These design and marketing elements and techniques that appeal and attract non-smokers and children and young people absolutely must be removed from packaging. Plain packaging is an established regulatory mechanism that resonates with young people and non-smokers and acts as a deterrent from product usage. As one aspect of a broader suite of regulatory reforms including the establishment of border control option 4, VicHealth supports the implementation of plain packaging on NVPs.

VicHealth notes, however, that packaging should also ***not*** be overly clinical in nature nor resemble pharmaceutical packaging. Avoiding this packaging would ensure NVPs are not mistaken as approved therapeutic products or inadvertently provided a health halo. The adoption of plain packaging, as one part of broader reforms, would also potentially allow for easier enforcement as it will be clear if an NVP is a legal product or has been/ is attempting to be illegally imported.

VicHealth is also in favour of implementation research being conducted to ensure the packaging approach remains up to date with evolving research, however this should be done post-implementation and should not delay the implementation of a plain-packaging approach nor delay the accompanying necessary and urgent reforms including border control option 4 outlined in section 1.

4. **Warning Statements**

As aforementioned, **VicHealth supports the introduction of additional warnings, as part of a suite of reforms including border control option 4, including a pregnancy warning, nicotine addictiveness warning, health risk to children, and unknown health risks warning.** As covered in the Generation Vape report, there is evidence that children and young people are particularly observant and influenced by health warnings on products they come into close contact with[xx]. Under this proposal, VicHealth notes that those who are accessing e-cigarettes as a smoking cessation device with medical supervision will still be able to receive

the balance of health information and evidence about the health risks of combustible cigarette and e-cigarette usage. Therefore, the additional health warnings should have limited impact on e-cigarette users following the prescription pathway and seeking health advice. However, these health warnings may have an important additional impact in dissuading young people and non-smokers from trying a product they see others using. Again, as noted in this submission and the consultation paper, reversing the rising usage trend among non-smokers and children and young people must be an important consideration for these regulatory reforms. VicHealth reiterates its position that such warning labels must exist as *one part* of a suite of reforms that includes border control option 4 as outlined in section 1 of this submission.

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

VicHealth supports the proposal to reduce the maximum nicotine concentration in order to reduce the risk of acute poisoning. We defer to others with relevant expertise about what the optimal level would be.

6. Limit the maximum volume of liquid NVPs

VicHealth supports the proposal to limit the maximum volume of liquid in order to reduce the risk of development of nicotine dependence and harms from excess use. Smaller quantities place a convenience barrier between users and consumption.

7. Remove access to disposable NVPs

Disposable NVPs are cheap, easy to use and easy to conceal. They are popular among children and young people and often contain very high nicotine concentrations. Survey data from Victoria suggests that they represent a high proportion of NVPs used by never smokers and a high proportion of products that are imported and/or supplied illegally.[xxi] Removing access to single-use disposable NVPs may assist with detection at the border of unlawfully imported products and would reduce litter from these products (which are both a form of e-waste and single-use plastics).

Section 4: Clarifying the Status of NVPs as 'therapeutic goods'

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

VicHealth supports the proposal to clarify the status of NVPs as therapeutic goods.

The scheduling of vaporiser nicotine in the Poisons Standard attracts a number of regulatory controls under state and territory medicines and poisons legislation and therapeutic goods legislation.

The TGA regulates NVPs as unapproved “therapeutic goods”. The TGA’s ability to take enforcement action in relation to the illegal import of NVPs and illegal advertising of NVPs is reliant on them being therapeutic goods. The proposal to clarify the status of NVPs as therapeutic goods will ensure that they are captured by the TGA regulatory framework in cases where the presence of nicotine has been concealed.

In this way, the clarification is expected to aid enforcement by the TGA and is therefore supported.

Summary

VicHealth is deeply concerned by the prevalent use of e-cigarettes and NVP’s by young people in Australia. VicHealth strongly urges the TGA to adopt and implement border control Option 4 in relation to all vaping products (whether or not they contain nicotine).

Section 1 - covering amendments to border controls - is the most crucial of the reforms for reducing the current epidemic use by young people in Australia. VicHealth supports the introduction of controls on the importation of all vaping products through the Customs (Prohibited Imports) Regulations 1956, to assist with the enforcement of the controls on NVPs. The need for action has never been more pressing, with recent research showing an alarming and rapid increase in the use of NVPs by young people.

VicHealth supports the strengthening of the TGO 110. It is critical that illegal importation of NVPs is addressed to protect children and young people from the harms of vaping, however without changes to border controls– option 4, the effect of such changes will be negligible. Therefore as part of the suite of reforms including border controls- option 4, VicHealth does support additional warning labels and the application of plain-packaging, to e-cigarette products to dissuade non-smokers and children and young people from trying the products.

VicHealth would like to reiterate its concern about the TGA’s proposal to introduce a pre-market assessment process for NVPs. The introduction of a pre-market assessment process would ‘lower the bar’ by applying a lesser standard to NVPs than is ordinarily required for prescription-only medicines and would continue the pattern of creating exceptions for NVPs (despite their known harms). Importantly, the introduction of a pre-market assessment process would not address the significant enforcement problems that arise from the widespread, deliberate mislabelling of NVPs to conceal their nicotine content. VicHealth’s recommended reforms to the Customs Regulations would make it possible to control the illegal importation of NVPs. Minimum standards for contents, packaging and labelling of prescribed products should be enforceable without burdening the TGA with pre-market assessments.

VicHealth implores the TGA to take strong action that safeguards the health of all Australians, both users and those at risk of second-hand vapour, but particularly to halt the growing epidemic of uptake among children and young people.

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