



**Lung
Foundation
Australia**

Lung Foundation Australia

Potential reforms to the regulation of nicotine vaping products

**Consultation Paper
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Executive Summary

Lung Foundation Australia is pleased to provide feedback on the consultation paper for potential reforms to the regulation of nicotine vaping products. We acknowledge the importance of reviewing the current nicotine vaping products model in the face of continuing e-cigarette use and identified health harms and stress the importance of immediate action to address the growing public health crisis resulting from the use of e-cigarettes. The potential reforms that will result from this consultation play an integral part in protecting public health, however, Lung Foundation Australia emphasise the need for more to be done by the Australian Government in addressing both nicotine and non-nicotine vapes which continue to be easily accessible by youths and non-smokers. Lung Foundation Australia have continuously called for stronger government action to curb the rising vaping use and protect the health of Australians as all vaping products cause significant health harms.

The current TGO110 prescription model was created to allow access to a smoking cessation tool, yet we are witnessing increasing numbers of individuals using nicotine vaping products for recreational use. Lung Foundation Australia support the implementation of:

- **Border controls: Option 4 as well as Option 2**
- **Pre-market TGA assessment of NVPs: Option 1**
- **Strengthened minimum quality and safety standards for NVPs**
- **Ensuring NVPs are classified as 'therapeutic goods'**

With a lack of long-term data on the health impacts of nicotine vaping products, it is important to maintain a cautious approach in allowing access and use of these products. We are experiencing a public health crisis that has the potential to mirror the impacts of cigarette smoking, which has required years of public health measures to reduce, and cost the health system and economy at large billions of dollars annually. The health impacts of e-cigarettes are not fully understood and with the array of chemicals that may be present, the long-term health impacts may be significant.

Vaping use has become a significant public health program, but promisingly there is also significant community support for change to protect our fellow Australians. Lung Foundation Australia recently completed a community survey which found **89% thought vapes were unsafe, 96% were extremely or moderately concerned about youths accessing vaping products. 95% thought the government should do more to protect Australians, and 95% also reported that they thought it is extremely or somewhat important to take urgent action on vaping products.**

Lung Foundation Australia urge the Australian Government to prohibit all non-nicotine vaping products which serve no purpose to the public. E-cigarettes cause known health impacts, and the control of nicotine vaping products will not adequately address the use of e-cigarettes by youths nor protect the health Australians who can continue to access vaping products. **Just like smoking, vaping provides no benefit to society and significantly impacts the health of Australians.**

We support the review of the TG0110 model as it marks the important beginning of addressing the current e-cigarette crisis in Australia.



Mark Brooke

Chief Executive Officer

Lung Foundation Australia

About Lung Foundation Australia

Lung Foundation Australia is Australia's only national charity and leading peak body dedicated to supporting people with a lung disease, including lung cancer. For over 31 years we have been a trusted, national touch point on matters of lung health for people living with lung disease, their families, carers, health professionals and the general community. There are over 30 different types of lung disease and together these impact one in three Australians. Our mission is to improve lung health and to reduce the impacts of lung disease on all Australians. We are working to ensure that lung health remains a community priority through activities including promoting lung health and early diagnosis and advocating for policy change and research investment.

We raise awareness about the symptoms and prevalence of lung disease, and we champion equitable access to treatment and care. As a patient-representative charity, we partner with people living with lung disease, health professionals, researchers, medical organisations, and the Australian community. Together, we can drive reform in the delivery of health services across the country and assist the more than seven million Australians impacted by lung disease and lung cancer. Lung Foundation Australia has offices across several Australian states. We are committed to achieving integration with state-based health systems so that the community has access to timely and accurate information and support.

Community Consultation

Lung Foundation Australia are guided by evidence-based research and support the precautionary approach to e-cigarette use. We work closely with other non-governmental organisations and researchers to inform consumers and advocate for better protection of public health from recreational use of e-cigarettes. E-cigarette use and regulations implemented globally has provided integral opportunities to learn and recognise what we must avoid in Australia to safeguard public health. Evidence and feedback from the community throughout the last year has emphasised the complexities of vaping in terms of prescribing and how the continued uptake of vaping is a cause for concern.

We acknowledge the importance of rigorous population level data however we also wanted to give the community the opportunity to have their say through the development of a short survey. Given the extremely short consultation period the survey was launched over Christmas, resulting in a small response rate. Considering the importance of this consultation, we would have preferred to gain a deeper understanding of opinions of health professionals and community members, and importantly reach a wider audience to inform the consultation. Lung Foundation Australia remain committed to supporting the government in effective policy decisions that are consumer informed from both health professionals and the community.

Nicotine Vaping Products Survey

In December 2022, Lung Foundation Australia developed a survey to understand the experiences of health professionals and opinions from the general community.

From the 13th of December 2022 to the 9th of January 2023, we received 559 responses from the following key groups:

- 26% health professionals (N=145) including:
 - Nurses
 - Allied health professionals
 - Specialists
 - Other health professionals
 - Pharmacists
 - General Practitioners
- 74% community members (N=414)

The initial results of the survey will be discussed below, and we will share a more comprehensive summary with The Department in the following weeks.

Questions in the survey focused on the use of smoking cessation guidelines, the experience of general practitioners prescribing NVPs, the experience of pharmacists filling NVP prescriptions, insights from other health professionals, views on proposed options discussed in the consultation paper and general opinions and attitudes towards vaping products. Quotes used throughout this submission are from the survey.

E-cigarettes and health impacts

A global systematic review on the health impacts of e-cigarettes by the Australian National University in 2022, identified health risks of e-cigarettes including: addiction, intentional and unintentional poisoning, acute nicotine toxicity, including seizures, burns and injuries, lung injury, indoor air pollution, environmental waste and fires, dual use with cigarette smoking, and increased smoking uptake in non-smokers.¹ Less direct evidence indicates adverse effects of e-cigarettes on cardiovascular health markers, including blood pressure and heart rate, lung function, and adolescent brain development and function.²

In June 2022, The National Health and Medical Research Council (NHMRC) CEO statement on e-cigarettes outlined the national advice on e-cigarettes based on the most up to date scientific evidence. The statement included:

89% of survey respondents think vapes are unsafe with a further 8% stating they don't know.

- All e-cigarette users are exposed to chemicals and toxins that have the potential to cause harm. In addition to nicotine, more than 200 chemicals have been associated with e-liquids.
- E-cigarettes containing nicotine are addictive and people who have never smoked are more likely to take up tobacco smoking.
- E-cigarettes have not been proven to be a safe and effective smoking cessation tool. There are however proven safe, evidence-based treatments available to help smokers quit such as nicotine replacement therapy (NRT), pharmacotherapy and behavioural interventions. Speak with your doctor about the most appropriate option for you.
- For former smokers, using an e-cigarette may increase the chance of smoking relapse.³

There is some evidence that vaping can cause inflammation of the mouth which can lead to gum disease and other oral health problems.⁴ A study published in December 2022 demonstrated that those who were vaping had a higher risk of developing caries.⁵ Evidence also suggests the potential for nicotine e-cigarettes to lead to oral cavity cancer creating a heightened awareness on the short- and long-term health risks of vaping.⁶

The escalating cases of EVALI (e-cigarette or vaping product use associated lung injury) in 2019, brought serious attention to the dangers of e-cigarette use.⁷ The inflammatory response in the lungs caused by inhaling substances was strongly associated with Vitamin E acetate and THC.⁸ By mid-February 2020, the Centers for Disease Control in the US reported more than 2,800 cases of lung injuries requiring hospitalisation and 68 deaths in the US.⁹

Additionally, breathing in secondhand vape or passive vaping may cause health harms, with research indicating secondhand nicotine vape exposure was associated with increased risk of bronchitic symptoms and shortness of breath among young adults.¹⁰ **Over 80% of survey respondents are concerned about breathing in secondhand vape**, and with e-cigarette use increasing this is becoming almost unavoidable for many. There is conclusive evidence that e-cigarette use results in increased airborne particulate matter in indoor environments.¹¹

"[We need a] campaign to inform public of where vaping products can be legally used and the impact it can have on those around them. It is almost impossible to walk down the street without getting a mouthful of someone's vape and it affects my asthma if I walk behind them. I usually walk fast to get ahead of them. There was some benefit of wearing a mask in COVID as the 'vape backdraft' was easier to tolerate."

Australian resident

Research is continuing to demonstrate the health impacts associated with the use of vaping products and the limited data currently available is identifying an array of negative health impacts to users. It is clear vaping products are not safe for any user and the health risks already known demonstrate the harm to public health.

*"They are very attractive to young people. I see a lot of sore throats associated with vaping."
General practitioner*

*"As a sufferer of chemical inhalation in my job and smoking for years anything other than fresh air going into anyone's lungs should be banned. I live the result and it isn't pleasant."
Australian resident*

Nicotine Poisoning in Children

Accidental vaping exposure in toddlers has increased substantially across Australia causing severe side effects. E-liquids contain a cocktail of chemicals including nicotine which can cause potential lethal side effects in small quantities. For toddlers, the common symptoms of vaping exposures are coughing, severe coughing fits and vomiting.¹² In serious cases, it can also cause loss of consciousness and seizures.¹³ Concerningly, a 10kg toddler would experience potentially lethal side effects by ingesting as little as 0.5mL of a 100mg/mL NVP.

Reports of increased calls to Poison Information Centres highlight the significant risk of NVPs. The Victorian Poisons Information Centre reported a **232%** increase in calls in the last four years about poisoning from e-cigarettes, with almost half of the calls last year related to children under the age of four.¹⁴ Additionally, other Australian states are experiencing a similar increase with 171 calls to the NSW Poisons Information Centre regarding children aged 15 and under regarding vapes and e-cigarettes in 2021.¹⁵ Similarly, The Queensland Poisons Information Centre noted a **486%** increase in calls for children exposed to e-cigarettes and vaping products since 2020.¹⁶

The nicotine in one vape can be the equivalent of 50 cigarettes, depending on the size of the vape and nicotine strength, it may even be higher.¹⁷ Vaping can cause poisoning in people of all ages and for young people and adults can cause nausea, dizziness, abdominal pain, confusion, seizures and decreased breathing.¹⁸

Gateway to smoking

Tobacco use remains the leading preventable cause of morbidity and mortality in Australia, responsible for 8.6% of the total burden of disease and injury in 2018.¹⁹ Recent studies have demonstrated a link between vaping and smoking, with those who vape more likely to go on to smoke regular cigarettes.²⁰ There is evidence that non-smokers who use e-cigarettes are three times more likely to go on to smoke combustible tobacco cigarettes.²¹ Whilst ever-vapers were 18 times more likely to be ever-smokers than those who had never vaped, and ever-smokers were seven times more likely to be ever-vapers than those who had never smoked.²²

*"I am very worried about the habit becoming ingrained in the youth society and this then leading to increases in tobacco smoking later."
Australian resident*

Public health measures have resulted in significant declines in smoking rates over the past two decades, with the smoking rate decreasing to 11.2% in Australians aged 15 and over.²³ Vaping use has been increasing significantly in recent years and has the potential to increase smoking rates in Australia, impacting the years of hard work that has been done to reduce smoking and protect public

health. **Just like smoking, vaping provides no benefit to society and significantly impacts the health of Australians.** It is important to take strong, swift action to address the current vaping situation and maintain low smoking rates in Australia.

“Australia has made great gains in reducing the incidence of tobacco smoking, but it has taken several decades. The positive improvements attained will quickly be eroded by the mass uptake of vaping products which are not only being used as smoking cessation products, but for recreational purposes by young people which is creating a pathway to smoking. Something urgently needs to be done to stop the easy access to these products.”

Australian resident

Vaping in Australia

E-cigarette use in Australia has been increasing year on year, with uptake particularly of concern in youths and young adults. Concern amongst the nation is growing with health impacts of e-cigarettes continuing to come to light and despite this, Australia has been unable to slow nor prevent use of these devices. **More than 95% of survey respondents think the government should do more to protect Australians from NVPs and 95% believe it is extremely or somewhat important to take urgent action on vaping products.**

E-cigarettes have become socially acceptable for young generations unlike smoking cigarettes which are most used daily by people aged 40–49 (15.8%) and 50–59 (15.9%).²⁴ Throughout 2022, there have been immense reports of children vaping at school, leading to the installation of smoke detectors in toilets and school based educational programs. Teachers and parents are becoming increasingly concerned about children vaping. In 2021 an Australian study incorporating 196 school staff found almost 80% of respondents expressed concern about current level of vaping in schools.²⁵ Additionally, around half reported negative outcomes relating to mental wellbeing, social/peer interactions, and school performance.²⁶

96% of survey respondents are extremely or moderately concerned about youths accessing vaping products.

“My grandson got his from friends at school and has had many mental health problems since he started, including panic attacks and hysterical moments where he gets out of control physically. He has been suspended from school for this. He was not like this before he started vaping.”

Australian resident

“I find many of my young adult patients with mental health problems are addicted to vapes. I am very disappointed in the government’s lack of action regarding vape use in young people and teenagers.”

Australian resident

In Australia, between 2016 and 2019 the proportion of people who had ever used e-cigarettes increased from 8.8% to 11.3% with a notable rise among youth and young adults.²⁷ Nearly 2 in 3 (64%) current smokers and 1 in 5 (20%) people who had never smoked aged 18–24 reported having tried e-cigarettes.²⁸ In 2022, New South Wales Cancer Council began the Generation Vape study to assess access and use of vaping products in NSW young people aged 14-17 years.²⁹ The study found almost one-third of the sample (32%, n=233) reported being an ever-vaper, of which more than half (54%) had never smoked prior to starting vaping.³⁰ More than half of ever-vapers had used a vape that they knew contained nicotine (53%, n=123) and “flavourings and taste” were rated as the most important characteristic of vapes.³¹

“My husband coaches junior rugby union girls’ teams and it’s terribly common to see 12-year-old kids vaping all the time, even at half time in sporting events.”

Australian resident

“I have a 14-year-old granddaughter who became addicted to vaping at 13 yrs. One parent vaped and didn’t see it an issue believing it to be safe. The other parent banned it leading to my granddaughter denying her use of it and hiding it in her room. She says all her friends vape! She has informed me of all the great flavours. She could not be convinced it could be harmful or addictive although now she admits she is addicted to vaping.”

Australian resident

The Victorian Smoking & Health Survey reported the number of Victoria adults vaping in 2022 (308,827) has almost double since 2018 (154,895 users).³² It is estimated that there is 77,200 never smokers who

currently vape, 88,726 former smokers who currently vape, 42,841 irregular smokers who also vape, and 100,060 regular smokers who currently vape.³³ Additionally, more than 70% of users who usually vaped nicotine purchased their e-cigarette devices from bricks-and-mortar stores, mainly tobacconists (41.2%), vape stores (20.7%), and convenience stores and milk bars (8.5%).³⁴

In a study by Fiftyfive5, found that those who smoke heavily and those who are older are more likely to have started vaping to reduce smoking cigarettes or for cravings, while those who are light smokers/non-smokers and younger are driven to vape due to social reasons, stress management and because of flavours available.³⁵ Further those who are older are more likely to perceive vapes as unsafe while less than 60% of those aged 18-34 years believe vapes are unsafe.³⁶

Vaping products have been designed carefully by tobacco companies and in many cases take similar form of a USB or highlighter. Vapes are discrete and can be easily used indoors and at any time of the day. **Vaping in public places is becoming increasing common with 70% of survey respondents stating they observed vaping daily or weekly and only 20% stating they rarely or never see someone vaping. Additionally, only 61% of respondents were aware that you cannot vape where you cannot smoke, demonstrating a gap in awareness and understanding of current vaping laws.**

“Laws around where you can't vape needs to be not only [be] more known, but also enforced. Vaping indoors, in restaurants or in high traffic areas where it is illegal is extremely common and not at all enforced.”
Australian resident

“Seems a lot of people don't realise the same rules apply to vaping as cigarettes as I see them vaping in places cigarettes are banned.”
Australian resident

In response to the growing use of vapes by youths, Australian States and Territories have developed social media campaigns addressing the harms of vaping, aiming to shift the message and reduce popularity of the activity. Likewise, school-based education about vaping has been developed and employed across many schools in Australia. These public health measures have only recently been implemented and thus the effectiveness of these is unknown at this point in time.

The availability of nicotine vapes in the community

It is clear, e-cigarette use is continuing to increase despite government efforts to control the use of nicotine vaping products via the introduction of the TG0110 model in October 2021. Both nicotine and non-nicotine vapes are being used by children and non-smokers across the nation, causing health harms and the potential of increased smoking rates. Australia can no longer continue to allow access to NVPs or vapes in the wider community and we strongly support strengthening regulations around NVPs to protect the health of all Australians. It is clear the nation wants action against e-cigarette use, with parents, families, friends, teachers and medical professionals expressing ongoing concern and worry for the health of those around them.

Significantly, 55% of survey respondents stated they think all vaping products should be banned (both nicotine and non-nicotine) whilst an additional 34% think vaping products should only be accessed through a prescription for smoking cessation. Only 6% of survey respondents stated the current model is good and a further 4% did not support restricting access to any vaping products.

Vaping products often contain the addictive drug nicotine which when used by adolescents can harm the parts of the brain that control attention, learning, mood, and impulse control.³⁷ Nicotine is harmful to the developing brain (development occurs until around 25 years of age) and may increase risk for future addiction to other drugs.³⁸ Nicotine dependence can quickly occur and when a person discontinues use, they may experience nicotine withdrawal symptoms including irritability, restlessness, feeling anxious or depressed, trouble sleeping, problems concentrating and cravings for nicotine.³⁹ Youths may use vapes as a way to manage stress or anxiety causing nicotine dependence which can in turn be a source of stress.⁴⁰ A tobacco survey from the United States found the most cited reason for current use of vapes was "I am feeling anxious, stressed, or depressed" (43.4%).⁴¹

Vaping is becoming increasingly common in Australia with the Generation Vape study by Cancer Council NSW finding more than half of ever-vapers had used a vape that they knew contained nicotine and a further 27% did not know whether they had used a vape containing nicotine or not.⁴² The flavoured and affordable disposable devices often contain nicotine salts which have a lower pH, allowing higher levels of nicotine to be inhaled with less throat irritation than free-base nicotine.⁴³

46% of survey respondents state they have a friend or family member who vapes.

72% of those respondents stated they know of someone who uses nicotine vapes without a prescription.

In 2021, Lung Foundation Australia developed a suite of educational resources for the campaign 'Unveil what you inhale' to bring attention to the harms and unknown risks of vaping.⁴⁴ An important study by Curtin University, funded by Lung Foundation Australia and Minderoo Foundation, found over 1 in 5 e-liquids sold over the counter contain nicotine and 100% of the e-liquids were incorrectly labelled.⁴⁵ In October 2022, a joint investigation by the University of Wollongong and the Daily Telegraph found the three most common vape brands sold in Australia contain significant levels of nicotine (around 20mg/ml), multiple artificial flavours and cooling agents.⁴⁶ The cooling agent WS23 can provide a cooling sensation to mask the traditional burn of nicotine and there is almost no information on potential inhalation or toxicity of that chemical.⁴⁷

*"Our now 18-year-old became addicted to vaping which he used from the age of 15 (with his mother's blessing as she remains a heavy smoker and thought it ok/better for him to vape vs smoking. We need educational health messages that this is not a better alternative to smoking. It took his cousins to talk him into quitting which he found far more difficult than he had thought."
Australian resident*

Nicotine Vaping Products for smoking cessation

Since October 2021, nicotine vaping products have been categorised as a smoking cessation tool only. Importantly, research is yet to determine if NVPs are suitable and effective as a smoking cessation method and whether their effectiveness is akin to current smoking cessation tools. Long term research regarding vaping products and health is not currently available, however both the known and unknown health impacts have the potential to cause harm. In Australia, we currently have a variety of approved forms of smoking cessation tools and Nicotine Replacement Therapies (NRTs) that are tested for safety, quality, and efficacy.

Pharmacotherapies provide support and assistance who those who smoke tobacco and want to quit and are particularly important for those who are more dependent on nicotine. Such therapies aim to reduce withdrawal symptoms and block the reinforcing effects of nicotine. NRTs comprise a variety of forms including gum, transdermal patch, nasal spray, oral inhaler and tablets.⁴⁸ In Australia, first-line treatments are those which are effective, safe and licensed for smoking cessation and include NRT, bupropion, and varenicline.⁴⁹

Research has demonstrated that NRTs increase the rate of quitting by 50 to 60% and increase the likelihood of reducing habit size among smokers who are not willing to stop smoking completely.⁵⁰ Each product varies in their level of efficacy and variable rates of nicotine absorption and are most effective when used alongside cessation counselling/behavioural therapy.⁵¹

We note the PBS post market review for medicines for smoking cessation found existing smoking products to be safe, efficacious, and cost effective. Given these products are tested, safe and approved and are currently available these products should be endorsed by health professionals, and we wholly support the use of these products to support smoking cessation.⁵²

Health professionals have expressed concern over prescription vaping products for smoking cessation noting a lack of training and information:

"I have never been given any education on how to prescribe NVPs and despite researching this it's hard to find any succinct information."

General practitioner

"As discussed, the prescription process needs to be simpler - doctors (and pharmacists need more training on the best vapes to prescribe - I've found that most doctors just do what the patient asks without really understanding strength, ingredients, safer vapes etc."

Pharmacist

Guidelines for Health professionals

Smoking cessation support is integral for those wanting to quit and subsequently guidelines have been created for health professionals. The Royal Australian College of General Practitioners (RACGP) created *Supporting smoking cessation: A guide for health professionals*, to guide all health professionals to support those wanting to quit smoking.⁵³ Additionally, for pharmacists the Pharmaceutical Society of Australia (PSA) published the *Guidelines for pharmacists providing smoking cessation support*.⁵⁴ The guidelines provide recommendations on how to best support patients given their individual circumstances and needs. The RACGP guidelines states NVPs may be a reasonable intervention along with behavioural support for those who have failed to achieve smoking cessation with first-line therapy (*combination of behavioural support and TGA-approved pharmacotherapy*) and are still motivated to quit.⁵⁵ However, the guidelines emphasise that NVPs are not first-line

treatments for smoking cessation and the strongest evidence base for efficacy and safety is for currently approved pharmacological therapies combined with behavioural support.⁵⁶

The Lung Foundation Australia Survey asked health professionals on their experiences and opinions of using smoking cessation guidelines in practice. Health professionals identified that they do not have time to read an entire smoking cessation guideline and anecdotal evidence collected indicated strong support for concise information and simple guides to assist patients.

*“Concise information on benefits and risks (and comparisons including NRT), key points for discussion with patients).”
Pharmacist*

*“Need consistent guidelines specific to vaping that identify harms and risks of using when associated with planned cessation.”
Health professional*

*“Clear concise vaping information aimed at teens and latest updates on quitting vaping techniques that work for teens. Printable booklets on quit techniques.”
Health professional*

Additionally, health professionals indicated the need for information and factsheets for Aboriginal and Torres Strait Islander peoples, as smoking rates remain considerably higher in these communities. The prevalence of smoking remains disproportionately high at 43.5% in 2018-2018 for Aboriginal and Torres Strait Islander peoples and since 1994-2018 there has been no considerable change in the gap of smoking prevalence between Aboriginal and Torres Strait Islander peoples and the non-Indigenous Australian adult population.⁵⁷ In 2018, tobacco smoking was responsible for 20% of the health gap between First Nations and non-Indigenous Australians.⁵⁸

*“Culturally safe - simple images for Aboriginal and Torres Strait Islanders.”
Health professional*

*“Easy to read information for patients. Culturally appropriate information also.”
Health professional*

*“Anything in simple form to hand out to clients. Especially Indigenous youth.”
Health professional*

We highlight the importance of having clear, usable smoking cessation guidelines for health professionals, particularly in the face of the NVP prescription model and increased use by the general public.

Feedback on the proposed options in the consultation paper

Lung Foundation Australia acknowledge the significance of this consultation and emphasise the importance of strengthening the current e-cigarette prescription model in Australia. Lung Foundation Australia has and will continue to take a precautionary approach to the use of e-cigarettes and support a ban of all vaping products outside of the NVP prescription model.

Border controls

Options

1. Make no legislative changes to current border controls.
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 (the Customs Regulations), 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)

Questions

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

Lung Foundation Australia support the implementation of option 4 - introducing controls on the importation of all vaping products to assist with the enforcement of the controls on NVPs (rather than with the aim of limiting access to non-nicotine vaping products). We also support the implementation of option 2 - prevent NVPs being imported under the Personal Importation Scheme exemption under the Therapeutic Goods Regulations 1990 (Option 4 as well as option 2, together).

Strengthened border control measures are needed and 90% of community respondents support or strongly support changes to border controls to reduce the rate of illegal vapes coming into Australia.

The Australian Border Force play an integral role in preventing nicotine vaping products from entering Australia and in the first eight months since the prescription model was implemented, the Border Force seized almost 250,000 vaping products, including 111,575 e-cigarettes and pods, 94,380 refillable vape devices and 47,327 liquid vape solutions.⁵⁹ Despite this, over the last two years, there have been significant increases in illegal nicotine vaping products being sold throughout Australia. In response to the widespread use, enforcement and compliance measures have been bolstered but remain insufficient compared to the scale of the issue. Border control checks cannot be completed on the volume of illegal vaping products entering Australia and vaping supplies far outweigh current resource capabilities and powers of border force officers. From January to May 2022, New South Wales Health seized more than \$1 million worth of illegal e-cigarettes and liquids containing nicotine.⁶⁰ Since 1 July 2020, more than \$3 million of illegal products have been seized in NSW alone.⁶¹ In 2022, Western Australia Health seized more than 15,000 disposable vapes valued at over \$500,00 in just six weeks.⁶² However, enforcement measures are not enough to curb the NVP market in Australia and more must be done to prevent the products from entering Australia.

95% of survey respondents think the government should do more to protect Australians from NVPs.

Option 4- Introducing controls on the importation of all vaping products

The introduction of Customs Regulations to strengthen the NVP prescription model is supported as it enables tighten controls of vaping products. We strongly recommend that all vaping products are classified as a prohibited import in the *Customs (Prohibited Imports) Regulations 1956*. To ensure access to NPVs is maintained for smoking cessation, there must be a clear exemption to the importation of these goods that are being supplied via the TGA's channels for unapproved therapeutic goods.

96% of survey respondents are extremely or moderately concerned about youths accessing vaping products.

We note that the importation of non-nicotine vaping products accompanied with supporting documentation may assist in reducing nicotine vaping products from entering the market, however, this process will require extensive resourcing and may lead to falsified documentation being used. This relies on guaranteeing that supporting documentation from a certified laboratory is factual and that nicotine vaping products are do not go undetected due to fraudulent documentation. Incoming vapes that are labelled as nicotine free will continue to be able to enter Australia freely, regardless of if this is true or not. As mentioned previously, a pioneering study, funded by Lung Foundation Australia and Minderoo Foundation, by researchers at Curtin University found 20% of vaping products tested contained nicotine despite it being illegal. Furthermore, regardless of the implementation of documentation, domestic manufacturing and supply of non-nicotine products will not be regulated as they will not be required to produce testing results from a certified, accredited laboratory to ensure nicotine is not present. The large number of vaping products entering Australia is causing a significant burden on border force and prevents effective removal of prohibited products.

The introduction of an import permit will strengthen border control and allow efficient and effective review of incoming NVPs into Australia. The scheme will ensure greater transparency of imported NVPs and ensure NVPs are only imported by those who are approved, ensuing NVPs are kept within the smoking prescription model. With the increase in vaping products entering Australia, **95% of community respondents agree that Australia needs increased transparency on who is importing NVPs.** By tightening regulations of the prescription model via prohibiting personal importation of NVPs and ensuring importation permits are required, this provides greater transparency on the volume of NVPs entering Australia.

Importantly, the requirement of an import permit assists in compliance and enforcement and does not require goods to be referred to TGA for assessment. We note the importance of a strong permit application review process to ensure permits are only granted to those who are supplying the products via the nicotine vaping prescription model. As mentioned in the consultation paper, vaping products containing nicotine but are not labelled as such would need to be referred to the TGA for testing. However, considering the volume of vapes entering the country and the known concealment of nicotine vapes by incorrect labelling it is plausible that nicotine vapes will continue to enter outside of the prescription scheme. The only way to ensure NVPs outside of the nicotine vaping prescription model are not entering the public market is to prohibit all vaping products excluding those imported as part of the prescription scheme.

The ongoing illegal vaping market has too placed significant pressure on the TGA noting 'widespread non-compliance of illegal vapes causing significant costs regarding litigation, policy making and administration.'⁶³ The implementation of a full ban of all vaping products with the exemption under the smoking cessation model would reduce costs and assist in enforcement ensuring public health of Australians can be protected.

Whilst NVPs are prohibited in Australia without a prescription, non-nicotine vaping products are legal, and this further complicates the border control process. We are seeing increasing amounts of

incorrectly labelled vaping products due to the legislation in place. This will cause ongoing issues and is a major cause for concern despite the above changes. Lung Foundation Australia highlight that the above regulations do not adequately address vaping products used by the general public, nor significant public concern regarding the rising issue of vaping in Australia. Both nicotine and non-nicotine products can cause health harms and all vaping products outside of the smoking cessation prescription model must be prohibited to import and sell in Australia, to tackle both internationally and national vape supplies.

Option 2- Personal Importation Scheme

We support the removal of the Personal Importation Scheme. The Personal Importation Scheme is allowing consumers to access NVPs easily via online websites and import large volumes of NVPs which may then be sold on. Additionally, consumers using NVPs are purchasing products from international sellers with limited information regarding safety of the products themselves.

The Personal Importation Scheme has created a significant gap in the legislative framework and creating additional health harms. Individuals without a medical background are left to source their own NVPs which may contain increased amounts of nicotine, unknown chemicals and may require individuals to refill their device, increasing risk of poisoning.

Due to the lack of captured data in Australia, we cannot fully understand the role of NVPs for smoking cessation. The prescription model implemented in Australia is a world first and we must rely on our own experiences to determine the effectiveness of the model and areas of concern. This cannot be achieved without capturing quality data including the number of prescriptions issued, how it has been effective/ineffective for smoking cessation and side effects/health impacts that may have arisen due to vaping.

Currently, prescriptions under the Personal Importation Scheme are not recorded despite any of Australians almost 100,000 registered medical practitioners being legally able to write this prescription without undertaking any approval process. The alternative pathway of accessing NVPs from an Australian pharmacy requires medical practitioners to be approved under the SAS B pathway or as an

Authorised Prescriber by the TGA and thus, medical practitioners may not use this process as it requires an approval process. Records regarding prescriptions are only captured if prescribed by an approved medical practitioner and this is merely a surface level understanding of the use of the prescription program. The personal importation scheme must be prohibited as it cannot be controlled nor effectively monitored. As NVPs and associated e-liquid are medical products, they must be treated as such and should only be available via a pharmacy. Pharmacists further play an important role

by offering advice to consumers, information about product use and are able to answer questions consumers may have upon filling or receiving a prescription.

The personal importation scheme must be prohibited for vaping products to ensure consumers are only accessing NVPs for smoking cessation via the prescription model. As with every other medication, pharmacists should be involved in supply consumers with their prescribed medications.

87% of community respondents support banning online sales and importation of e-cigarettes for individual use.

91% of health professionals support the banning of importation of all vapes, except by pharmacies for those who smoke with a prescription.

2. Would any of these options have an impact on you?

How? 3. In relation to options 2, 3 and 4, 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?

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Pre-market TGA assessment of NVPs

Options

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 would be 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).

Questions

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

Lung Foundation Australia support option 1 of making no changes. Due to the lack of data regarding efficacy, safety, and quality of NVPs as well as the unknown and known health concerns, NVPs should not be considered an approved product. An approved NVP product by the TGA provides a wider understanding that NVPs are considered safe to use and this may cause vaping of both nicotine and non-nicotine to be falsely viewed as a safe practice. Research demonstrates e-cigarettes are not safe and can cause harm.

89% of survey respondents think vapes are unsafe with a further 8% stating they don't know.

Currently there is no approved NVP for smoking cessation internationally due to the safety concerns and lack of health data on e-cigarettes. E-cigarettes have not been proven to be an effective smoking cessation tool and can pose serious health concerns for users. The health impacts already identified in studies is cause for concern and furthermore, the long-term health impacts cannot be established at this time.

94% of community respondents strongly agree or agree that health professionals should always offer evidence-based smoking cessation tools and pathways.

We continue to support and highlight the need for a cautious approach to NVPs and that use of NVPs must only be used as a short-term smoking cessation tool. However, we currently have successful and safe treatment and support options for smoking cessation, without risking the health of Australians.

NVPs should only be used as a last line of treatment and considered only when all other smoking cessation tools have been deemed ineffective. Additionally, dual use of both cigarettes and e-cigarettes is increasing. The use of both at the same time provides no benefit to consumers and rather puts them in more danger of negative health impacts.

"They are being promoted as an alternative NRT but there is insufficient information to suggest this."

Pharmacist

"NVP's should not be accessible at all. We have many other safer methods for smoking cessation that do not expose people to harmful inhalants."

Health professional

"[We need] increased education around the dangers of vaping. I have clients who are telling their cardiologists that they are 'non smokers' when they are regular vapers, but they really think that they have quit and are doing the healthy alternative."

Health professional

Despite general practitioners being able to prescribe NVPs and Pharmacists being able to fill a prescription, these products are not TGA approved, and consumers may not understand what this means and the unknown health risks that may occur. It is integral that doctors are able to fully explain the risk of using vapes as a smoking cessation tool. The RACGP notes when determining/prescribing NVPs for smoking cessation, medical practitioners must undertake an evidence-informed shared decision-making process to ensure the patient is aware of:

- 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.⁶⁴

In study by Fiftyfive5, respondents were asked about a product known as Nicovape to determine thoughts regarding prescription nicotine vaping products.⁶⁵ 73% of respondents who were shown Nicovape believed it was a registered medicinal product with 63% reporting this as it is via a prescription only and 39% reporting this due to it being available only in a pharmacy.⁶⁶ Upon learning that such a product is not registered with the TGA, 84% of respondents were surprised, 76% felt misled/fooled and 76% felt confused.⁶⁷

We do not support TGA employing option 2 of requiring pre-market assessment of NVPs as this will falsely give consumers the impression that TGA endorses NVPs and cause misunderstandings regarding the safety and quality of these products.

Article 5.3 FCTC

Australia signed the World Health Organization Framework Convention on Tobacco Control in 2003 and since then has achieved milestones in reducing tobacco use by strengthening regulatory control, creating awareness through health campaigns, and enhancing smoking cessation services. Despite this, Australia must do more to meet the articles outlined in the FCTC and protect the health of Australians into the future.

Article 5.3 of the WHO FCTC relates to protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry.⁶⁸ Australia's obligations under Article 5.3 extend to new and emerging products, such as e-cigarettes and heated tobacco products, due to the increasing integration between their manufacturers and the tobacco industry.⁶⁹ We note Australia supports the decision of the Sixth Conference of the Parties to the WHO FCTC, which invited parties to consider taking measures to: "protect tobacco-control activities from all commercial

and other vested interests related to ENDS/ENNDS (i.e e-cigarettes or electronic nicotine delivery systems/electronic non-nicotine delivery systems], including interests of the tobacco industry".⁷⁰

Transnational tobacco companies commenced marketing and selling new products in repose to the declining smoking prevalence and have shifted focus to 'reduced harm' alternatives to nicotine products.⁷¹ Tobacco companies now own many of the leading e-cigarette brands after major international companies have invested heavily in e-cigarettes in recent years.⁷²

The Australian Government must employ article 5.3 and protect public health policies from commercial and other vested interests of the tobacco industry which now expands to e-cigarettes and related products. Implementing option 2, pre-market assessment of NVPs by the TGA is in breach of Article 5.3 as NVPs are not held to the same standards as other prescription only medicines and would provide preferential treatment to the tobacco industry.

2. Would any of these options have an impact on you?

How? 3. In relation to options 2, 3 and 4, 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? What impact would any requirement to pay a fee have on you?

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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. (Except for the option to require additional warning statements, preferred option).

Questions

Lung Foundation Australia support the implementation of option 7, however with the inclusion of additional warning statements.

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?

Lung Foundation Australia supports prohibiting all flavours of NVPs other than tobacco flavour. Nicotine is considered harsh on the throat and flavouring can reduce this harshness, reduce perceived risk, and increase appeal of NVPs.⁷³ The use of flavourings can make the act of vaping more pleasant and encourage uptake and continued use of vapes in youths and non-smokers.⁷⁴ E-cigarettes are available in a variety of flavours predominately, fruity, and sweet to appeal to younger generations.⁷⁵ The RACGP already recommend that prescribers avoid flavours or limit to only tobacco flavour to reduce these risks.⁷⁶

Internationally flavourings in e-cigarettes, other than tobacco flavouring, has been banned in Finland, Hungary, Netherlands, Ukraine, Lithuania and China. Additionally, Canada and the United States have sub-national restrictions in place. Evidence is demonstrating a strong link between youth uptake and flavours of vaping products and bans on flavours are now being implemented to make vaping less appealing to the general public and particularly young generations. Additionally, research has found that the use of e-cigarettes by teens was significantly lower when flavours were restricted; making it a key policy change to reduce the appeal of e-cigarettes.⁷⁷

Currently, the effectiveness of banning flavours to reduce uptake of vaping as a recreational activity is unknown however, the NSW Generation Vape study reported flavourings have become increasingly popular amongst youths with flavourings and taste rate the most important characteristic of vapes in the Generation Vape study of 14–17-year-olds.⁷⁸

We support prohibiting all flavours other than tobacco flavour.

84% of community respondents and 90% of health professionals support prohibiting all flavours for vapes except tobacco flavour.

2. Do you think any other ingredients should be restricted in addition to those currently restricted? If so what ingredients? Why?

No, there are no additional ingredients that must be restricted in addition to those currently restricted. However, the ingredients in vaping products and the act of vaping is unsafe to human health and can cause severe health impacts. We reiterate our support for a ban on all flavours except tobacco flavour and have no further comment to add.

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?

Lung Foundation Australia support the introduction of packaging similar to other prescription only medication. NVPs are a prescription only medicine used only as a smoking cessation tool and must be treated as such. However, we highlight that packaging NVPs as a prescription only medicine may cause confusion for consumers and give the impression that NVPs are an approved medication when this may not be true.

Packaging requirements for NVPs is integral, as current vaping products are appealing to youths and may be driving youth uptake. NVPs should not contain bright packaging or designs and should be treated as a medical product and held to the same standards.

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?

Lung Foundation Australia support the introduction of additional warning statements for NVPs. In our survey health professionals (n=145) stated further warnings should be included with:

85% Supporting warnings about the unknown health risks of vaping

79% Supporting nicotine addictiveness warnings

76% Supporting warnings about the health risks of nicotine including accidental consumption by children

68% Supporting pregnancy warnings

65% Supporting toxicity and first aid treatment statement

<1% No additional warnings

We support the addition of further warning statements on NVPs, noting the health risks that have been identified from using these products.

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?

Lung Foundation Australia support restricting nicotine concentrations to 20mg/mL for all NVPs. Globally, at least 39 countries/jurisdictions regulate concentration/volume of nicotine in e-cigarettes.⁷⁹ In the EU, United Kingdom, Canada and New Zealand, the maximum nicotine concentration is 20mg/mL which is significantly lower than current maximum nicotine concentration in Australia which is 100mg/mL.⁸⁰

It is completely unacceptable that Australia allows such high concentrations of nicotine in comparison to other countries and importantly smoking cessation guidelines such as the RACGP do not recommended prescribing freebase nicotine over 20mg/mL.

It is integral to control the level of nicotine to ensure an NVP can be used as an effective smoking cessation tool. The amount of nicotine in a regular combustible cigarette range from 0.5 to 1.5mg in comparison to the amount of nicotine inhaled from NVP which can vary between 0.5 and 4 mg with 15 puffs.⁸¹ The RACGP smoking cessation guidelines state to **avoid prescribing free-base nicotine at concentrations over 20 mg/mL**, noting two trials showing NVP efficacy used a concentration of ≤ 20 mg/mL free-base nicotine.⁸² According to the RACGP higher concentrations of nicotine (18–20 mg/mL) may be needed for more dependent smokers.⁸³

93% of health professionals strongly agree or agree that the maximum nicotine concentration should reduce to 20mg/mL.

The European Tobacco Products Directives state the limit of 20mg/mL allows delivery of nicotine at a concentration comparable to the permitted dose of nicotine from a standard cigarette during the time taken to smoke a cigarette.⁸⁴ However, importantly the relationship between nicotine concentration in liquid and nicotine delivering by an e-cigarette is complex and factors including the device itself, the composition of the liquid and user behaviour can impact the nicotine inhaled.⁸⁵ This furthermore, supports the need to reduce the nicotine concentrations of NVPs.

90% of community respondents definitely think the maximum nicotine concentration should reduce to 20mg/mL.

Lung Foundation Australia do not support the use of nicotine salt products for NVPs. According to the RACGP, there are currently no trials of the efficacy of nicotine in salt form to assist smoking cessation.⁸⁶ The use of nicotine salts in vapes resulted in higher ratings of appeal, sweetness, and smoothness, whilst having lower reports of bitterness and harshness compared to free base nicotine.⁸⁷ These effects were more prominent among never-smokers and such research demonstrates that nicotine salt formulations can enhance appeal and sensory experience of vaping.⁸⁸

6. Do you support limiting the maximum volume of liquid NVPs? If so, what maximum volume should be specified?

Lung Foundation Australia support limiting the maximum volume of liquid NVPs. E-cigarettes can contain large volumes of liquid in each device which may encourage and allow use beyond the requirement as a smoking cessation tool. Access to large volumes can entrench nicotine addiction, make it easier to share vapes and increase the potential for children to be exposed to nicotine resulting in severe and possibly fatal poisonings. E-cigarettes are easily accessible and can be used at any time of day both outside and indoors discreetly. NVPs should be used to supplement smoking cigarettes but should not encourage the user or lead the user to believing the source of nicotine is endless. As with every other medical product, NVP use should be monitored under the supervision of a health professional and concentrations reviewed regularly to support smoking cessation.

92% of community respondents and 82% of health professionals support limiting the maximum volume of liquid in NVPs.

7. Do you support preventing access to disposable NVPs?

While Lung Foundation Australia reiterate our position regarding banning all vaping products, within the remit of this consultation we do not support preventing access to disposable NVPs when there are similarly unsafe alternatives. We support the use of closed devices that cannot be refilled due to potential poisonings, altering concentrations and use of e-liquids outside of the prescription model. NVPs must be closed devices, meaning that they cannot be refilled or tampered with. The use of NVPs must be only as a smoking cessation tool and in the same context as other medicines available. We support the recommendation made by the RACGP; support for NVPs in closed systems to minimise the risk of poisoning, addition of toxic/illegal substances and contamination.⁸⁹

We note that NVPs that are open devices and refillable allow the user to vape any e-liquid on the market regardless of safety or quality of the liquid. This may also result in user abusing the device and using it to obtain higher concentrations of nicotine, increasing nicotine dependency. The expansive illegal market of NVPs in Australia, means nicotine e-liquid is widely available in unknown concentrations to those who smoke, non-smokers and children. As a smoking cessation tool, NVP use must be monitored closely by a health professional, who can determine the most suitable nicotine concentration to assist with reducing nicotine dependency.

87% of community respondents and 85% of health professionals support removing access to refillable NVPs.

Environmental harms of e-cigarettes

We must acknowledge that disposable NVPs are causing significant environmental harm and damage.

There is no doubt that the volume of disposable vaping products being used in Australia and across the world is causing extreme environmental damage. Disposable vaping products are readily used in Australia as they are simple to use and often cheaper to purchase.⁹⁰ The Generation Vape Study in NSW identified disposable vapes containing nicotine are commonly used with 86% reporting the use of disposable products.⁹¹ This reiterates international behaviour studies as the disposable vaping product JUUL is the preferred product for young people in the US.⁹² E-cigarettes pose a serious threat to environments due to the nicotine and the concoction of chemicals they contain.⁹³ Additionally, e-cigarettes are a source of metal contamination to the environment due to both the direct breakdown of the electronic components and indirectly via contaminated e-liquids.⁹⁴ E-cigarettes commonly

contain aluminium, barium, cadmium, chromium, copper, iron, lead, nickel, silver, tin and zinc.⁹⁵ Potentially toxic compounds have also been detected in e-cigarette filters, mouthpieces, rubber stoppers and pod plastic.⁹⁶ As most e-cigarettes are made of single-use plastic and contain batteries that cannot be removed, these products are unable to be recycled.⁹⁷ E-cigarette litter can leach chemicals in the soil and water, and pose a danger wildlife and plants.⁹⁸

Lung Foundation Australia reiterate our support for the ban of all vaping products both disposable and refillable outside of the smoking cessation model – which would significantly reduce the volume of waste and thus environmental harms associated with these products. We stress that e-cigarette waste is becoming an increasingly significant concern as vaping products remain predominantly freely available to the general public.

The nicotine vaping prescription model should maintain access to only closed devices as they enable nicotine to be delivered, while reducing risk of poisonings. Lung Foundation Australia are committed to protecting the environment particularly given the significant impact the environment has on health and respiratory health, as such we encourage further consideration of policy options and investment in environmental protection associated with tobacco and vaping use.

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

Lung Foundation Australia champion lung health for all, providing support and services for the 1 in 3 Australians living with a lung disease whilst also advocate for public health reforms that will protect lung health into the future.

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?

Lung Foundation Australia do not require time to become familiar with the reforms before they come into effect. Lung Foundation Australia can assist in supporting health professionals through the transition to new reforms and through sharing the reforms with the wider community, given the high public interest and personal interest of the lung cancer and lung disease community.

10. Are there any other potential minimum requirements for unregistered NVPs that the TGA should consider including in TGO 110?

There are no further potential minimum requirements for unregistered NVPs that TGA need to consider.

Clarifying the status of NVPs as 'therapeutic goods'

Section 7 of the TG Act permits the Secretary (in practice, a senior executive of the TGA) to declare classes of goods to be therapeutic goods. In light of the increasing practice of concealing the presence of nicotine in NVPs, it is desirable to utilise this power and clarify the regulatory status of these products. Making an order under s 7 would ensure that the TGA is able to take regulatory action in relation to NVPs that contain nicotine, but are not labelled as such, under the therapeutic goods laws framework.

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

Lung Foundation Australia support regulating NVPs that contain nicotine but are not labelled as containing nicotine under the therapeutic goods framework. There are increasing numbers of NVPs becoming available in the general community due to mislabelled products and intentionally concealment of products. In a ground-breaking study, funded by Lung Foundation Australia and Minderoo Foundation, Curtin University tested the e-liquids used in 52 flavoured e-liquids for sale over the counter in Australia and found over 1 in 5 vapes contained nicotine.

Due to the increasing illegal market of NVPs it is integral that the TGA are able to take appropriate regulatory action in relation to NVPs that contain nicotine despite being labelled differently. Enforcement, monitoring and compliance action must continue to be ramped up in the face of a serious and established illegal market across Australia.

The reforms put forward in this review will strengthen current legislation and reduce the importation of NVPs, however, as regulations against NVPs are tightened this may result in increased cover up of NVPs. The TGA must be able to respond to this effectively, as enforcement and compliance are necessary to maintain the regulations and ensure they are effective in reducing entry of illegal products into Australia.

Summary

Thank you for the opportunity to provide feedback on the consultation paper for potential reforms to the regulation of nicotine vaping products. We acknowledge the importance of strengthening the legislation for NVPs noting the significant ongoing rise in youth vaping and access to these products outside of the prescription model. E-cigarette use in Australia has increased significantly in recent years, causing a new public health crisis particularly amongst youths.

96% of survey respondents are extremely or moderately concerned about youths accessing vaping products and 95% of survey respondents think the government should do more to protect Australians from NVPs.

Over the last 30 years tobacco control measures have been implemented to prevent disease and death, and yet over 10% of Australians continue to smoke and put their lives at risk. We are in danger of replicating this public health crisis with e-cigarettes, and action can no longer wait.

We acknowledge the importance of the reforms proposed in this review and strongly support the consultation and immediate implementation of reforms to strengthen regulations of TGO110. The widespread use of NVPs in Australia is harming children and non-smokers and the proposed reforms have the potential to reduce access, appeal to youths and ensure such products can be used only as a smoking cessation tool.

As discussed above, Lung Foundation Australia support the implementation of:

- **Border controls: Option 4 as well as Option 2**
- **Pre-market TGA assessment of NVPs: Option 1**
- **Strengthened minimum quality and safety standards for NVPs**
- **Ensuring NVPs are classified as 'therapeutic goods'**

Lung Foundation Australia supports a ban on all vaping products excluding the use of the nicotine vaping products under the prescription model for smoking cessation. Just like smoking, vaping provides no benefit to society and significantly impacts the health of Australians. The Australian Government must do more to protect the health of Australians from the known health impacts of vaping and we urge the government to take immediate action to rectify and prevent the ongoing public health crisis unfolding.

If you would like to discuss our submission further, please contact Paige Preston, Senior Manager, Policy Advocacy and Prevention at Lung Foundation Australia at Paigep@lungfoundation.com.au.

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