

**From:** s22  
**To:** [Minister Butler](#)  
**Cc:** s22, s22, [s22@fromthefieldsinc.com](mailto:s22@fromthefieldsinc.com), s22  
**Subject:** From the Fields Pharmaceutical Pty Ltd - TGA Review of potential reforms to the regulation of nicotine vaping products  
**Date:** Friday, 13 January 2023 1:59:08 PM  
**Attachments:** [image001.png](#)  
[FTF-Submission-on-regulation-of-NVPs-Jan 2023 Final.pdf](#)  
[Tackling Australias Vaping Health Crisis Media Release 13 January 2023.pdf](#)

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**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Minister,

On behalf of From the Fields Pharmaceutical Pty Ltd (FTF) and s22, we wish to provide you with an advanced copy of our submission into the **TGA Review of Potential reforms to the regulation of nicotine vaping products**. We also provide a media statement that is being issued today.

Please find both attached. We have also provided this documentation through the formal Ministerial correspondence channel through the health.gov.au website.

We have provided you copies as the responsible Federal Minister and acknowledge the proactivity of the reform agenda you are undertaking. As well as a courtesy we have also informed your Assistant Health Ministers given their responsibilities across the country and in community sectors where vaping has become a major problem.

Please note we have also put this material before the TGA Review ahead of the 16 January deadline.

Should you have any questions or wish to make contact with us, please do not hesitate at any time. We see this matter as evolving over the coming weeks and months and would naturally welcome the chance for dialogue with you and/or your office including a relevant Adviser.

**Some further information is outlined below:**

From the Fields Pharmaceutical Pty Ltd (FTF) is an independent company providing Australian standards nicotine vaping products with its WILD By Instinct Nicotine vaping brand. This occurs under the current TGO 110 regulatory framework.

We support a pragmatic solution for adult smoker cessation with NVPs under a therapeutics goods framework. We are also taking a bold public step to urge the Albanese Government to ban the product in Australia unless it is prescribed by a GP.

Our detailed submission (see Attached) to the TGA outlines the urgency for reform, including new enforcement measures to address both illegal and out-of-control vaping in Australia, in particular amongst Australia's youth & minors.

Our 5-point + outline presents further reform and regulation of nicotine vaping products (NVPs) and includes:

- NVPs or e-cigarettes have become an effective tool for quitting smoking, serving as a substitute when prescribed through a healthcare professional.
- Australian authorities must back in the medical prescription only model in place for NVPs sold. This GP prescribed / pharmacy sold product is a pathway for better health outcomes for Australian smokers.
- Address the illicit black market for vape sales to adult and young Australian consumers.
- Assure public authorities that revising standards and proper enforcement of regulations in the illicit sale of NVPs across Australia will not create supply side constraints for NVP consumer

demand as TGA approved product can replace in physical and online pharmacies.

- Under revised public policy and regulatory enforcement, Australia can achieve <5% adult smoker rates by year 2030 if nicotine vaping is used actively as a smoker cessation tool.

The submission also outlines:

- Remove Personal Importation Scheme exemption for NVPs
- Tighter controls NVPs importation (only licensed S4 product wholesalers & distributors)
- Treat Nicotine and Non-Nicotine NVP's as same category for importation and border control.

Future contact can be made with s22 (Royce) on s22

s22 @royce.com.au and s22

s22 @fromthefieldsinc.com

More information is available on the company website at <https://ftfpharmaceutical.com/media>

As Royce we are acting on From the Fields Pharmaceuticals' behalf and they are on our Federal lobbying register.

With kind regards,

s22 | s22



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## MEDIA RELEASE

For Immediate Release

13<sup>th</sup> January 2023

### Tackling Australia's Vaping Health Crisis

- Australian youth should not vape or smoke, says leading vape supplier
- The black-market sales of illicit vaping products exceed 10 million units a month
- Medical fraternity is watching this growing public health crisis from the sidelines
- Australia could achieve less than 5% adult smokers in the next 3-5 years if nicotine vaping is used actively as a smoker cessation tool

A global manufacturer of nicotine vaping products (NVPs) is urging the Albanese Government to ban the product in Australia unless it is prescribed by a GP.

From the Fields Pharmaceutica **s22** and **s22** said that new enforcement measures were needed to address illegal and out-of-control vaping in Australia, especially among Australia's youth.

"Since October of last year, the law states that in order to purchase a nicotine e-liquid in Australia you must have a valid vaping prescription," **s22** said.

"However, this rule of law is not working. Around 1.5 million adult Australians vape today. The vast majority of these Australians are vaping illegally thanks to unscrupulous retailers and traders, and despite the best intentions of local lawmakers to restrict the purchase of vapes to a medical prescription only."

**s22** said that any registered medical practitioner in Australia can write a vape prescription.

"The main reason a doctor will write a vaping prescription is to assist with quitting smoking, particularly for those individuals who have tried other methods and have been unable to quit.

"However, one of the problems is that too many doctors are reticent to write this type of prescription, despite compelling evidence that e-cigarettes are effective quitting aids and an effective substitute for smoking.

"The awareness and process of doctors becoming an authorised prescriber of nicotine vaping products (NVPs) has been poorly understood and communicated. Sadly, there is a deep reluctance within the medical fraternity to support vaping as a harm reduction pathway for addicted smokers.

"The current prescription model has failed largely due to a lack of support and communication by the RACGP, Pharmacy Guild, and other professional bodies. As a result, the scourge of illegal vaping is evident in the increasing number of teenagers who have purchased a vape product illegally," **s22** said.

From the Fields Pharmaceutical has delivered a submission to the Therapeutic Goods Administration (TGA) Review recommending multiple solutions to the vaping health crisis.

“We must tackle the illegal, unregulated trade in vaping, which has created an exploding and major public health issue in Australia,” s22 said.

“Currently the black market of illicit vaping products, where 10 million units are sold each month, provides too easy access of nicotine vaping products to minors.

“The loophole allowing mislabelled vaping products needs to be closed. The importation of non-nicotine should be under the same import pathway as nicotine products to avoid general trade importing under false labelling and fuelling a black market.

“Moves to enforce sales of NVPs only by medical prescription is the means to increase smoking cessation, drive down adult smoking rates, and achieve improved public health outcomes.

“Our company supports a pragmatic solution for adult smoker cessation with NVPs under a therapeutic goods framework. We welcome the Albanese Government’s intention of further reform to address illegal vaping and win back control of this serious public health issue,” he said.

Some of the key statements made by From the Fields Pharmaceutical in its submission to the TGA Review, include:

1. NVPs or e-cigarettes have become an effective tool for quitting smoking, serving as a substitute when prescribed through a healthcare professional.
2. Australian authorities need to back in the medical prescription only model in place for NVPs sold. This GP prescribed/pharmacy sold product is a pathway for better health outcomes for Australian smokers.
3. Properly address the current illicit black market for vape sales to so many adult and Australian youth.
4. Assure public authorities that revising standards and proper enforcement of regulations in the illicit sale of NVPs across Australia, will not create supply chain constraints for NVP patient demand for Australian standard, smoking cessation designed products, which can be dispensed through physical and online pharmacies.
5. Australia could achieve less than 5% adult smokers by 2030, if nicotine vaping is used actively as a smoker cessation tool.

“Putting in place a simpler approach for less complex enforcement at the border for imported, but mislabelled NVPs now entering Australia, can meet existing and future regulations, while importantly backing in better health outcomes,” s22 added.

**From the Fields Pharmaceutical’s submission to the TGA Review is attached:**

<https://ftfpharmaceutical.com/media>

-Ends-

**Contact:**

s22 @royce.com.au

s22 @royce.com.au

### **About From the Fields Pharmaceutical**

From the Fields Pharmaceutical Pty Ltd (FTF) is an independent company providing Australian standards nicotine vaping products via the current TGO 110 regulatory framework in Australia with its *Wild By Instinct* Nicotine vaping brand. From The Fields’ mission is to provide a pathway to wellness for adults, with a focus on smoking cessation. The company is Australian owned and operated.

s22

**From:** Butler, Mark (MP) <Mark.Butler.MP@aph.gov.au>  
**Sent:** Monday, 12 December 2022 3:20 PM  
**To:** Minister Butler  
**Subject:** FW: The Therapeutic Goods Administration review to vaping regulations  
**Attachments:** Vaping Info Sheet 10-12-22.pdf

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-----Original Message-----

From: s22 @hotmail.com>  
Sent: Saturday, 10 December 2022 12:34 PM  
To: Butler, Mark (MP) <Mark.Butler.MP@aph.gov.au>  
Subject: The Therapeutic Goods Administration review to vaping regulations

December 10, 2022

Hon. Mark Butler  
Member for Hindmarsh  
Minister for Health and Aged Care  
Deputy Leader of the House  
PO Box 6022  
House of Representatives  
Parliament House  
Canberra ACT 2600

The Therapeutic Goods Administration in Australia is reviewing the need for changes to vaping regulations including: a crackdown on imports, \*introducing quality and safety standards and \*restricting labels and flavours to make e-cigarettes less appealing to children.

Many Health professionals have made it clear it's going to be a tough fight, but we are also up to the task with your help.

The Taskforce for Drug Prevention needs help in bringing the existing state and territory regulations onside. We are all fully aware of the tobacco industry's infamy in using manipulative and misleading tactics in marketing their products, particularly to children and marginalized populations, not to forget their historical disempowering influence on preventative tobacco legislation.

E-Cigarettes and other Vaping products is being aggressively promoted and sold online by the cannabis industry, as 'safer' method to be used for smoking Cannabis/Marijuana.

In and ever emerging reality, e-cigarettes and 'vapes' are being sold to children at corner shops with no identification required and no prescriptions. Kids believe it's just 'sweet, flavoured nothingness that looks cool with the tricks, shapes and veritable fruit salad of flavours available to them.'

This irresponsible active promotion of these products via social media to our youth is promoting practices such as:

- \*Disguising regular use even right in front of teachers/parents
- \*Vaping in unauthorised areas using deceptive techniques (Stealth Vaping),
- \*Promoting myths around contents in Vapes as 'health benefits' (especially mental health) and, also encouraging the 'Hack' of the vape devices themselves and create their own bespoke e-juice.

The Taskforce for Drug Prevention would like to bring to your attention the failure of the present legislation regarding vaping here in Australia. Please see attached bulletin entitled: Vaping info Sheet.

The Australian Therapeutic Goods Administration (TGA) is seeking comments on potential reforms to the regulation of nicotine vaping products (NVPs) in Australia. We are also keen to initiate more relevant legislation to protect the many young people who find vaping an attractive option.

We urge you to provide your important feedback by completing TPG online survey on the TGA Consultation Hub <https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.tga.gov.au%2Fresources%2Fconsultation%2Fconsultation-proposed-reforms-regulation-nicotine-vaping-products&data=05%7C01%7C%7C76dca110a5224112d3ea08dad7dfcec4%7C84df9e7fe9f640afb435aaaaaaaaaaa%7C1%7C0%7C638059653567655065%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=5y4XwBX440R%2Fe9i7rTf83L31%2BBRma%2FNhHx34Fe1o4FA%3D&reserved=0>

May we also suggest you email your feedback to [info@tga.gov.au](mailto:info@tga.gov.au) <<mailto:info@tga.gov.au>>

As a community, we need to alert the TGA that we all take protecting our children's health and well-being seriously and that this should be one of our society's highest priorities. Your advice on these matters would be very much appreciated.

Australia beat cigs, Let's now tackle Vapes'

Some of the key figures behind Australia's world-renowned campaign against tobacco say they are alarmed by rapid rise in vaping and the ballooning black market they do not want the next generation addicted to nicotine like previous generations were.

The worldwide cannabis industry is selling cannabis vapers online. Here in Australian the TGA urgently needs to close the present loophole in the vaping legislation to not only apply to nicotine but THC, CBD, HEMP Delta-8-tetrahydrocannabinol.

Drug Free Australia Queensland and Dalgarno would appreciate your comments on this latest data and how you might assist in disseminating information to your contacts and constituents.

Kind Regards

s22  
[Redacted signature]

Drug Free Australia  
s22  
Prevent. Don't Promote Drug Use  
s22

Prevent. Don't Promote Drug Use.

E: **s22** [redacted]@drugfree.org.au

E: **s22** [redacted]@drugfree.org.au

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# Vaping

## Harm Reduction or Harm Promotion?

Get the Facts – Make the Healthier Choice!



Coalition of Alcohol and Drug Educators

**Dalgarno**  
INSTITUTE

/DALGARNOSNB

NOBRAINER\_DRUGS

DALGARNOINSTITUTE.ORG.AU



### IS VAPING BAD FOR YOU? AND 12 OTHER FAQs

Vaping has risks, regardless of what you vape. Although it's [less risky than smoking cigarettes](#), the safest option is to avoid vaping and smoking altogether.

Effects on heart

Effects on lungs

Effects on teeth and gums

Other physical effects

Vaping vs. smoking

Vaping vs. Juuling

With vs. without nicotine

Marijuana and CBD oil

Fluid flavor

Ingredients to avoid

How to minimize side effects

For more search [‘vaping’ on healthline.com](#)

VAPING:  
THE HIT YOUR  
BRAIN TAKES

**Dangerous to All**  
**– But MORE to Teens!**

CLICK TO WATCH.



### HERE'S HOW A SINGLE SESSION OF VAPING CAN HURT YOUR LUNGS

Researchers are learning how vaping e-cigarettes can cause lung damage.

- One vaping session can result in changes in blood flow.
- Researchers worry vaping can lead to hardening of arteries over time.
- Vaping remains most popular with young people under 30.

For more go to [Vaping? #NotEvenOnce](#)

## E-CIGARETTES EVIDENCE ON HEALTH IMPACTS

### A GATEWAY TO SMOKING

**3x**

Non-smokers who vape are three times as likely to take up regular smoking as non-smokers who don't vape.

### SMOKING CESSATION UNCLE



Evidence that e-cigarettes are effective for smoking cessation is limited. Most smokers who use e-cigarettes continue to smoke.

### CAUSES INJURY

Impacts include poisoning, seizures, burns, and lung disease.

### HARMFUL TO THE ENVIRONMENT

E-cigarettes contain single-use plastics & lithium batteries, cause pollution & can start fires.



Australian National University

Source: [https://nceph.anu.edu.au/research/projects/health\\_impacts\\_electronic\\_cigarettes#health\\_outcomes](https://nceph.anu.edu.au/research/projects/health_impacts_electronic_cigarettes#health_outcomes)

EVIDENCE-BASED RESOURCE GUIDE SERIES

### Reducing Vaping Among Youth and Young Adults



This guide supports health care providers, systems, and communities seeking to prevent vaping. It describes relevant research findings, examines emerging and best practices, identifies knowledge gaps and implementation challenges, and offers useful resources.

CLICK TO ACCESS



## E-CIGARETTES ARE HARMFUL AND ADDICTING YOUTH. (REPORT: ANU).

The major review found use of nicotine e-cigarettes increases the risk of a range of adverse health outcomes, particularly in youth, including taking up smoking, addiction, poisoning, seizures, trauma and burns and lung injury.

"We reviewed the global evidence in order to support informed choices on vaping for Australia," lead author Professor Emily Banks from the ANU National Centre for Epidemiology and Population Health said.

"The evidence shows e-cigarettes carry significant harms. Nicotine is a key ingredient and one of the most addictive substances known. Vaping is causing addiction in a new generation of users.

"Young non-smokers who vape are around three times as likely to take up smoking than non-vapers. Nicotine use in children and adolescents can lead to lifelong addiction issues as well as difficulties in concentration and learning. Vaping is also illegal if it isn't on prescription."

The report found early warning signs of adverse effects of e-cigarettes on cardiovascular health markers, including blood pressure and heart rate, and lung functioning.

"The evidence is there for some of the risks but for most major health outcomes, like cancer, cardiovascular disease and mental illness, we don't know what the impacts of e-cigarettes are. Their safety for these outcomes hasn't been established," Professor Banks said.

"There are myths targeting young people; the false ideas that vapes wouldn't be widely available if they were dangerous and 'it's just water vapour'.

"Vapes deliver hundreds of chemicals - some of them known to be toxic and many others with unknown effects.

"In Australia, over two million people have used e-cigarettes, more common among youth, particularly young male smokers and the majority is not for the purpose of cessation."

The report found more than half, 53 per cent, of current



use in Australia is by people who also smoke, 53 per cent is by past smokers and 15.5 per cent is people who have never smoked.

"The report found limited evidence that nicotine e-cigarettes were effective to help people quit smoking in the clinical setting," Professor Banks said.

"Most people who quit smoking successfully do so unaided.

"E-cigarettes are likely to be harmful for non-smokers and for people who use them while continuing to smoke - the commonest use pattern currently.

"E-cigarettes may be beneficial in the small number of smokers who use them to quit smoking completely and promptly, but there is a huge uncertainty about their effectiveness and the overall balance of risks and benefits for quitting."

The report supports national and international efforts to avoid e-cigarette use in the general population, particularly in non-smokers and youth.

"Our young people have been through a lot and they deserve the best future possible," Professor Banks said.

"The evidence is in that avoiding e-cigarettes should be part of that."

Source: <https://www.anu.edu.au/news/all-news/e-cigarettes-are->

## CHILD VAPING 'SKYROCKETING'

"A single 30-minute vaping session can significantly increase cellular oxidative stress. Middlekauff et al demonstrated that vaping is associated with adverse changes in the body that can presage future health problems."

Source: <https://jamanetwork.com/journals/jamapediatrics/article-abstract/2782800>





## NHMRC 2022 CEO STATEMENT ON ELECTRONIC CIGARETTES

### PRODUCT SAFETY:

- E-liquids can contain nicotine (even when labelled 'nicotine-free') and many other chemicals. More than 200 chemicals have been detected in e-liquids.
- E-cigarettes can be harmful. All e-cigarette users are exposed to chemicals and toxins that can harm your health.
- Use of e-cigarettes can result in serious burns and injuries. In some cases, these burns and injuries have resulted in death. Poor quality e-cigarette batteries or high-power devices increase the risk of explosions that can cause serious burns and injuries.

### HEALTH EFFECTS:

- Use of e-cigarettes can result in seizures in some users.
- Exposure to e-liquids that contain nicotine can result in poisoning for some users which, although it may not happen to everyone, can be severe and cause death.
- E-cigarette-related calls to Australian Poisons Information Centres have increased over the past 5 years. Most poisonings occur in toddlers and adults.
- Use of e-cigarettes can result in a serious and sometimes fatal lung condition known as E-cigarette or Vaping Associated Lung Injury (EVALI) in some users. Most cases of EVALI reported in the United States of America were linked to cannabis oils and vitamin E acetate, but other chemicals may also contribute to this condition.
- Use of e-cigarettes that contain nicotine probably results in throat irritation, cough, dizziness, headaches and nausea.
- There is not enough information from human research studies to know about the potential impacts of e-cigarette use on conditions such as cancer and cardiovascular disease, reproductive health, respiratory conditions (e.g. asthma) and mental illness.
- Lack of information does not mean that e-cigarettes are safe. More information is needed to know if long-term e-cigarette use is safe or if it harms your health.
- Can cause serious burns and injuries.

### SPECIFIC HEALTH EFFECTS BY TOBACCO SMOKING STATUS:

- If you have never smoked tobacco cigarettes and you use or are thinking of using e-cigarettes. There are no health benefits of using e-cigarettes if you do not currently smoke tobacco cigarettes. You can become addicted if you use e-cigarettes

that contain nicotine. If you are a current tobacco smoker and you use or are thinking of using e-cigarettes you will probably experience immediate increases in heart rates and blood pressure and stiffening of the arteries if you use e-cigarettes. You may become addicted to e-cigarettes if they contain nicotine and you may use e-cigarettes in excess.

- If you are a former tobacco smoker and you use or are thinking of using e-cigarettes
- You may experience a decrease in blood pressure after you have switched.

### E-CIGARETTE USE AND TOBACCO SMOKING:

- **Tobacco smoking uptake** – If you have never smoked tobacco cigarettes and you use or are thinking of using e-cigarettes
- **You are more likely to try tobacco smoking or become a tobacco smoker if you use e-cigarettes.**
- **Tobacco smoking cessation**
- If you are a current tobacco smoker and you use or are thinking of using e-cigarettes
- **There are other proven safe and effective options to help you quit smoking. E-cigarettes are not proven safe and effective smoking cessation aids.**
- **Short-term e-cigarette use may benefit you if you are able to quit smoking and have been previously unsuccessful with other smoking cessation aids. However, not everyone finds e-cigarettes helpful for quitting.**
- Research studies have found that it was more common for smokers to become dual users (using both e-cigarettes and tobacco products at the same time) than quit if they used nicotine e-cigarettes. For some smokers, using nicotine e-cigarettes may assist them to quit; however, more research is needed to confirm the harms and benefits of using them for this purpose. For additional assistance to quit tobacco smoking or quit e-cigarettes you are encouraged to seek further information from reliable sources, such as your healthcare practitioner or quit services.
- **Relapse to tobacco smoking:** If you are a former tobacco smoker and you use or are thinking of using e-cigarettes. Using an e-cigarette may increase your chance of smoking relapse.  
(Source: <https://www.nhmrc.gov.au/health-advice/all-topics/electronic-cigarettes/ceo-statement>)

## VAPING MESSES WITH YOUR GENES & IMPACTS IMMUNITY.

"Our study, for the first time, investigates the biological effects of vaping in adult e-cigarette users, while simultaneously accounting for their past smoking exposure. Our data indicates that vaping, much like smoking, is associated with dysregulation of mitochondrial genes and disruption of molecular pathways involved in immunity and the inflammatory response, which govern health versus disease state..." Ahmad Besaratinia, PhD, Professor of research population and public health sciences at Keck School of Medicine. **Full Research:** <https://www.nature.com/articles/s41598-021-01965-1>

## VAPING ANYTHING IS BAD – CBD VERY MUCH INCLUDED!

(US military have a blanket ban on vaping CBD products)

"Depending on the temperature and atmosphere, 25–52% of CBD was transformed into other chemical substances:  $\Delta 9$ -THC,  $\Delta 8$ -THC, cannabidiol and cannabichromene were the predominant pyrolysates in both conditions, all formed by cyclization reaction. THC was the main pyrolysis product at all temperatures under both oxidative and inert conditions. *Our results point out that CBD in e-cigarettes can be considered as a precursor of THC, thus it bears all the dangers related to this psychoactive compound.* Our findings are fundamental contributions to the safety profile of CBD-based e-cigarettes." Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC76212/>





**OTHER ARTICLES:** (CLICK TO VISIT)



**E-Cigarettes and Vaping-Related Disease**



**Vaping and popcorn lung?**



**Adolescents' Use of "Pod Mod" E-Cigarettes – Urgent Concerns**



**CDC, FDA, States Continue to Investigate Severe Pulmonary Disease Among People Who Use E-cigarettes**



**DON'T BUY STREET VAPING PRODUCTS, CDC, FDA WARN**



**Officials Warn People Against Vaping Amidst Outbreak of Mysterious Lung Disease**



**School vaping ban goes into effect as students return**



**New York State Dept of Health: Unexplained Vaping-associated Pulmonary Illness**



**India proposes ban on e-cigarettes, with jail terms for offenders**



**North Carolina Says It Is Suing 8 E-Cigarette Companies**



**What's New in E-Cigarette Regulation?**



**Youth Vaping and Associated Risk Behaviors – A Snapshot of Colorado**



**Juul is the new Big Tobacco? Wave of lawsuits signal familiar problems**



**Vaping-Related Injuries Surge; "Consider Not Using" e-Cigs: CDC**



**Kansas confirms first death due to vaping, sixth vaping-related death nationwide**



**What we know about the mysterious vaping-linked illness and deaths**



**Not so fast CDC is not ready to blame illicit street vapes for illnesses**



**Pulmonary Illness Related to E-Cigarette Use in Illinois and Wisconsin – Preliminary Report**



**Imaging of Vaping-Associated Lung Disease**



**Vaping Illnesses: Consumers can Help Protect Themselves by Avoiding Tetrahydrocannabinol (THC) – Vaping Products**



**FDA warns JUUL Labs for marketing unauthorized modified risk tobacco products, including to outreach to youth**



**FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatments for Serious Diseases,**



**US Government looks to ban flavoured vaping products**



**What you should know about the outbreak of severe lung problems linked to e-cigarettes and vaping – Gold, MD**



**Vaping: As an imaging scientist I fear the deadly impact on people's lungs**



**#PotVaping – Facts & Talking Points**



**VAPING In Australia – Not Reducing Harm!**



**CDC – Centre for Disease Control (Outbreak of Lung Injury Associated with E-Cigarette Use, or Vaping)**

s22

-----Original Message-----

From: [health.noreply@govcms.gov.au](mailto:health.noreply@govcms.gov.au) <[health.noreply@govcms.gov.au](mailto:health.noreply@govcms.gov.au)>

Sent: Friday, 13 January 2023 11:47 AM

To: Assistant Minister Kearney <[Assistant.Minister.Kearney@health.gov.au](mailto:Assistant.Minister.Kearney@health.gov.au)>

Subject: Webform submission from: Contact a minister > Content blocks

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Submitted on Fri, 2023-01-13 11:46

Submitted by: Anonymous

Submitted values are:

Title: s22



Given name: s22  
Family name: s22  
Email: s22@royce.com.au  
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City/Suburb: s22  
State: s22  
Postcode: s22

Organisation: Royce Communications - MELBOURNE, VIC Minister name: The Hon Ged Kearney  
Enquiry subject: TGA Review into regulation of nicotine vaping products Details of your enquiry/comments:

On behalf of From the Fields Pharmaceuticals Australia Pty Ltd (FTF) and s22 is the s22 and s22, we wish to provide you with an advanced copy of our submission into the TGA Review of Potential reforms to the regulation of nicotine vaping products.

We have also provided a copy the Federal Health and Aged Care Minister, Hon. Mark Butler MP. We, however, wished to also alert you to this submission on this important topic as the Assistant Minister.

From the Fields Pharmaceuticals Australia Pty Ltd (FTF) is an independent company providing Australian standards nicotine vaping products with its WILD By Instinct Nicotine vaping brand. This occurs under the current TGO 110 regulatory framework.

We support a pragmatic solution for adult smoker cessation with NVPs under a therapeutics goods framework. We are also taking a bold public step to urge the Albanese Government to ban the product in Australia unless it is prescribed by a GP.

Our detailed submission (see Attached) to the TGA outlines the urgency for reform, including new enforcement measures to address both illegal and out-of-control vaping in Australia, in particular amongst Australia's youth & minors. Our 5-point + outline presents further reform and regulation of nicotine vaping products (NVPs) and includes:

- NVPs or e-cigarettes have become an effective tool for quitting smoking, serving as a substitute when prescribed through a healthcare professional.
- Australian authorities must back in the medical prescription only model in place for NVPs sold. This GP prescribed / pharmacy sold product is a pathway for better health outcomes for Australian smokers.
- Address the illicit black market for vape sales to adult and young Australian consumers.
- Assure public authorities that revising standards and proper enforcement of regulations in the illicit sale of NVPs across Australia will not create supply side constraints for NVP consumer demand as TGA approved product can replace in physical and online pharmacies.
- Under revised public policy and regulatory enforcement, Australia can achieve <5% adult smoker rates by year 2030 if nicotine vaping is used actively as a smoker cessation tool.

The submission also outlines:

- Remove Personal Importation Scheme exemption for NVPs
- Tighter controls NVPs importation (only licensed S4 product wholesalers & distributors)
- Treat Nicotine and Non-Nicotine NVP's as same category for importation and border control.

We would be only too happy to facilitate a discussion with the Ministerial office and/or the Minister in the coming period. Contact can be made with s22 (Royce) on s22@royce.com.au and s22 (From the Fields) s22@fromthefieldsinc.com

Media Statement – From the Fields Pharmaceutical Australia Pty Ltd Our company has issued this media statement today – 13 January 2023.

Tackling Australia's Vaping Health Crisis • Australian youth should not vape or smoke, says



leading vape supplier • The black-market sales of illicit vaping products exceed 10 million units a month • Medical fraternity is watching this growing public health crisis from the sidelines • Australia could achieve less than 5% adult smokers in the next 3-5 years if nicotine vaping is used actively as a smoker cessation tool

A global manufacturer of nicotine vaping products (NVPs) is urging the Albanese Government to ban the product in Australia unless it is prescribed by a GP.

From the Fields Pharmaceuticals Australia <sup>s22</sup> and <sup>s22</sup> said that new enforcement measures were needed to address illegal and out-of-control vaping in Australia, especially among Australia's youth.

"Since October of last year, the law states that in order to purchase a nicotine e-liquid in Australia you must have a valid vaping prescription," <sup>s22</sup> said.

"However, this rule of law is not working. Around 1.5 million adult Australians vape today. The vast majority of these Australians are vaping illegally thanks to unscrupulous retailers and traders, and despite the best intentions of local lawmakers to restrict the purchase of vapes to a medical prescription only."

<sup>s22</sup> said that any registered medical practitioner in Australia can write a vape prescription.

"The main reason a doctor will write a vaping prescription is to assist with quitting smoking, particularly for those individuals who have tried other methods and have been unable to quit.

"However, one of the problems is that too many doctors are reticent to write this type of prescription, despite compelling evidence that e-cigarettes are effective quitting aids and an effective substitute for smoking.

"The awareness and process of doctors becoming an authorised prescriber of nicotine vaping products (NVPs) has been poorly understood and communicated. Sadly, there is a deep reluctance within the medical fraternity to support vaping as a harm reduction pathway for addicted smokers.

"The current prescription model has failed largely due to a lack of support and communication by the RACGP, Pharmacy Guild, and other professional bodies. As a result, the scourge of illegal vaping is evident in the increasing number of teenagers who have purchased a vape product illegally," <sup>s22</sup> said.

From the Fields Pharmaceuticals Australia has delivered a submission to the Therapeutic Goods Administration (TGA) Review recommending multiple solutions to the vaping health crisis.

"We must tackle the illegal, unregulated trade in vaping, which has created an exploding and major public health issue in Australia," <sup>s22</sup> said.

"Currently the black market of illicit vaping products, where 10 million units are sold each month, provides too easy access of nicotine vaping products to minors.

"The loophole allowing mislabelled vaping products needs to be closed. The importation of non-nicotine should be under the same import pathway as nicotine products to avoid general trade importing under false labelling and fuelling a black market.

"Moves to enforce sales of NVPs only by medical prescription is the means to increase smoking cessation, drive down adult smoking rates, and achieve improved public health outcomes.

"Our company supports a pragmatic solution for adult smoker cessation with NVPs under a therapeutic goods framework. We welcome the Albanese Government's intention of further reform to address illegal vaping and win back control of this serious public health issue," he said. Some of the key statements made by From the Fields Pharmaceutical in its submission to the TGA Review, include:

1. NVPs or e-cigarettes have become an effective tool for quitting smoking, serving as a substitute when prescribed through a healthcare professional.
2. Australian authorities need to back in the medical prescription only model in place for NVPs

sold. This GP prescribed/pharmacy sold product is a pathway for better health outcomes for Australian smokers.

3. Properly address the current illicit black market for vape sales to so many adult and Australian youth.

4. Assure public authorities that revising standards and proper enforcement of regulations in the illicit sale of NVPs across Australia, will not create supply chain constraints for NVP patient demand for Australian standard, smoking cessation designed products, which can be dispensed through physical and online pharmacies.

5. Australia could achieve less than 5% adult smokers by 2030, if nicotine vaping is used actively as a smoker cessation tool.

“Putting in place a simpler approach for less complex enforcement at the border for imported, but mislabelled NVPs now entering Australia, can meet existing and future regulations, while importantly backing in better health outcomes,” s22 added.

s22

**From:** s22 [redacted] <[redacted]@racgp.org.au>

**Sent:** Monday, 19 December 2022 11:46 AM

**To:** Minister Butler <Minister.Butler@Health.gov.au>

**Cc:** s22 [redacted] <[redacted]@health.gov.au>

**Subject:** Therapeutic Goods Standard for Nicotine Vaping Products

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Minister Butler,

On behalf of s22 [redacted], please find the attached letter outlining the concerns expressed by our members regarding the implementation of TGO-110.

Kind regards,

s22 [redacted]

s22 [redacted]  
[redacted]  
[redacted]



s22 [redacted] <[redacted]@racgp.org.au|racgp.org.au>

The Royal Australian College of General Practitioners Ltd  
Wurundjeri Country  
100 Wellington Parade, East Melbourne VIC 3002

*We recognise the traditional custodians of the land and sea on which we work and live*



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**MC22-024133**

15 December 2022

The Hon Mark Butler MP  
Minister for Health and Aged Care

Via email: s22 [REDACTED]@health.gov.au [REDACTED]

CC: s22 [REDACTED]@health.gov.au [REDACTED]  
[REDACTED]

Dear Minister Butler,

**Re: Therapeutic Goods Standard for Nicotine Vaping Products (TGO 110)**

As you will be aware, the RACGP advocates strongly for smoking cessation and produces evidence-based clinical guidelines relevant to all healthcare professionals who provide support for people wishing to quit smoking. [Supporting smoking cessation: a guide for health professionals](#), reflects the [REDACTED] e-liquids in response to the Therapeutic Goods (Standard for Nicotine Vaping Products) TGO 110 which came into effect on 1 October 2021, making the supply of nicotine by e-liquids prescription only.

The RACGP was represented at the Department of Health and Aged Care recent roundtable discussion on *Tobacco control and e-cigarettes in Australia*. Feedback from our representative raised concern regarding the ease of obtaining nicotine e-cigarettes by young Australians, despite the TGO 110 requiring access to these products by prescription. An alarming increasing prevalence of vaping amongst Australian youth, including those who have not been smokers previously, is supported by recent population survey data<sup>i, ii</sup>. The RACGP urges the Government to strengthen border controls to reduce the illegal importation and also to encourage state and territory jurisdictions to prosecute those who are breaking the law by selling these products.

In addition to the alarming ease of illegal access to nicotine e-liquids without a prescription, poisonings of young children by vaping liquids has increased. More than 50 children under the age of four have been exposed to vaping liquid in the past year<sup>iii</sup>. The RACGP has recommended against the use of highly concentrated e-liquids and warned of the risks of open system devices due to risk of poisoning, the addition of toxic or illegal substances, and contamination.

The RACGP guideline recommends the use of the Authorised Prescriber and Special Access Scheme prescribing pathways, instead of the Personal Importation Scheme. This recommendation was made to minimise risk of the patient accessing nicotine vaping products that do not comply with the minimum safety and quality TGO 110 labelling and packaging requirements. The guidelines also recommend that the prescriber send the prescription directly to the patient's nominated pharmacy.





In order to make it more likely that nicotine vaping products prescribed by medical practitioners meet the TGO 110 standard, the RACGP strongly recommends closure of the Personal Importation Route. This may also assist Border Force in identifying that nicotine vaping products entering Australia are not doing so legally.

If you have any queries regarding this submission, please contact s22

@racgp.org.au.

Yours sincerely,

s22

s22

<sup>i</sup> Bayly M., Mitsopoulos E., Durking S., et al., 2022 E-cigarette use and purchasing behaviour among Victorian adults: Findings from the 2018-19 and 2022 Victorian Smoking and Health Surveys,. Prepared for: Quit Victoria. Centre for Behavioural Research in Cancer, Cancer Council Victoria: Melbourne, Australia, October 2022.: Available from: [E-cigarette use and purchasing behaviour among Victorian adults.pdf](#).

<sup>ii</sup> Watts C., Egger S., Dessaix A., et al., 2022 Vaping product access and use among 14-17-year-olds in New South Wales: a cross-sectional study. Aust NZ Public Health, Online, doi: 10.1111/1753-6405.13316

<sup>iii</sup> Delibasic S., 2022 [Shock number of Victorian kids under four poisoned by vapes](#) 20 November 2022, The Herald Sun.

The Heart Foundation acknowledges the Traditional Owners and custodians of country throughout Australia and their continuing connection to land, waters and community. We pay our respect to them and their cultures, and Elders past, present and future.

For heart health information visit [heartfoundation.org.au](http://heartfoundation.org.au)



T: s22 | M: s22

Canberra, ACT

s22

s22

Kind regards

Please do not hesitate to contact me if you have any questions.  
Please find attached correspondence for Minister Butler regarding e-cigarettes.

Good afternoon

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**REMEMBER:** Think before you click! This email originated from outside our

**Subject:** Correspondence for Minister Butler

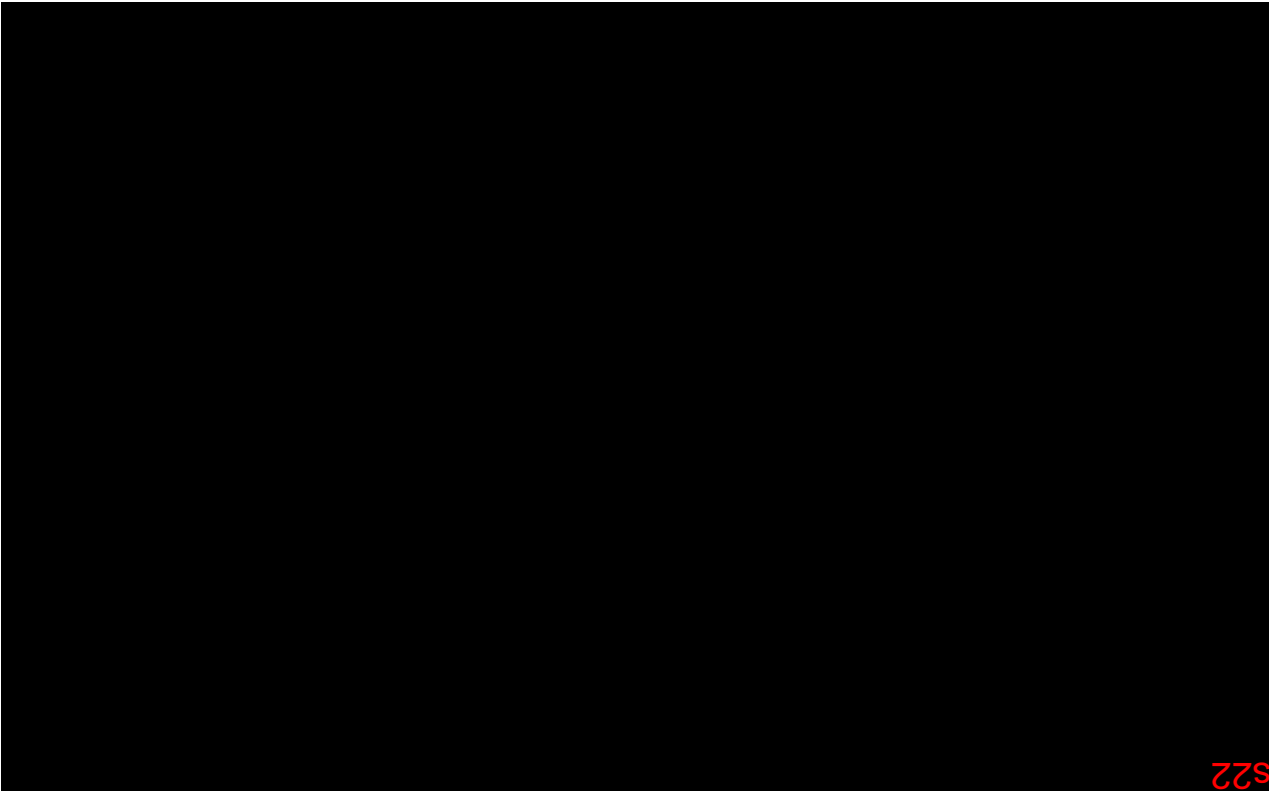
[s22@heartfoundation.org.au](mailto:s22@heartfoundation.org.au)

**Cc:** s22 <[s22@health.gov.au](mailto:s22@health.gov.au)>

**To:** Minister Butler <[Minister.Butler@health.gov.au](mailto:Minister.Butler@health.gov.au)>

**Sent:** Wednesday, 22 February 2023 4:19 PM

**From:** s22 <[s22@heartfoundation.org.au](mailto:s22@heartfoundation.org.au)>



s22

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22 February 2023

The Hon. Mark Butler MP  
Minister for Health and Aged Care  
PO Box 6022  
House of Representatives  
Parliament House  
Canberra ACT 2600

National Heart Foundation  
of Australia  
ABN 98 008 419 761

Level 2, 850 Collins St  
Docklands VIC 3008  
T: 13 11 12

### **Call for action on tobacco and e-cigarette control at the meeting of Health Ministers**

Dear Minister,

I am writing ahead of Friday's Health Minister's meeting to express the Heart Foundation's strong support for further action to curb the increasing illicit sale of nicotine e-cigarettes and vaping products. I appreciate your positive commitment to tackle this important public health issue and your work to overcome differences between governments on developing an effective regulatory framework.

I believe Friday's meeting provides an important opportunity for decisive action to reduce tobacco use, as well as an opportunity to tackle the rising use of e-cigarettes and vapes. The Heart Foundation strongly supports the release of a new National Tobacco Strategy and we hope this is supported by all jurisdictions. We are willing and available to help promote awareness of the Strategy and initiatives involved.

Given the significant impact e-cigarettes are having across the country, I would like to urge you to consider further actions by the Australian Government to stop the illegal importation of nicotine e-cigarettes. In addition, I ask you to encourage your state and territory colleagues to work collectively to halt the vaping epidemic that is sweeping through our nation.

Thank you for ongoing support on this important issue. Please do contact me if you require any further information.

Yours sincerely,

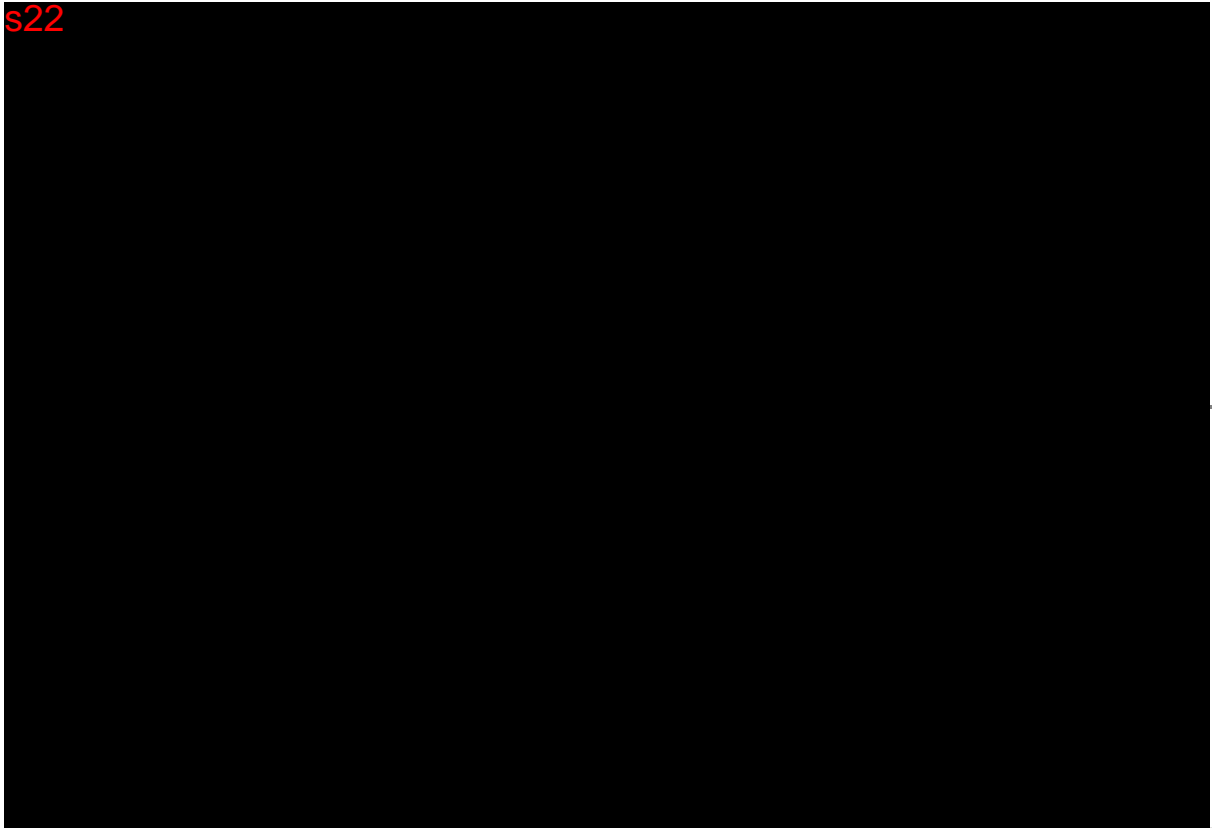


s22

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The National Heart Foundation

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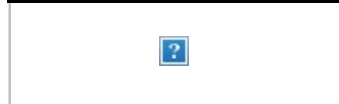


**From:** [redacted] <[\[redacted\]@lungfoundation.com.au](mailto:[redacted]@lungfoundation.com.au)>  
**Sent:** Wednesday, 22 February 2023 2:56 PM  
**To:** Minister Butler <[Minister.Butler@Health.gov.au](mailto:Minister.Butler@Health.gov.au)>  
**Cc:** s22 [redacted] <[\[redacted\]@lungfoundation.com.au](mailto:[redacted]@lungfoundation.com.au)>; s22 [redacted] <[\[redacted\]@Health.gov.au](mailto:[redacted]@Health.gov.au)>;  
s22 [redacted] <[\[redacted\]@health.gov.au](mailto:[redacted]@health.gov.au)>  
**Subject:** Letter of support for action at HMM - National Tobacco Strategy

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Dear Minister Butler,  
Please find attached correspondence from Lung Foundation Australia [redacted] ahead of the upcoming Health Ministers' Meeting – impressing on you to reach agreement of, and then launching and investing in, the National Tobacco Strategy which must take a strong stance on e-cigarettes.  
Kind regards,

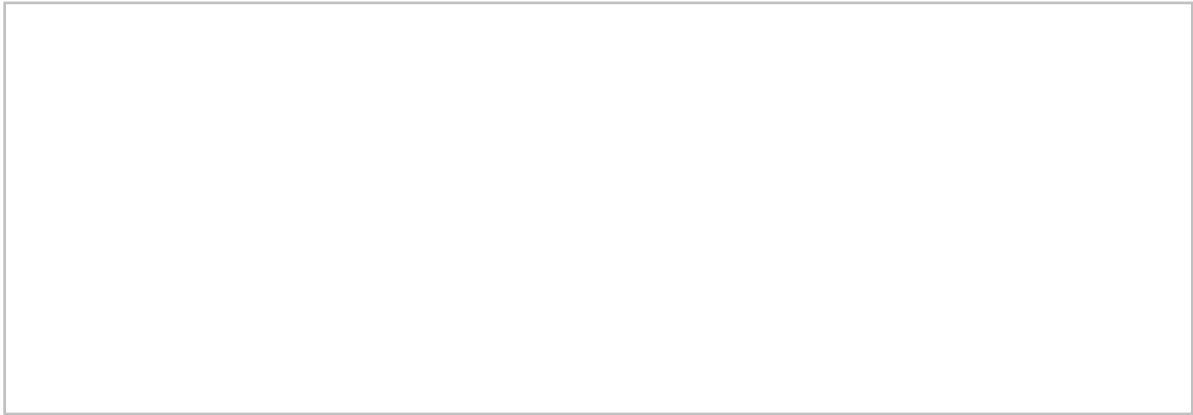
s22  
[redacted]



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||

22<sup>nd</sup> February 2023

Hon. Mark Butler  
Minister for Health and Aged Care  
PO Box 6022, House of Representatives  
Parliament House, Canberra ACT 2600

Via email only: [Minister.Butler@health.gov.au](mailto:Minister.Butler@health.gov.au)

Dear Minister Butler,

### Support for the National Tobacco Strategy 2022-2030: Urgent need for e-cigarette and tobacco control

Lung Foundation Australia urges that the National Tobacco Strategy (NTS) is included among the Health Ministers' Meeting (HMM) priorities for 2023. With your long standing commitment to tobacco control and Australia's goal of reducing smoking rates to under 5% by 2030, the strengthening, launch and investment in the NTS in 2023 is vital.

As you stated on the 10<sup>th</sup> anniversary of Labor's tobacco plain packaging laws, "Australia needs to reclaim its position as a world leader on tobacco control". We strongly welcomed the *Reignite the Fight Against Tobacco Addiction* reforms you announced that day but reiterate that they must be supported by a strong, well-funded NTS. There has not been national coordination in tobacco control for many years – at this week's HMM we encourage you to request that the state and territory governments sign-off on the NTS and commit to working together on its implementation. We reiterate that reducing tobacco use and nicotine addiction is a key pillar of the *National Preventive Health Strategy 2021-2030 (NPHS)*. As Australia's lung health peak body, Lung Foundation Australia is committed to supporting government to achieve the policy priorities outlined in the NPHS.

The revitalisation of the NTS must also include an amplified focus on e-cigarettes. As you know, we are seeing rates of e-cigarette use among young people and non-smokers rising at an alarming rate, and the community is demanding action. In 2022, a YouGov survey commissioned by Lung Foundation Australia found that **83% of Australians think the government should do more to protect children from vaping**. Following the release of the TGA review on potential reforms for nicotine vaping products, we also surveyed health professionals and the community. A summary of the key results is **attached** – they show strong support for action to protect public health. I know from the vaping roundtable I attended with you in November that you are committed to addressing this issue with the urgency it requires. We have also written to state and territory Health Ministers reiterating our position and encouraging them to commit to coordinated action.

Fundamental to a comprehensive NTS is strong policy, and this must include action to reduce industry influence, substantially increase monitoring and enforcement, and increase community education through a national tobacco campaign. Lung Foundation Australia particularly stress the importance of messaging and initiatives that do not stigmatise people who smoke or vape, as stigma can result in people postponing seeking support and hiding

their smoking status from health professionals. We work hard to reduce stigma and subsequent psychological distress and we are happy to provide support on this issue to your department.

Effective tobacco control requires consistent action that is sustained and coordinated. Lung Foundation Australia called for the launch and funding of the NTS in our 2022 Federal Election Priorities and again in our 2023-2024 Pre-Budget Submission (also **attached**). I would be pleased to meet with you to discuss our recommendations. To arrange a meeting, please contact

s22

[\[REDACTED\]@lungfoundation.com.au](mailto: [REDACTED]@lungfoundation.com.au).

Sincerely,

s22

s22

Lung Foundation Australia

s22

[\[REDACTED\]@health.gov.au](mailto: [REDACTED]@health.gov.au)

s22

[\[REDACTED\]@health.gov.au](mailto: [REDACTED]@health.gov.au)



# Lung Foundation Australia

## 2023-2024 Pre-Budget Submission

December 2022

Contact:

s22

@lungfoundation.com.au or s22

## Key recommendations

Lung Foundation Australia understands the significant budgetary constraints that Australia is facing but we also stress the economic benefits that can be reaped by improving the health of Australians. 1 in 3 Australians live with a lung disease, and this is responsible for significant health system expenditure, at approximately \$8 Billion annually. In addition to the direct health system costs, the loss of life and inability to contribute to the workforce adds to the cost. We commend the announcement that the October budget will include a wellbeing lens, which we hope will shine a light on the benefits of keeping Australians healthy and enabling them to lead healthy and productive lives.

In light of the current economic challenges, Lung Foundation Australia make four recommendations for urgent funding in the October budget, and then note additional recommendations that we will look to raise ahead of the following budget. **We reiterate that our recommended actions will directly improve the health of Australians and see a return-on-investment in the short- and long-term.**

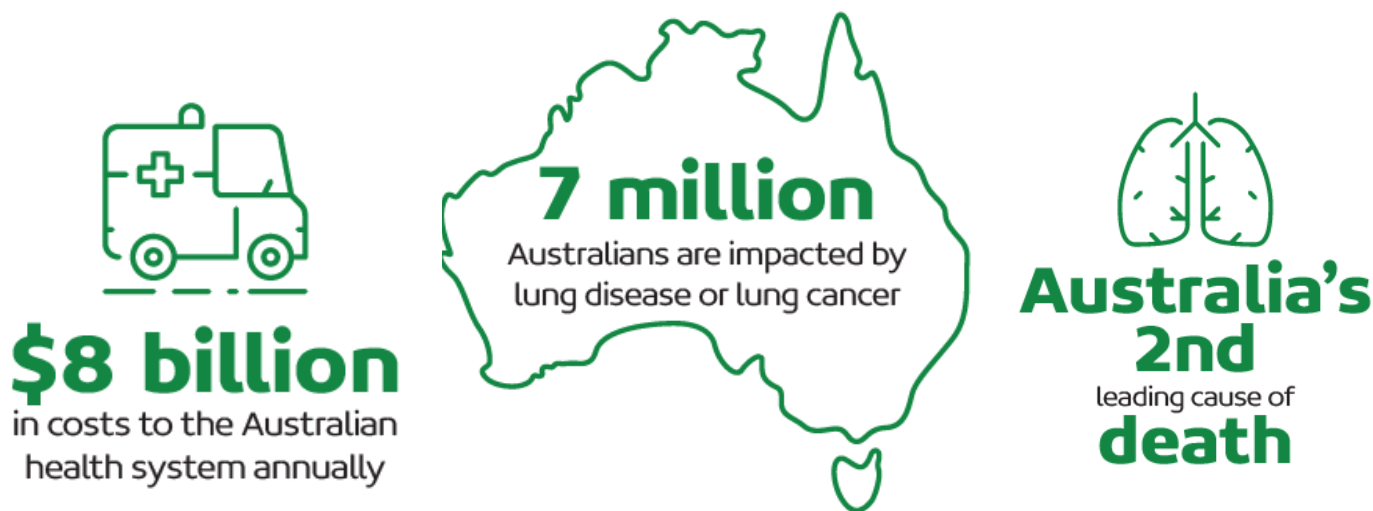
Priorities for urgent funding:

1. Implement the targeted lung cancer screening program **\$300m over 5 years**
2. Invest in dedicated specialist lung cancer nurses - **\$5million**
3. Ensure quality training for primary healthcare professionals does not stall, meets demand, and achieves sustainability - **\$700,000**
4. Essential funding for service continuation - enhancing chronic respiratory disease self-management - **\$600,000**
5. Address research inequities by establishing a dedicated MRFF Respiratory Health Mission **\$500,000**
6. Launch and fund the National Tobacco Strategy

Lung Foundation Australia's recommendations align with the Australian Government Department of Health's National Strategic Action Plan for Lung Conditions, and can drastically improve the lives of Australians, reduce the burden on the health system, and create a healthier and more productive society.

# About Lung Foundation Australia

## Lung disease in Australia



Don't let smoking be the first thing you think of. Other risk factors include:



Exposure to asbestos, radon and occupation materials



Air pollution



Family history



Personal history of lung disease



Genetics

## What we do

Lung Foundation Australia is the only national charity and leading peak-body dedicated to supporting anyone with a lung disease including lung cancer. For over 31 years, we have been the trusted national point-of-call for patients, their families, carers, health professionals and the general community on lung health.

Our mission is to improve lung health and reduce the impact of lung disease for all Australians. We will continue working to ensure lung health is a priority for all, from promoting lung health and early diagnosis, advocating for policy change and research investment, raising awareness about the symptoms and prevalence of lung disease and championing equitable access to treatment and care.

There are over 30 different types of lung disease currently impacting 1 in 3 Australians. Lung disease is also our nation's second leading cause of death, taking more lives than dementia and diabetes, yet until COVID-19 caused a renewed focus on lung health and the necessity to breathe freely, it has consistently been underfunded compared to other prominent diseases.

Through the Commonwealth's Health Peak Advisory Body Program, Lung Foundation Australia are formally recognised as the peak lung health organisation in Australia, and we will be further supporting the Commonwealth through the provision of expert advice, disseminating information to Australians, and consulting with consumers and clinicians on a range of topics.



# Priorities for the Federal Budget 2023-2024

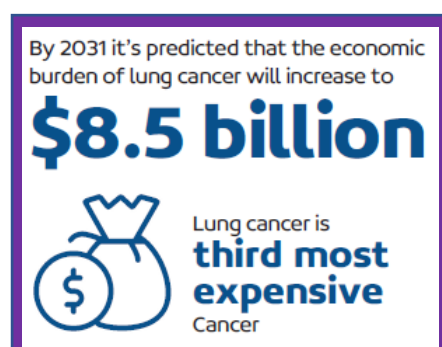
## Priority 1: Implement the targeted lung cancer screening program

Lung cancer is the leading cause of cancer death in Australia, and the key to improving survival and quality of life is to diagnose lung cancer early, where more treatment options are available. A targeted lung cancer screening program will position Australia as a world leader and the benefits are far reaching.

Following the Government's independent agency's positive recommendation (by the Medical Services Advisory Committee (MSAC)) recommendation to implement a targeted National Lung Cancer Screening Program, we request funding be allocated in the 2023-2024 budget to begin formal pilot testing in various locations across Australia.

Now that lung cancer screening has been formally recommended, meaning it has been assessed to be cost effective and of benefit to the community, we urge the Australian Government to make an investment of **\$300million over 5 years in this life saving program**, with an initial investment in the 2023-2024 budget.

To put this figure into perspective, lung cancer costs the health system \$448m *each year*, which does not account for the cost to society that results from disease and death. These costs are set to soar over the next decade, placing significant burden on the economy if not addressed. Every year that investment in establishing this screening program is delayed, lives are lost, and the cost to the health system and the economy grow.



### Why do we need a targeted lung cancer screening program?<sup>1</sup>

Cancer Australia's Lung Cancer Screening Enquiry report from 2020 recommended a targeted lung cancer screening program be pursued as a priority, based on international and national evidence of clinical effectiveness and safety. What it proposed was a feasible model utilising existing infrastructure in the Australian healthcare system and included a cost-effective economic evaluation. It found that in the first 10 years, a targeted program would:

- Diagnose lung cancers earlier, with around 70% of all screen detected lung cancers diagnosed at an early stage, bringing it closer to the survival rate of the other common cancers (72% bowel, 92% breast, 95% prostate, 96% skin cancer).
- Save lives by preventing over 12,000 deaths
- Improve quality of life, with up to 50,000 quality adjusted life years (QALYs) gained
- Be cost-effective, with an incremental cost-effectiveness ratio of \$83,545 per QALY gained<sup>98</sup>.
- Reduce lung cancer mortality in Australia by 20% in the screened population, and improve the survival, quality of life and productivity of Australians affected by lung cancer.
- Reduce inequities - lung cancer has a greater proportional impact on First Nations people, people in regional and rural areas, and those of lower socioeconomic status.

*"In 2017 I was diagnosed with two primary cancers; breast cancer and lung cancer. I was not experiencing symptoms of either cancer. The breast cancer was picked up early, through screening, and was cured through two surgeries. A devastating diagnosis but an excellent outcome. Unfortunately the lung cancer was only found by accident, it had already spread, and it will most likely kill me. I wish there had been a lung cancer screening program in place to find my cancer early, just like the breast cancer"*

*- Lorraine, living with lung cancer*

## Priority 2: Invest in dedicated specialist lung cancer nurses - \$5million

Specialist Lung Cancer Nurses are desperately needed by the 22,800 Australians living with lung cancer currently, who have unmet needs, lower quality of life and poorer outcomes. Current investment in Commonwealth funded nurses is **inequitable** and contributing to poor health and economic outcomes through loss of life, lower participation in the workforce and worse mental health. \$15.4m will fund 100 nurses, and support nearly half of the Australians living with lung cancer, delivering \$18m in health savings. **We acknowledge that funding 100 nurses in the 2023-2024 budget is likely not feasible, as such we request an initial commitment of \$5million\* as support is needed urgently.**

\*Full budget available on request

### Why does Australia need specialist lung cancer nurses?

- Each year over 13,800 Australians are diagnosed with lung cancer, and they need support to navigate the healthcare system and throughout their cancer journey<sup>2</sup>.
- Current care for lung cancer patients is not sufficient or equitable compared to other common cancers
- Specialist lung cancer nurses, like breast cancer and prostate cancer nurses, are proven to facilitate crucial care and support for people diagnosed with cancer.
- People living with lung cancer die earlier by an average of 11years compared to the general population. This amounted to around 137,600 years of life lost in 2018 alone.
- The economic cost due to life lost - \$6.9 billion in 2018.
- Our nurses will ultimately aid in improving health outcomes for patients with lung cancer, reduce emergency department presentations, and will be an invaluable part of the health system.

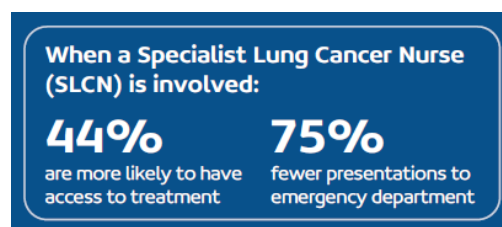


Table 1: Lung, breast, and prostate cancer comparison<sup>3 4 5 6 7 8</sup>

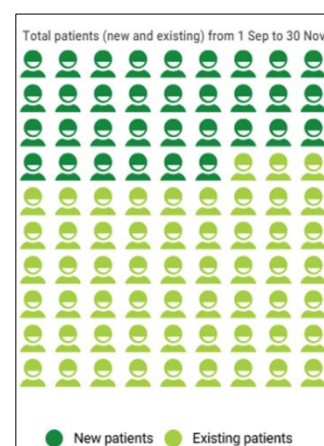
	Cancer related disease burden	No. of DALYs	5-year survivorship	Cancer related cause of death	No. of deaths	No. of nurses	Commonwealth funding for nurses since 2019
Lung Cancer	#1	159,723	20%	#1	8,739	<37	<\$1 million
Breast Cancer	#3	71, 248	92%	#4	3,243	440+	\$30 million
Prostate Cancer	#5	51,305	95%	#3	3,582	80+	\$23 million

### Australian Government funded Pilot project – Progress update and need for expansion

LFA have successfully established the project framework, recruited and onboarded nurses, and 146 locals have received support from the specialist nurses in the first 12weeks. There were a total of 429 encounters with patients during the first 3 months, which is significant and has been growing - highlighting demand.

The uptake and success of this pilot to date, as well as the published evidence on effectiveness of these nurses, reiterate the need to rapidly scale up funding for further pilot sites across other locations in Australia. Following the positive recommendation for lung cancer screening it is imperative that the Australian Government rapidly scale up funding for specialist lung cancer nurses in through this model, which is so desperately needed by the community, and currently over-subscribed across Australia. A \$5million investment will form part of the preparation for the implementation of lung cancer screening, which will require the minimum of 2 years investment to ramp up and ensure the workforce is able to cope with demand.

From our initial round of recruitment and advertising for the nurse positions we know that a career progression in specialist lung cancer nursing is highly desirable, and that Lung Foundation has had no issue with the recruitment of highly skilled nurses to take up the roles.



### Priority 3: Ensure quality training for primary healthcare professionals does not stall, meets demand, and achieves sustainability - \$700,000

Lung Foundation Australia was funded through the Department of Health, and successfully delivered the first two phases of our Lung Learning project. This project is focussed on workforce competency building and ensuring that primary care health professionals are provided with high quality, evidence-based training to improve patient outcomes. We are committed to ensuring that this program achieves meaningful outcomes, and we intend to reach the point of financial sustainability in maintaining the program without needing further Government investment.

**With funding coming to an end, the gains made in ensuring health professionals have access to quality education and training are at risk. Lung Foundation Australia request a commitment of \$700,000\* for 2023-2024. This will ensure continuation of service, meet a growing demand, support achievement of reaching sustainability, and is reflective of the amount requested in the original application for funding.**



<http://www.lunglearninghub.com.au>

#### What is the Lung Learning project?

Aligned to the Australian Government's National Strategic Action Plan for Lung Conditions, the purpose of this program is to develop a national lung health training and education framework for Primary Healthcare Professionals to improve awareness, knowledge and understanding in the identification, diagnosis, and management of lung conditions.

**The program has been designed with similar principles that underpin the National Strategic Framework for Chronic Conditions (2017 -2025):**

- Moves away from a disease-specific approach
- Supports a stronger emphasis on coordinated, multidisciplinary care
- Acknowledges and builds on work already in place that supports chronic conditions
- Provides flexibility and responsive action towards future and emerging priorities
- Allows innovative approaches in prevention, earlier diagnosis and management of chronic conditions

#### **Further funding will:**

- Increase the interactive functions of the program Hub to strengthen user experience and support growth in the number of primary care health professionals accessing education and training
- Deliver robust monitoring and evaluation to support outcome-based learning, contribute to best-practice respiratory healthcare, and work towards sustainability
- Enhancing third-party education and training courses via a strong quality assurance process
- Address gaps by developing and delivering new education programs and materials

[The Lung Learning Framework](#) is a world-first in respiratory healthcare, and one of Australia's most innovative approaches to improving outcomes for patients. In collaboration with Australia's leading peak health bodies including RACGP, PSA, ACCRM and NACCHO, the Framework, if fully funded and implemented, will substantially transform the early diagnosis of lung diseases and lung cancer which overwhelmingly impact people from low socio-economic areas, First Nations peoples, and those living in rural areas.

The next phase of the program sees the implementation and scale up of the Framework, with collaborating partners in every State and Territory, to advance nine of the 24 recommendations from the National Strategic Action Plan for Lung Conditions. Building on partnerships with Primary Health Networks, the additional funding will enable Lung Foundation Australia and its consortium partners at Asthma Australia and the Thoracic Society of Australia and New Zealand to realise the program outcomes. With the current uncertainty around funding continuing through individual strategic action plans for chronic conditions, we request that this funding is considered as a high priority for bridging funding for 12 months.

\*Full budget available on request

## Priority 4: Essential funding for service continuation - enhancing chronic respiratory disease self-management - \$600,000

Lung Foundation Australia are currently funded to deliver services to the community that enhance chronic respiratory disease self-management, and are proven to reduce the burden of these diseases on the health system. The highly skilled team deliver a range of services that enhance health literacy, provide valid referral pathways, enable people to manage their condition more effectively, and link with appropriate information and resources. **With funding coming to an end, and the service currently not able to keep up with demand, if service delivery stalls there will be an additional strain on the already burdened primary care and hospital system. Lung Foundation Australia seek a budget commitment of \$600,000\*. This will ensure continuation of service, meet a growing demand, and ultimately ensure that the Australians living with chronic lung disease are able to be effectively managed within the community.**

\*Full budget available on request

The service LFA provides is considered complimentary care, and is an essential adjunct to local care services, by helping patients navigate all aspects of their disease management. The service is integral for strong primary care, and we note that currently the service is oversubscribed and there is a long wait list, which was made worse through COVID-19 as there was limited access to healthcare services for patients with chronic respiratory diseases. Lung Foundation Australia have established a community of practice and are trusted to deliver this essential service. We remain committed to providing this service with the goal of helping Australians to live well with chronic respiratory disease.

About the service: This service offers a series of interactions for people with chronic lung disease to engage in essential self-management strategies. This nurse-led intervention supports people to identify gaps in their care according to evidence based guidelines for management. Via the provision of information and education the nurse motivates them to work, in collaboration with their treating healthcare team, to achieve evidence-based care, including physical activity, medication adherence and management of exacerbations.

Recent evaluation of the program demonstrated the following outcomes:

- ✓ Improved patient health
- ✓ Improved patient health-related quality of life
- ✓ Cost-effective
- ✓ Reduced healthcare utilisation
- ✓ 50% reduction in ED presentations
- ✓ 30% reduction in hospitalisations

*“I was taught about my condition and how to cope with it with confidence. My nurse was efficient, compassionate and always listened to me. It’s difficult to ask questions when you don’t know what to ask. The Respiratory Nurse anticipated this.” – LFA patient*

*“I have made a number of changes since speaking to the Lung Foundation these include; airway clearance routine, breathing exercises with the assistance of a physiotherapist, pneumonia and flu injections, seeing a respiratory specialist and booking a sputum test, drinking more water and doing more exercise”. – LFA patient*

*“Having someone whom I trusted in my corner, motivated me to be proactive and use the resources I have available. I am sure that without the encouragement and motivation from [LFA’s nurse] I would have sat back and withdrawn and be in a far worse position that I am now.” – LFA patient*

*“Personalised care and advice over the phone, doctors and specialists visits can be rushed at times so these three appointments on the phone over one year helped me track my progress in detail an excellent service providing a lot of support and information” – LFA patient*

## Priority 5: Address research inequities by establishing a dedicated MRFF Respiratory Health Mission

Respiratory diseases have a major impact in Australia, both in terms of healthcare utilisation, and lost quality of life and productivity for individuals, communities and governments. As part of the Lung Health Alliance, alongside The Thoracic Society of Australia and New Zealand, National Asthma Council Australia, Cystic Fibrosis Australia and Asthma Australia, we urge funding of a dedicated **MRFF Respiratory Health Mission, with establishment costs amounting to \$500,000.**

### Why does Australia need a dedicated MRFF Respiratory Health Mission?

- Lung disease accounts for 9% of total disease burden in Australia , yet only receives 2% of research investment
- The NGO sector has been trying to fill this gap in Government funding by supporting Fellowships and other research positions where possible, but this cannot continue.
- 1 in 3 Australians are impacted by lung disease, with research being critical if we are to reduce disease burden, mortality rate as well as social and economic costs.
- COVID has highlighted the importance of healthy lungs and a strong research sector, and as respiratory conditions and viruses grow a dedicated Mission can enable Australia to take a leading role globally.

A MRFF Mission allows researchers to think big and are programs of work with ambitious objectives that are only possible through significant investment, leadership and collaboration. Missions bring together researchers, health professionals, stakeholders, industry partners and patients as part of a joint effort to support the discovery of new techniques and treatments, leading to healthier Australians.

Lung conditions pose a substantial burden on individuals, their families, the healthcare system, and the broader economy. Not being able to breathe is a health challenge that is without parallel. Recent catastrophic bushfires and pandemics have forced Australians to turn towards respiratory experts for their research and clinical care. We need to respond to this momentum and invest in discoveries in medical research and innovations, in optimising health service delivery, in supporting our people in their holistic form, in their community and family unit, by ensuring robust evidence translation. The most impactful approach will be through a Respiratory Health Mission, which will result in world class collaborations from across sector and industry to extract answers and solutions to these real challenges. The goal of the mission would be to reduce the avoidable burden of respiratory disease in Australia: reduce deaths, reduce hospital presentations, increase quality of life and reduce the burden, and reduce the onset of respiratory disease.

In order to ensure no further delays to the funding and effectiveness of this vital MRFF mission, we suggest an initial investment of \$500,000 which would be used to complete pre-requisite steps, including:

- Establishment of the governance structures to support this initiative
- Appointment of the project implementing team to execute this 'startup' phase and establish the base for the remainder of the 10 year mission
- Coordination of the local and international consultation processes to validate and establish the pillars and phases of the Respiratory Health research mission
- Establishment of the platforms, databases, tools and resources necessary for the effective collaboration of stakeholders engagement in the mission.

The resulting MRFF mission amounts to \$200million over 10 years, which would then be ready for funding in the 2023-2024 budget. This mission has been developed by the Lung Health Alliance and details have been provided to the Australian Medical Research Advisory Board, with recommended investment at the same level of funding as the current Cardiovascular Health Mission.



## Priority 6: Launch and fund the National Tobacco Strategy

**We urge the Australian Government to ensure the National Tobacco Strategy is launched as a matter of urgency in 2023, and appropriate funding is allocated in the 2023-2024 budget to begin implementation of this important national strategy.**

Tobacco is the leading cause of death and disease in Australia. Tobacco use is responsible for around \$137 billion annually in direct and indirect costs.<sup>9</sup> In addition to the burden of tobacco smoking products, e-cigarettes are presenting an emerging challenge in Australia, with use among youth being particularly problematic. Use of e-cigarettes has become widespread and despite nicotine-containing e-cigarettes being illegal without a prescription we know Australians, including children, are accessing these harmful devices. The evidence is clear that these products are dangerous, and we are putting the health of future generations at severe risk if we continue to delay any action. A coordinated multi-strategy and multi-agency approach is needed for Australia to further reduce smoking rates and address the e-cigarette crisis, and the National Tobacco Strategy is an important guiding document for this action, which will be in alignment with the National Preventive Health Strategy.

Our request for launch of the National Tobacco Strategy and an accompanying investment follows the recent announcement of the Albanese Government's *Reignite the Fight Against Tobacco Addiction* reforms, which aim to bring together all of Australia's current tobacco measures along with 11 new measures, into a single streamlined and effective Act of Parliament that will reignite the fight against tobacco and e-cigarettes. We commend the proposed reforms and encourage the Albanese Government to include budget for 2023-2024 to address tobacco and e-cigarettes from a national perspective, which can for example include a comprehensive revitalised national tobacco campaign. We do however note that previous national anti-tobacco campaigns, while successful at the time, have resulted in lung disease and lung cancer becoming highly stigmatised. New campaigns must be conscious of perpetuating stigma, as the unintended consequences can be severe and solidify smoking behaviours as a means of rebellion. As the peak lung health organisation Lung Foundation Australia welcome the opportunity to support the development of a national tobacco strategy in thorough consultation with the community.

### Why do we need a National Tobacco Strategy and what should it include?

- Smoking costs Australia around \$137 billion annually in direct and indirect costs
- Smoking is responsible for a huge disease burden
  - In 2015, tobacco use contributed to approximately 21,000 deaths in Australia (13% of all deaths) and 9.3% of the total burden of disease.
  - Smoking remains the leading cause of Chronic Obstructive Pulmonary Disease (COPD), which is responsible for the 4<sup>th</sup> highest disease burden in Australia, and lung cancer which is responsible for the 5<sup>th</sup> highest disease burden.
- Second-hand smoke can significantly impact people with pre-existing respiratory conditions, and with approximately 7 million Australians experiencing a respiratory condition this is a significant issue
- E-cigarettes are now a significant challenge in Australia, with youth use being particularly problematic

While Australia has been successful in reducing smoking rates through implementation of a range of world-leading policy levers, public awareness campaigns and program supports, a renewed focus is needed. A coordinated multi-strategy and multi-agency approach is needed for Australia to further reduce smoking rates, and the National Tobacco Strategy is an important guiding document for this action, which will be in alignment with the National Preventive Health Strategy. We are committed to supporting the Australian Government in this important work.

<sup>1</sup> Cancer Australia 2020. *Report on the Lung Cancer Screening enquiry*. <https://www.canceraustralia.gov.au/publications-and-resources/cancer-australia-publications/report-lung-cancer-screening-enquiry>

<sup>2</sup> Australian Institute of Health and Welfare, 2021. *Cancer data in Australia*. Cat. No: CAN122, Canberra.

<sup>3</sup> Ibid, *Cancer data in Australia*. 2021.

<sup>4</sup> Australian Institute of Health and Welfare AIHW 2021, *Health System Expenditure on cancer and other neoplasms in Australia, 2015-16*. Cat. No: CAN142. Canberra.

<sup>5</sup> Australian Institute of Health and Welfare 2021, *Australian Burden of Disease Study: Impact and causes of illness and death in Australia 2018*. Cat. No: BOD29, Canberra.

<sup>6</sup> Minister for Health Media Release, 2020. \$23 million investment for prostate cancer nurse program. Available at: <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/23-million-investment-for-prostate-cancer-nurse-program>

<sup>7</sup> Minister for Health Media Release, 2021. \$3 million for McGrath Breast Care Nurses. Available at: <https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/3-million-for-mcgrath-breast-care-nurses>

<sup>8</sup> Australian Government Budget factsheet, 2019. *Budget 2019-20: Fighting Cancer – McGrath Foundation breast care nurses*. Available at: <https://www.health.gov.au/resources/publications/budget-2019-20-fighting-cancer-mcgrath-foundation-breast-care-nurses>

<sup>9</sup> National Drug Research Institute, 2019. *Identifying the Social Costs of Tobacco Use to Australia in 2015/16*. Curtin University.



# Community and health professional views on vaping in Australia

The public health crisis unfolding due to rising e-cigarette use in Australia has the potential to undo the years of work made to reduce smoking rates in Australia. The known health impacts of vaping are of great concern and Lung Foundation Australia urges the Australian Government to take prompt strong action. Announced in November 2022, the TGA consultation on *Potential reform to the regulation of nicotine vaping products*, provided an integral opportunity to strengthen current laws regarding nicotine vaping products and prevent these products from being used by youths and non-smokers.

In 2022, Lung Foundation commissioned a YouGov survey (national representative sample of over 1000 Australians). The results revealed **83%** of respondents think the government should do more to protect children from vaping and **75%** were concerned about the potential dangers of vaping.

Lung Foundation Australia highlight the importance of the consumer and clinical voice in major reforms, and provided the opportunity for Australians to share their opinions of the current vaping laws. To gain an understanding of the perspectives, experiences and concerns related to vaping in Australia, Lung Foundation Australia developed a short survey for health professionals and community members.

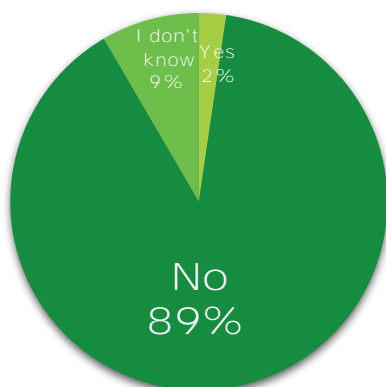
From the 13<sup>th</sup> of December 2022 to the 9<sup>th</sup> of January 2023, we received 559 responses from the following key groups:

- 🌿 26% health professionals (N=145) including nurses, allied health professionals, specialists, other health professionals, pharmacists and general practitioners.
- 🌿 74% community members (N=414)

The below information summarises the key findings from the recent survey, and ultimately showcase high support for strengthened vaping laws.

## Thoughts on vaping:

Do you think vapes are safe?

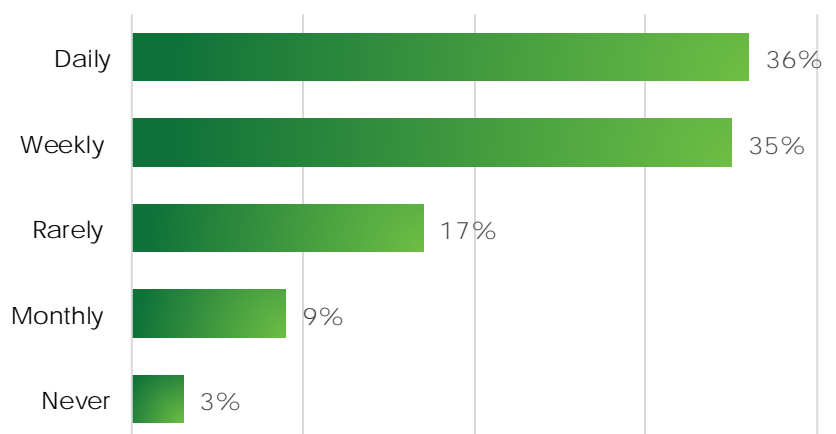


**80%**  
are concerned about  
breathing in secondhand  
vape



**46%** have a friend or family member who vapes

How often do you see someone vaping?



# Nicotine Vaping Products in Australia – TGA Reforms

## Support to strengthen border controls:

**90%** of community respondents support changes to border controls to reduce the rate of illegal vapes coming into Australia.

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

**95%** of community respondents agree that Australia needs increased transparency on who is importing NVPs.

**95%** think the government should do more to protect Australians from NVPs.



*"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." – Health Professional*

## Support for strengthened quality and safety standards:

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

**90%** of community respondents, and **93%** of health professionals, definitely think Australia should be brought into line with other countries and reduce the maximum nicotine concentration to 20mg/mL.

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

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

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

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

*"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*

*"[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*

## Youth vaping

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

**95%** believe it is extremely or somewhat important to take urgent action on vaping products.

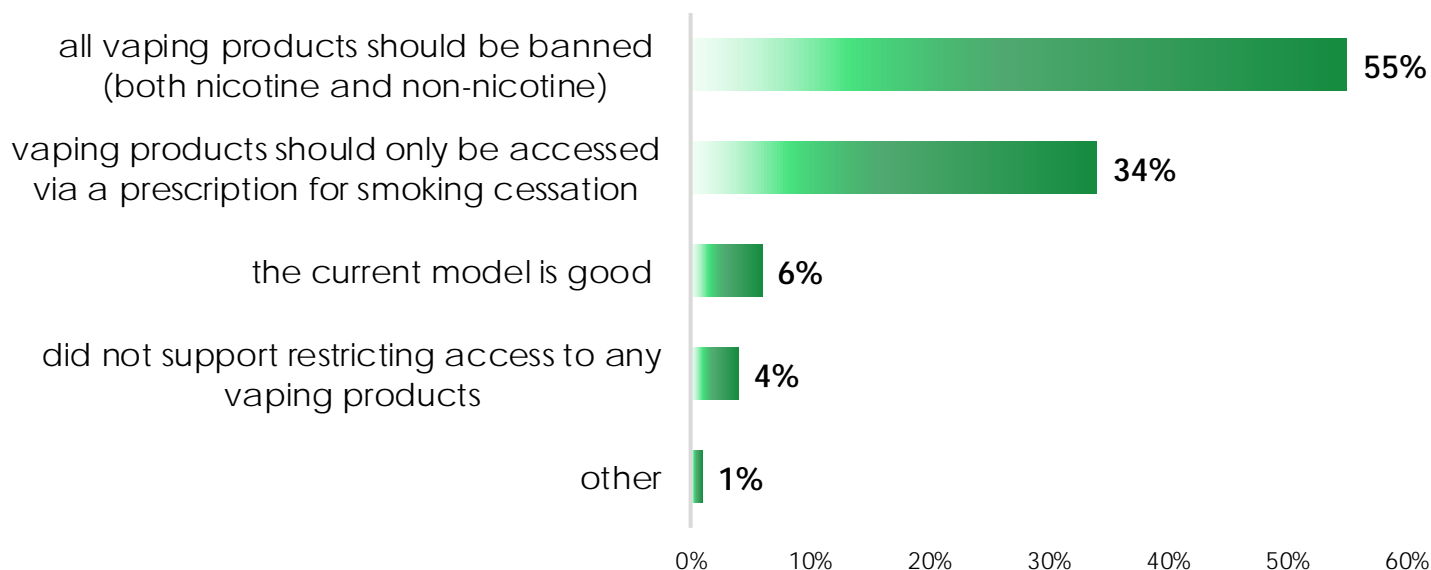
*"I am very worried about the habit becoming ingrained in the youth society and this then leading to increases in tobacco smoking later." - Australian resident*

*"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 as 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*



### Access to vaping products in Australia



\* Over half of those who think the current model is good or think vapes should be accessible, believe vapes are safe or that they did not know about safety.

Lung Foundation Australia supports banning all vaping products outside of the use of NVPs for smoking cessation. Vaping by children and non-smokers continues to increase and we urge the government to protect the health of Australians and act now. Just like smoking, vaping provides no benefit to society and significantly impacts the health of Australians.

s22

**From:** s22 [redacted] <[redacted]@acosh.org>

**Sent:** Wednesday, 8 March 2023 1:41 PM

**To:** Minister Butler <Minister.Butler@Health.gov.au>

**Cc:** s22 [redacted] <[redacted]@aph.gov.au>; s22 [redacted] <[redacted]@acosh.org>; s22 [redacted] <[redacted]@health.wa.gov.au>; s22 [redacted] <[redacted]@acosh.org>

**Subject:** ACOSH Letter re Action on the E-Cigarette Crisis

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear Minister Butler and team,

Please find attached a letter from ACOSH, the Australian Council on Smoking and Health, re action on the E-Cigarette Crisis.

Kind Regards

s22 [redacted]



8 March 2023

The Hon. Mark Butler MP  
Minister for Health and Aged Care  
PO Box 2038  
Port Adelaide,  
SA, 5015

Sent via email

Dear Minister Butler,

On behalf of the Australian Council on Smoking and Health (ACOSH), we commend you and all the Health Ministers on endorsing the National Tobacco Strategy 2023-2030 and welcome the establishment of a national E-Cigarette Working Group to address the supply and uptake of vaping products that is reaching crisis point.

As leaders in tobacco control advocacy, ACOSH is keen to support the implementation of a strong, comprehensive strategy in any way we can. We would appreciate a meeting to discuss this with you either online or on your next visit to Perth.

ACOSH has had a major role in successfully advocating for the major milestones in tobacco control over the last 50 years, including when our former CEO, Maurice Swanson, took his place at the Tobacco Control Stakeholder Roundtable last September.

s22

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We, and the coalition of public health organisations to which we belong, are very conscious of the urgency of this e-cigarette crisis. Daily, we are hearing from community members who are extremely agitated about what they call the epidemic that is affecting our young people in particular. They are all asking the same question – when this will be stopped? Last week we talked with the President of the Western Australian Council of State School Organisations, who represent Parents and Citizens' Associations (P&Cs) within state schools. Parents are worried sick about primary school students who are being touted vapes on the way to school, at school and on the way home. Secondary schools that we visit have spent thousands of dollars of precious funds on vape detectors but are not any closer to containing the problem

At a meeting with the WA Aboriginal Tobacco Control Strategic Leadership Team, which ACOSH facilitates, members talked about the exponential increase in vapes in their regional

areas and the slim window that exists to stop the spread to remote communities. They are telling us they also need action immediately.

While ACOSH appreciates the establishment of the working group and the TGA Public Consultation, we are keen to understand the timeline of both initiatives given the pressing nature of the issue.

We also remain committed to our call for your immediate action in stopping the importation of all e-cigarette products (both non-nicotine and nicotine) at our national borders. Banning the importation of these products, unless accompanied by a prescription, is the only way to stop the supply to our children and young people – and needs to be your first priority.

We look forward to working with you and your team in whatever way we can to achieve this end goal.

Yours faithfully

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Submitted on Fri, 2023-01-13 11:39

Submitted by: Anonymous

Submitted values are:

Title: s22

Given name: s22

Family name: s22

Email: s22@royce.com.au

Street address: s22

City/Suburb: s22

State: s22

Postcode: s22

Organisation: Royce Communications - MELBOURNE, VIC

Minister name: The Hon Mark Butler

Enquiry subject: TGA Review into regulation of nicotine vaping products

Details of your enquiry/comments:

On behalf of From the Fields Pharmaceuticals Australia Pty Ltd (FTF) and s22, we wish to provide you with an advanced copy of our submission into the TGA Review of Potential reforms to the regulation of nicotine vaping products.

From the Fields Pharmaceuticals Australia Pty Ltd (FTF) is an independent company providing Australian standards nicotine vaping products with its WILD By Instinct Nicotine vaping brand. This occurs under the current TGO 110 regulatory framework.

We support a pragmatic solution for adult smoker cessation with NVPs under a therapeutics goods framework. We are also taking a bold public step to urge the Albanese Government to ban the product in Australia unless it is prescribed by a GP.

Our detailed submission (see Attached) to the TGA outlines the urgency for reform, including new enforcement measures to address both illegal and out-of-control vaping in Australia, in particular amongst Australia's youth & minors. Our 5-point + outline presents further reform and regulation of nicotine vaping products (NVPs) and includes:

- NVPs or e-cigarettes have become an effective tool for quitting smoking, serving as a substitute when prescribed through a healthcare professional.
- Australian authorities must back in the medical prescription only model in place for NVPs sold. This GP prescribed / pharmacy sold product is a pathway for better health outcomes for Australian smokers.
- Address the illicit black market for vape sales to adult and young Australian consumers.
- Assure public authorities that revising standards and proper enforcement of regulations in the illicit sale of NVPs across Australia will not create supply side constraints for NVP consumer demand as TGA approved product can replace in physical and online pharmacies.

- Under revised public policy and regulatory enforcement, Australia can achieve <5% adult smoker rates by year 2030 if nicotine vaping is used actively as a smoker cessation tool.

The submission also outlines:

- Remove Personal Importation Scheme exemption for NVPs
- Tighter controls NVPs importation (only licensed S4 product wholesalers & distributors)
- Treat Nicotine and Non-Nicotine NVP's as same category for importation and border control.

We would be only too happy to facilitate a discussion with the Ministerial office and/or the Minister in the coming period. Contact can be made with s22 (Royce) s22 @royce.com.au and s22 (From the Fields) s22 @fromthefieldsinc.com

Media Statement – From the Fields Pharmaceutical Australia Pty Ltd  
Our company has issued this media statement today – 13 January 2023.

#### Tackling Australia's Vaping Health Crisis

- Australian youth should not vape or smoke, says leading vape supplier
- The black-market sales of illicit vaping products exceed 10 million units a month
- Medical fraternity is watching this growing public health crisis from the sidelines
- Australia could achieve less than 5% adult smokers in the next 3-5 years if nicotine vaping is used actively as a smoker cessation tool

A global manufacturer of nicotine vaping products (NVPs) is urging the Albanese Government to ban the product in Australia unless it is prescribed by a GP.

From the Fields Pharmaceuticals Australia s22 and s22 said that new enforcement measures were needed to address illegal and out-of-control vaping in Australia, especially among Australia's youth.

“Since October of last year, the law states that in order to purchase a nicotine e-liquid in Australia you must have a valid vaping prescription,” s22 said.

“However, this rule of law is not working. Around 1.5 million adult Australians vape today. The vast majority of these Australians are vaping illegally thanks to unscrupulous retailers and traders, and despite the best intentions of local lawmakers to restrict the purchase of vapes to a medical prescription only.”

s22 said that any registered medical practitioner in Australia can write a vape prescription.

“The main reason a doctor will write a vaping prescription is to assist with quitting smoking, particularly for those individuals who have tried other methods and have been unable to quit.

“However, one of the problems is that too many doctors are reticent to write this type of prescription, despite compelling evidence that e-cigarettes are effective quitting aids and an effective substitute for smoking.

“The awareness and process of doctors becoming an authorised prescriber of nicotine vaping products (NVPs) has been poorly understood and communicated. Sadly, there is a deep reluctance within the medical fraternity to support vaping as a harm reduction pathway for addicted smokers.

“The current prescription model has failed largely due to a lack of support and communication by the RACGP, Pharmacy Guild, and other professional bodies. As a result, the scourge of illegal vaping is evident in the increasing number of teenagers who have purchased a vape product illegally,” s22 said.

From the Fields Pharmaceuticals Australia has delivered a submission to the Therapeutic Goods Administration (TGA) Review recommending multiple solutions to the vaping health crisis.

“We must tackle the illegal, unregulated trade in vaping, which has created an exploding and major public health issue in Australia,” s22 said.

“Currently the black market of illicit vaping products, where 10 million units are sold each month, provides too easy access of nicotine vaping products to minors.

“The loophole allowing mislabelled vaping products needs to be closed. The importation of non-nicotine should be under the same import pathway as nicotine products to avoid general trade importing under false labelling and fuelling a black market.

“Moves to enforce sales of NVPs only by medical prescription is the means to increase smoking cessation, drive down adult smoking rates, and achieve improved public health outcomes.

“Our company supports a pragmatic solution for adult smoker cessation with NVPs under a therapeutic goods framework. We welcome the Albanese Government’s intention of further reform to address illegal vaping and win back control of this serious public health issue,” he said.

Some of the key statements made by From the Fields Pharmaceutical in its submission to the TGA Review, include:

1. NVPs or e-cigarettes have become an effective tool for quitting smoking, serving as a substitute when prescribed through a healthcare professional.
2. Australian authorities need to back in the medical prescription only model in place for NVPs sold. This GP prescribed/pharmacy sold product is a pathway for better health outcomes for Australian smokers.
3. Properly address the current illicit black market for vape sales to so many adult and Australian youth.
4. Assure public authorities that revising standards and proper enforcement of regulations in the illicit sale of NVPs across Australia, will not create supply chain constraints for NVP patient demand for Australian standard, smoking cessation designed products, which can be dispensed through physical and online pharmacies.
5. Australia could achieve less than 5% adult smokers by 2030, if nicotine vaping is used actively as a smoker cessation tool.

“Putting in place a simpler approach for less complex enforcement at the border for imported, but mislabelled NVPs now entering Australia, can meet existing and future regulations, while importantly backing in

better health outcomes," **S22** added.



Potential reforms to the regulation of nicotine vaping products  
Submission by from the fields pharmaceuticals Australia Pty Ltd (ACN  
662 953 826)  
16<sup>th</sup> January 2023

## Introductory statement

From the fields pharmaceuticals Australia Pty Ltd (FTF) is an independent company manufacturing and supplying Australian standards nicotine vaping products via the current TGO 110 regulatory framework in Australia with its Wild By Instinct Nicotine vaping brand.

As an independent company, our products are only sold with a prescription from an authorised prescriber (AP), dispensed via Pharmacies. Our range consists of a 50mg, 18mg, and 0mg in precise dose closed pods of 1ml, which is equivalent to a daily smoker's consumption, 4-day prefilled disposable for primarily elderly & non-technical patients and nicotine liquid in 30ml & 60ml bottles for patients with their own vaping device. Our liquids are primarily manufactured in the USA in very high-quality facilities that meet cGMP standards. Our closed pods and disposables are filled in ISO 13485 facilities.

Our business has been at a disadvantage due to the growth of the black market. As a legitimate business, that follows Australian standards that provides genuine products, FTF Pharmaceuticals is currently only able to reach 2% of the adult vaping population who have a valid prescription. In contrast, the black market, which has an estimated monthly average of over 1 million consumers, is able to sell 30 million units (equivalent of 1ml PODs) per month.

The lack of effective enforcement and regulation, particularly in regard to non-nicotine products, has led to a public health crisis and threatens the sustainability of patient treatment with legitimate adult smoking cessation products. The ambiguity of TGO 110 regulations only adds to this problem.

We support a pragmatic solution for adult smoker cessation with NVPs under therapeutics goods framework. We want the Government to make the sale of NVPs illegal unless sold by a pharmacist to adults wanting to break their cigarette addiction. We believe we are part of the solution, not the problem. The key to a workable solution is preventing the black market, which in turn curtails youth access, while advocating regulation that considers the potential benefits of approved NVPs for adult smokers, which can be substantial, immediate, and potentially lifesaving.

It is important for regulators to find the right balance between these concerns. We have based our submission on 5 key overarching points;

- 1. There is a strong body of evidence suggesting that e-cigarettes (NVP) can be an effective tool for quitting smoking and can serve as a substitute for traditional cigarettes. By correctly regulating and prescribing e-cigarettes through a healthcare professional, we can achieve better, faster, and more clearly demonstrated public health outcomes.**

There have been several types of studies, including randomized controlled trials, observational studies, and population data, that have found that e-cigarette use is associated with a reduction in smoking and a corresponding positive impact on public health.

The Royal College of Physicians (London) in its 2016 report highlighted, E-cigarettes appear to be effective when used by smokers as an aid to quit smoking. (Nicotine without Smoke: tobacco harm reduction, [link](#)) A systematic review and meta-analysis published in the journal Addiction in 2020 found that e-cigarette use was associated with a significantly higher likelihood of smoking cessation compared to no aid or other quitting methods. An observational study published in the journal PLOS ONE in 2018 found that e-cigarette use was associated with a higher likelihood of smoking cessation and a reduction in cigarette consumption among smokers who were not planning to quit. A population study published in the journal Tobacco Control in 2017 found that e-cigarette use was associated with a reduction in smoking prevalence among adults in the United Kingdom.

- 2. Key Issue – It is still early days in Australia for the prescription model. However, it can properly work for better health outcomes for Australians who smoke. The model is presently severely hamstrung by the failure of medical authorities and organisations (such as RACGP, Pharmacy Guild) to not agreeing to adopt NVPs nor communicating to their members, that NVPs are a smoking cessation ‘tool’.**

The awareness and process of doctors becoming authorised prescribers have been poorly understood and no clear communication provided by the above-mentioned professional associations.

There seems to be a reluctance politically to support NVP's as a harm reduction pathway for addicted smokers. Formal and informal Communication restrictions placed on professional media (B2B) by professional bodies such as the Pharmacy Guild of Australia has meant effective communication reaching both doctors and pharmacies has been problematic.

There is significant amounts of research for the RACGP and the Pharmacy Guild to have confidence in supporting NVP's as a smoking cessation tool instead of forming bias views based around general media publications. We continue to seek to get more of the medical fraternity across Australia to get on board.

- 3. Key Issue – There is a serious, rampant black market for vaping (an estimated market ~1.5m Australians) and it is particularly impacting on Australian youth.**

With no enforcement of legislation on the importation of NVP's by general trade, there has been the creation of a thriving black market with easy access for youth to vaping product. The illegal, unregulated trade has rapidly created a major public health issue in Australia. This now needs to be immediately addressed.

The prevalence of youth vaping is a legitimate concern. Young people should not vape or smoke. Currently the black market and illicit products sold in general trade are responsible in providing access to products to young Australians including minors.

If there were a complete ban on importing nicotine and non-nicotine vaping products, with

the exception of the S4 importation model, the access of this product to Australian youth will be significantly reduced.

Multiple sources identified there are estimated to be 1.1m to 1.5m adults vaping. Further to this, from a youth perspective, the Australian Alcohol and Drug Foundation (ADF) latest published research has shown around 14% of 12 to 17-year-olds have tried an e-cigarette, with around 32% of these students having used one in the past month.[8] According to a study conducted by the Queensland University of Technology (QUT), the prevalence of e-cigarette use among Australian youth has increased from 1.3% in 2013 to 8.8% in 2018.

Further, the vast majority of Australians are accessing vape product via illegal trade channels. The ability for an adult vaper to simply walk into a general trade store and unknowingly purchase an illicit vape means there is no real motivation for consumers to gain a prescription and purchase Australian standard products from pharmacies.

**4. Key Issue – Firms like FTF Pharmaceuticals Australia can address the supply side constraints should there be a major contraction or immediate regulatory change to product availability and can effectively implement the TGO110 standards if proper enforcement and support is in place.**

From a supply chain point of view, the Australian market requirements could be met withing 12 weeks at earliest post reforms under enforced, major regulatory change to product accessibility. Legitimate products manufactured in cGMP, ISO 13485 and fully compliant to TGO 110 could be procured. This includes a 4-week shipping lead time from a supply chain point.

As an independent company we have invested in assessing the potential demand based on the current (TGO 110) model. We have conducted an 8- week trial, which commenced in November 2022 in two LGA's in Sydney. We have approached 150 doctors and informed the process of becoming an authorised prescriber (AP). Currently 75 have successfully been approved to be AP's. Furthermore nearly 500 pharmacies in the surrounding areas have shown interest to dispense prescriptions.

**5. Towards and Below 5% - Australia could achieve less than 5% adult smokers by 2030 if nicotine vaping is used actively as a smoker cessation tool.**

Public health benefit of use of prescribed NVPs to smokers estimates improvement of a smoker age after 35 years as 3 months per year. If the public health benefit could be realised, this will add back 12-13 years for a smoker's life.

(The Example) - By vaping we assume the health improvement of a smoker age after 35 years is 3 months per year and based on the average life expectancy in Australia of 84 years. This gives back 12-13 years of life. As another measure, if we assume this includes 32 years of working life and 17 years of retirement that is a 65% or 8 years lift by individual productivity.

## Options for border control

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

FTF Pharmaceutical would support options 2 & 3 with some modification included from option 4.

- Support the Remove Personal Importation Scheme exemption for NVPs. Australian physical pharmacy or Australian online pharmacy are fully capable of transitioning quickly to ensure continuity of supply with current legal TGO 110 Australian standard products. Currently there are 5500 physical pharmacies and many online pharmacies to provide adult access to support our local market. If no significant changes to the current TGO 110 Australian standards on product ingredients and labeling supply chain could meet the immediate requirements to replace current illicit products in market.
- We support tighter controls on the importation of NVP's. However, we would also propose to extend the same requirements to non-nicotine products as well. Permit the importation to only a licensed S4 warehouse and permit the wholesale distribution only by S4 dealer licensed wholesalers. This would be a simpler approach and enable for a less complex enforcement at the border. Today's black market is fueled by mislabeled products entering Australia.
- Treat Nicotine and Non-Nicotine NVP's as same category for importation and border control purpose. The role of non-nicotine is to generally address behavior requirements under a smoking cessation and nicotine cessation program. Generally, this is a final stage of treatment. The size of market for non-nicotine is relatively small (estimated <2%) in countries such as UK. Not regulating non nicotine will still allow the black market to thrive and make it very hard for border force to enforce.

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

- Options 2,3,4 with modifications would support our goal of providing adult smokers with an Australian standard nicotine vaping products via a prescription model. By eliminating the illicit importation our Australian independent company would become sustainable.

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 organize procurement of compliant products as necessary, before the reforms come into effect

- Currently our product range is compliant to TGO 110 standards. If no change is required to labeling, packaging and ingredients normal supply chain timing would apply. Any increase in demand could be met within a 8-12 weeks supply. Our range at FTF Pharmaceutical will meet all vapers needs of disposable, prefilled pods or liquids. Furthermore, our products are only imported in to a S4 licensed warehouse.



## Options for pre-market assessment of NVPs by TGA

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

A pre-market notification option is preferred rather than a pre-market approval.

- A pre-market notification system for nicotine liquids could be established in Australia, which requires manufacturers to notify the regulatory body that their products meet Australian standards and provide supporting data before being allowed to be marketed. This system could streamline the process for manufacturers and ensure that only compliant products are introduced to the market. This would also provide vital clarity to authorised prescribers and dispensing pharmacies, of what products to prescribe or dispense. A similar model is used in the following countries:
  - New Zealand. All products are registered with the Ministry of Health's Vaping Regulatory Authority's Health Advisory and Regulatory Platform (HARP). All notified products are recorded in a publicly available searchable database eg the HARP database in New Zealand [\[link\]](#)
  - United Kingdom. Under the [TPD](#), 6 months prior to marketing, producers must supply a list of all ingredients in the product (liquid); Emissions from the product and Toxicological data and Components of the product.

It is not advisable for the Therapeutic Goods Administration (TGA) to require pre-market authorisation for every product, as this process can be costly, time-consuming, and burdensome. The U.S. Food and Drug Administration's use of pre-market authorisation has faced difficulties and lawsuits, with over 4 years of delays in decisions. Pre-market approval process in the US is now more than 4 years post announcement with very little progress.

Pre-market authorisation may unfairly disadvantage reduced-risk products in comparison to cigarettes, which do not need to undergo such assessment. It may also serve as a barrier to entry and innovation for manufacturers of nicotine vapor products (NVPs), potentially giving an advantage to big tobacco companies that have the resources to make such submissions. Any complicated premarket authorisation such as the US PMTA would also only allow the black market to further thrive.

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

Yes, currently our products are developed based on the TGO 110 standards. Any unnecessary and significant change would place a significant financial burden on an independent company such as ours. Our products could meet EUTPD, UK and NZ regulatory requirements. As these markets are advanced in the NVP space we feel that standards are adequate. We support a pre-market notification system.

### 15. If changes are made to pre-market assessment of NVPs by the TGA, 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?

If similar to the NZ product standards – Quality of vaping substance ingredients or the UK's

Tobacco & related products regulation we may require 3-6 months to prepare documentation and upload product details. In the interim reporting of Australian standards certificate of analysis could be provided and uploaded immediately. Fees for this process should be minimal. Any fees will also financially impact independent companies like ours in an effective start-up market.

## Minimum quality and safety standards for NVPs

### 18. Which option to restrict flavours in NVPs do you prefer? Why?

We say make no change to the list of currently restricted flavoring agents in NVPs.

Recommendation for flavours could include

- a. Simple adult pallet-based flavours with simple descriptions of flavour profiles only eg 'mint', 'blueberry', 'tobacco', 'mango'. Flavours to be found to have a material risk to health should be banned as in the prohibited ingredient list. The EUTPD & FDA have lists that can be referenced.
- b. Prohibit however descriptive flavour names that specifically appeal to youth eg 'dragon vomit' 'candy Floss'

Flavored e-cigarettes have been a controversial topic in recent years, with some arguing that they are primarily marketed towards youth and contribute to the youth vaping epidemic. However, it is important to recognize that flavored e-cigarettes can also be a useful tool for adult smokers looking to switch to a potentially less harmful alternative. Flavours are an integral part of transitioning an adult smoker to vaping as part of smoking cessation journey. Restricting non tobacco flavours would reduce the transition of smokers to vaping and lead to more smoking and smoking-related death and disease. Non tobacco flavoured e-liquids also increase quit rates compared to tobacco flavours and reduce the rate of relapse. [3,4] Those who vape with non tobacco flavours also have higher odds of making a quit attempt. [4]

One study published in the New England Journal of Medicine found that adults who used e-cigarettes containing flavors other than tobacco or menthol were more likely to successfully quit smoking compared to those who used non-flavored or menthol-flavored e-cigarettes. This suggests that flavors may be an important factor in helping adults switch to e-cigarettes.[6]

Another study published in the journal Tobacco Control also found that flavors can play a role in reducing cigarette consumption among adult smokers. The study surveyed over 6,000 adult smokers and found that those who used flavored e-cigarettes were more likely to report decreased cigarette consumption and an increased likelihood of trying to quit smoking.[7]

Overall, the evidence suggests that flavors can be an important factor in helping adult smokers switch to e-cigarettes and potentially reduce their cigarette consumption. However, it is also important to ensure that e-cigarettes are regulated in a way that prevents youth access and use. Non tobacco flavour bans would also lead to increased black-market supplies.

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

Yes

similar to the NZ product standards – Quality of vaping substance ingredients or UK’s Tobacco & related products regulation, we believe restriction should focus on hazardous agents in quantities that pose a material risk to users

**20. 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?**

No

As prescribed products are sold via pharmacies as a S4 medicine there is no need of plain packaging. Furthermore, there are adequate advertising and marketing restrictions relevant to S4 medicine, therefore plain packaging is a unnecessary requirements.

**21. 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 a prescription-only medicine?**

No

Currently the consumer medicine information (CMI) and relevant information by the medical practitioner should be sufficient for patients to be adequately informed of the dangers. Furthermore, child restrictive packaging and other safety mechanics are sufficient. The product is dispensed via AP's and Pharmacists who are responsible in communicating warnings.

**22. 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?**

No

We support similar to the NZ product standards – Quality of vaping substance ingredients products regulation.

The strength of free-base nicotine in a vaping substance must not exceed 20 mg/mL.

The strength of nicotine salt in a vaping substance must not exceed 50 mg/mL.

A 10 stick daily cigarette smoker (8mg) will consumer 80mg nicotine per day. A 1ml / 50mg closed pod user will still consumer less than a cigarette smoker. A 1ml / 50mg closed pod user will still consumer less than a cigarette smoker.

A freebase adult consumer uses between 3 to 12mg per 1 ml and vapes on average 5mls a day. That means they ingest between 15mg and 60mg of nicotine a day.

A nicotine salt consumer vapes between 18mg to 50mg per 1ml and vapes between 1 and 1.5mls a day. That means they ingest between 18mg and 75mg of nicotine a day.

This is why the NZ legislation is written the way it is, to cap ingestion at below 100mg per day.

Nicotine salt is mostly used in disposable and precise dose closed pod devices. These devices require a lower heat to vaporize and consequently have lower emissions. Freebase nicotine used mainly by open tank users.

**23. Do you support limiting the maximum volume of liquid NVPs? If so, what maximum**

## **volume should be specified?**

Yes

We support no more than 800 puff equivalent in disposable vaping units which is sufficient for 4-5 days of dosage. A 1ml / 50mg closed pod system as its similar to current daily nicotine intake of an average smoker.

We support a maximum amount of nicotine per container similar to the New Zealand limit of 1800mg nicotine per container is a sensible compromise. [\[link\]](#) This would be 100mL of 18mg/mL or 36mL of 50mg/mL.

All bottles should have child-proof caps, and be leak proof, unbreakable (PET plastics) and have anti-spill protection making accidental poisoning very unlikely.

## **24. Do you support preventing access to disposable NVPs?**

No

Disposable vape devices are a popular aid for adults transitioning from smoking as they are convenient, easy-to-use, require no maintenance or charging and provide good nicotine delivery. They are especially useful for elderly, disabled and non-technical users. Disposable devices are also most appropriate device for a hospital inpatient as they require no refilling or recharging and are tamper proof.

## **25. Would any of the options set out in questions 18 to 24 have an impact on you? How?**

Yes

Excessive regulation can have negative effects such as limiting patient choice, impeding innovation, and potentially endangering adult smoker lives by delaying access to necessary products to support smoking cessation such as NVPs.

It can also create barriers to entry that make it difficult for independent companies to enter the market, while giving an advantage to established, large tobacco companies already here in Australia with significant budgets and control the rate of smoker cessation.

## **26. If changes to product quality and safety standards are made, how much time would you require, if any, to become familiar with the reforms, and to organise the procurement of compliant products as necessary, before the reforms come into effect?**

3 months

If similar to the NZ product standards – Quality of vaping substance ingredients or the UK's Tobacco & related products regulation we may require 3 months to procure compliant products. Provision to run out current TGO 110 compliant stock would be required.

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

Yes

- Standards for the manufacture of vaping liquids
- Standardised testing regimes
- Emission testing



## Clarifying the status of NVPs as 'therapeutic goods'

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

No

All products with nicotine should be labelled correctly. Many illegally imported products currently in the Australian market do not list nicotine to avoid detection by the Border Force. This is the single biggest driver of black market, greater youth access and underpinning this emergent public health crisis.

Non nicotine vaping products are only designed for smokers to address a behavioral purpose. In a nicotine reduction and smoking cessation strategy having a gradual reduction in nicotine strengths and ultimately a non-nicotine product may assist in the behavioral aspects. The importation of non-nicotine should be under the same pathway of S4 nicotine products to avoid general trade importing under false labeling and fueling a black market, which is now already well-established with the commensurate poor public health and societal outcomes.

## References

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2. Hartmann-Boyce J, Lindson N, McRobbie H, Butler AR, Bullen C, Begh R, et al. Electronic cigarettes for smoking cessation. *Cochrane Database of Systematic Reviews*; 2022.; 2022. [accessed 2022 November 19]. Available from: <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub7/fu>
3. Farsalinos, K. E., & Polosa, R. (2020). E-cigarettes and smoking cessation: A review of the evidence. *Addiction*, 115(2), 213-220.
4. Zhu, S. H., Zhuang, Y. L., Wong, S., Cummins, S. E., & Tedeschi, G. J. (2018). Association between electronic cigarette use and changes in quit attempts, success of quit attempts, use of smoking cessation pharmacotherapy, and use of stop smoking services in England: Time series analysis of population trends. *PLOS ONE*, 13(11), e0207330.
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6. West, R., Brown, J., & Beard, E. (2015). Role of e-cigarettes in smoking cessation: a systematic review and meta-analysis. *New England Journal of Medicine*, 372(9), 629-637.
7. Farsalinos, K. E., & Polosa, R. (2014). Safety evaluation and risk assessment of electronic cigarettes as tobacco cigarette substitutes: a systematic review. *Therapeutic Advances in Drug Safety*, 5(2), 67-86.
8. <https://adf.org.au/talking-about-drugs/vaping/vaping-youth/vaping-australia/>

**From:** s22  
**To:** s22  
**Cc:** s22  
**Subject:** RE: Meeting request - Imperial Brands [SEC=OFFICIAL]  
**Date:** Thursday, 2 February 2023 11:35:00 AM  
**Attachments:** [image001.gif](#)  
[image002.gif](#)  
[image003.png](#)  
[image004.png](#)

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Hi s22,

Unfortunately I am not in a position to talk to yourself or your client regarding Tobacco reform because under Article 5.3 of the WHO Framework Convention on Tobacco Control (FCTC) Australia is legally obliged to take steps to protect its public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry.

In light of Imperial Brands commercial interests in tobacco and e-cigarette products and Australia's obligations, our office cannot participate in a meeting with this organisation to discuss issues related to tobacco control and e-cigarettes.

Best,

s22

s22

Minister for Health and Aged Care

s22

E: s22@health.gov.au

PO Box 6022, Parliament House, Canberra ACT 2600, Australia

*I acknowledge the Traditional Custodians of the land on which I work and their continued connection to land, sea and community. I pay my respects to all Elders past and present.*

---

**From:** s22@cgrp.com.au>  
**Sent:** Thursday, 2 February 2023 10:08 AM  
**To:** s22@Health.gov.au>  
**Cc:** s22@cgrp.com.au>; s22@cgrp.com.au>  
**Subject:** RE: Meeting request - Imperial Brands

Hi s22

Apologies for the mix-up on our end, s22 was speaking to s22 from your office yesterday, not your CoS.

Thanks,

s22



s22

Head Office: [Level 10, Park House](#)  
[187-191 Macquarie Street, Sydney N.S.W](#)



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**From:** s22  
**Sent:** Thursday, 2 February 2023 9:33 AM  
**To:** s22 @Health.gov.au  
**Cc:** s22 @cgrp.com.au>; s22  
@cgrp.com.au>  
**Subject:** Meeting request - Imperial Brands

Hi s22

My colleague s22 was speaking to your CoS yesterday who passed along your details. I'm writing on behalf of our clients, Imperial Brands, who are listed on the Federal Lobbyist Register.

We'll be in Canberra next week (Tuesday and Wednesday) and were hoping you might have time for quick catch up to discuss the Government's proposed tobacco reforms?

Thanks,  
s22

s22

**From:** s22  
**Sent:** Monday, 23 January 2023 5:04 PM  
**To:** s22  
**Cc:** s22  
**Subject:** RE: Update - From the Fields Pharmaceutical - TGA Review into NVPs [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good afternoon s22

Thanks so much for your note and the respective update including where the TGA process is at in terms of consultation updates.

And noted s22 is the primary go to within the Ministerial office, but you'll also be across.

s22 if you would like a brief discussion with From the Fields Pharmaceutical do let me know.

Our client's overarching position around medically prescribed NVPs, as part of their 5-point position, including addressing the proliferation of vapes currently in a black market, we hope will be given due consideration by the TGA. Happy to facilitate a Teams/Zoom discussion if you see value.

My contacts are below.

Kind regards,

s22 (on their behalf)

s22



M s22

E s22@royce.com.au

A P.O. Box 3034, South Melbourne 3205

W [www.royce.com.au](http://www.royce.com.au)

---

**From:** s22@Health.gov.au>

**Sent:** Monday, 23 January 2023 11:36 AM

**To:** s22@royce.com.au> ■

**Subject:** RE: Update - From the Fields Pharmaceutical - TGA Review into NVPs [SEC=OFFICIAL]

Hi s22

Thanks for the update.

My colleague s22 is leading on the issue, but I am keeping in close contact with the process. TGA is scheduled to update us on the consultation towards the end of next week.

Rgds

s22

---

**From:** s22@royce.com.au>

**Sent:** Friday, 20 January 2023 9:33 AM

**To:** s22@Health.gov.au>

**Cc:** s22@royce.com.au>

**Subject:** Update - From the Fields Pharmaceutical - TGA Review into NVPs



**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning s22

Thanks for the reach back late last week. I appreciate with the early/mid-January period a lot of people are at or only partially back at work.

Not much rest in consulting land at this time, but I did grab a great get-away in the lead-up to Christmas.

Just simply wanted to say thanks for the reach-back on From the Fields and their thinking around the TGA Review into NVPs.

Not sure if you had any additional questions or if at some point you wanted to get their perspective. This can be arranged and Teams is as efficient as anything as s22 their s22 is in Sydney, their other key exec is in Perth and I/we operate out of Melbourne, but do get to Canberra pretty often On that front it would be good to connect in Canberra at some stage soon if that works.

As you've seen various industry and advocacy groups are dribbling out their positions for the TGA Review. FTF Pharmaceutical is likely to get some media coverage this weekend, likely the News Ltd – Sunday papers.

Look forward to staying in touch and if you need some additional insight, perspective or feedback, don't hesitate to reach out. Similarly happy to make a time with you soon that suits. I've re-attached their statement.

Kind regards,

s22 for From the Fields Pharmaceutical

s22



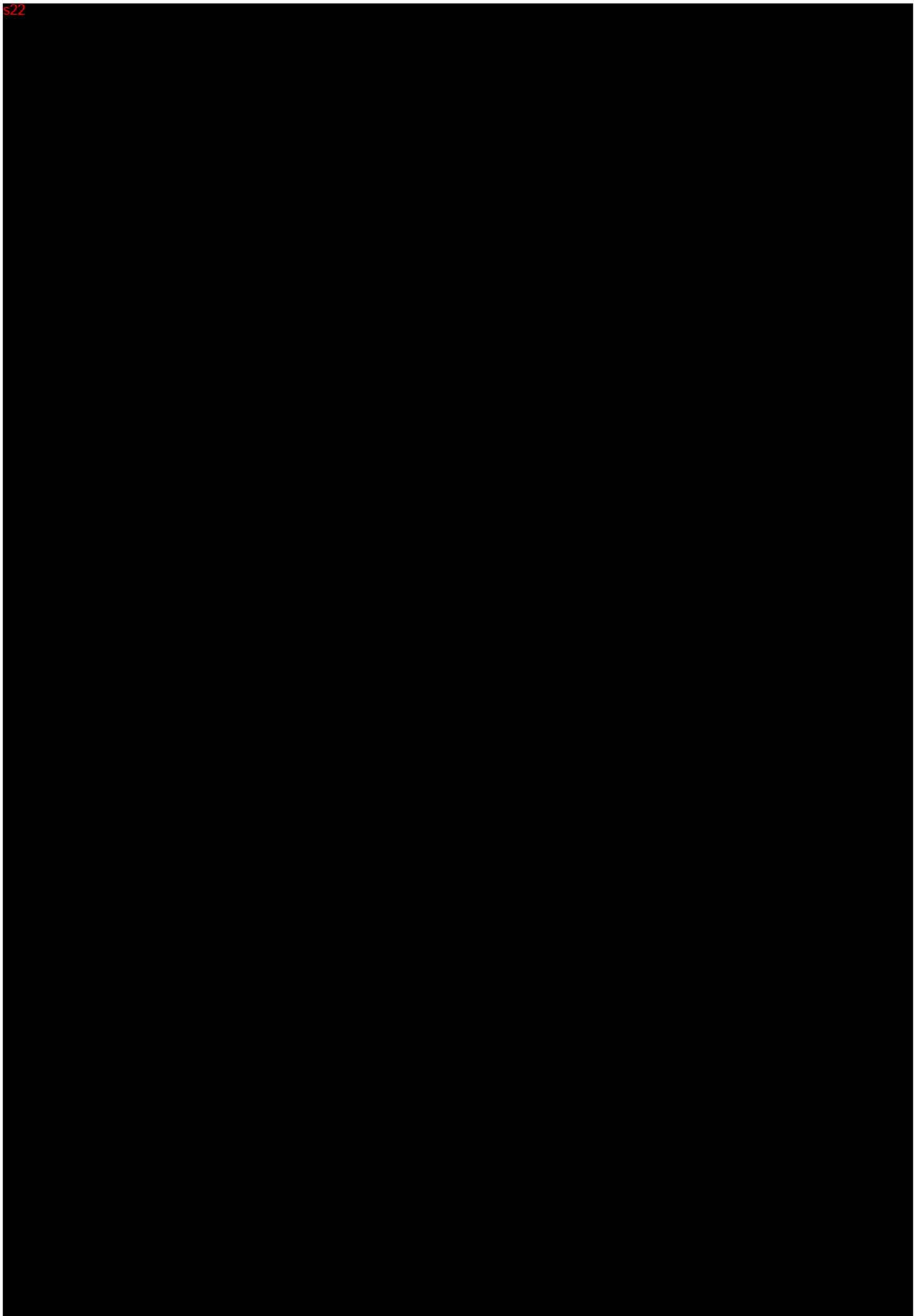
s22

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s22

From: s22 @Health.gov.au>  
Sent: Friday, 10 March 2023 2:14 PM  
To: Minister Butler DLO <Minister.Butler.DLO@Health.gov.au>  
Cc: s22 @Health.gov.au>; s22 @Health.gov.au>  
Subject: MEETING BRIRF | Heart Foundation | Meeting with Minister Butler 4pm on 22 March | Due noon 20/3 [SEC=OFFICIAL]

Hi team

Can I please request a MB on this one with bios etc. and covering the specific topics below. I think there is enough existing material to cover the vaping one. Note attached if needed.

- Heart Foundation pre-Budget Submission (specifically continuation or permanency of MBS Heart Check items)
- CVD Risk Guidelines and Launch (I've discussed with s22 and will follow-up now she has spoken to the Dept about this)

And about tobacco control and vaping as I recall you raised in previous correspondence.

Due 20/3 by noon.

Any questions please let me know.

Thanks

s22

---

From: s22 @heartfoundation.org.au>  
Sent: Friday, 10 March 2023 9:42 AM  
To: s22 @Health.gov.au>  
Subject: RE: Meeting with Minister Butler [SEC=OFFICIAL]

H s22

Thanks for your help with this. Please find attached the meeting form.

Thanks

s22

s22  
s22  
Canberra, ACT  
s22  
s22 s22 s22 s22

[REDACTED]

For heart health information visit  
[heartfoundation.org.au](http://heartfoundation.org.au)

*The Heart Foundation acknowledges the Traditional Owners and custodians of country throughout Australia and their continuing connection to land, waters and community. We pay our respect to them and their cultures, and Elders past, present and future.*

---

From: s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>  
Sent: Thursday, 9 March 2023 1:20 PM  
To: s22 [REDACTED] <[\[REDACTED\]@heartfoundation.org.au](mailto:[REDACTED]@heartfoundation.org.au)>  
Subject: RE: Meeting with Minister Butler [SEC=OFFICIAL]

Thanks s22 [REDACTED]. Can offer 4PM ACT time on 22/3 or 11.30am on 23/3 both in Canberra (in case he was staying longer).

Alternatively 31 March around 1.30/2pm in Adelaide is suitable (Adelaide time). Once confirmed if you could also fill in the attached and return that would be great. One of the adviser team will also sit in on the session.

Cheers

s22 [REDACTED]

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From: s22 [REDACTED] <[\[REDACTED\]@heartfoundation.org.au](mailto:[REDACTED]@heartfoundation.org.au)>  
Sent: Thursday, 9 March 2023 1:04 PM  
To: s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>  
Cc: s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>; s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>; s22 [REDACTED] <[\[REDACTED\]@Health.gov.au](mailto:[REDACTED]@Health.gov.au)>  
Subject: RE: Meeting with Minister Butler [SEC=OFFICIAL]

Hi s22 [REDACTED]

Thanks for your help with this and for getting back to me.

s22 [REDACTED] will be in Canberra on 14 March and also 22 March, but is also frequently in Adelaide so could meet in the EO.

Thanks

s22 [REDACTED]

[REDACTED]

s22 [REDACTED] s22 [REDACTED]

Canberra , ACT

s22 [REDACTED]



For heart health information visit  
[heartfoundation.org.au](http://heartfoundation.org.au)

*The Heart Foundation acknowledges the Traditional Owners and custodians of country throughout Australia and their continuing connection to land, waters and community. We pay our respect to them and their cultures, and Elders past, present and future.*

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**From:** s22 [redacted] <[s22@Health.gov.au](mailto:s22@Health.gov.au)>  
**Sent:** Thursday, 9 March 2023 1:02 PM  
**To:** s22 [redacted] <[s22@heartfoundation.org.au](mailto:s22@heartfoundation.org.au)>  
**Cc:** s22 [redacted] <[s22@Health.gov.au](mailto:s22@Health.gov.au)>; s22 [redacted] <[s22@Health.gov.au](mailto:s22@Health.gov.au)>; s22 [redacted] <[s22@Health.gov.au](mailto:s22@Health.gov.au)>  
**Subject:** RE: Meeting with Minister Butler [SEC=OFFICIAL]

H s22 [redacted]

Sorry for the delay in response.

Minister is pleased to meet on the below from your email:

- Heart Foundation pre-Budget Submission (specifically continuation or permanency of MBS Heart Check items)
- CVD Risk Guidelines and Launch (I've discussed with s22 [redacted] and will follow-up now she has spoken to the Dept about this)

And about tobacco control and vaping as I recall you raised in previous correspondence.

We will refer the launch of risk guidelines to AM Ged Kearney.

You mentioned a few dates when we last spoke – can you send through again and will finalise in.

Thanks

s22 [redacted]

---

**From:** s22 [redacted] <[s22@heartfoundation.org.au](mailto:s22@heartfoundation.org.au)>  
**Sent:** Thursday, 23 February 2023 10:04 AM  
**To:** s22 [redacted] <[s22@Health.gov.au](mailto:s22@Health.gov.au)>  
**Subject:** FW: Meeting with Minister Butler [SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.



Hi s22

Any chance you can give me a call on s22 to discuss?

Thanks for your help with this

s22

[Redacted]  
[Redacted] s22 [Redacted]  
[Redacted]  
Canberra, ACT  
[Redacted] s22 [Redacted]  
[Redacted]  
[Redacted]

[Redacted]  
[Redacted]

For heart health information visit [heartfoundation.org.au](http://heartfoundation.org.au)

*The Heart Foundation acknowledges the Traditional Owners and custodians of country throughout Australia and their continuing connection to land, waters and community. We pay our respect to them and their cultures, and Elders past, present and future.*

---

From: s22 [Redacted] <[\[Redacted\]@Health.gov.au](mailto:[Redacted]@Health.gov.au)>  
Sent: Wednesday, February 22, 2023 9:45 AM  
To: s22 [Redacted] <[\[Redacted\]@heartfoundation.org.au](mailto:[Redacted]@heartfoundation.org.au)>  
Cc: [Redacted] <[\[Redacted\]@Health.gov.au](mailto:[Redacted]@Health.gov.au)>  
Subject: RE: Meeting with Minister Butler [SEC=OFFICIAL]

s22

Thanks for the note.

I've copied Minister's s22 [Redacted] who can advise on a meeting.

Rgds  
s22

---

From: s22 [Redacted] <[\[Redacted\]@heartfoundation.org.au](mailto:[Redacted]@heartfoundation.org.au)>  
Sent: Wednesday, 22 February 2023 9:39 AM  
To: s22 [Redacted] <[\[Redacted\]@Health.gov.au](mailto:[Redacted]@Health.gov.au)>  
Subject: Meeting with Minister Butler

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

I was hoping I could take you up on your offer to help facilitate a meeting between s22 and Minister Butler.

s22 will be in Canberra on 14 March, is there any chance the Minister will be as well?

By way of an agenda s22 is keen to discuss the following:

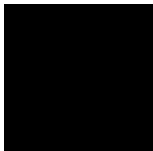
- Heart Foundation pre-Budget Submission (specifically continuation or permanency of MBS Heart Check items)
- CVD Risk Guidelines and Launch (I've discussed with s22 and will follow-up now she has spoken to the Dept about this)

Naturally I'm happy to ensure s22 can update the Minister or cover anything else the Minister maybe find useful.

Could you possible direct me to whoever manages Minister Butler's diary?

Thanks for your help

s22



s22

s22

Canberra , ACT

s22



For heart health information visit [heartfoundation.org.au](http://heartfoundation.org.au)

*The Heart Foundation acknowledges the Traditional Owners and custodians of country throughout Australia and their continuing connection to land, waters and community. We pay our respect to them and their cultures, and Elders past, present and future.*

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not use, copy, retain, disclose or distribute this information. Please notify the sender immediately by return e-mail and delete the message from your system. Any personal opinion expressed in this communication is that of the individual sender and does not constitute official pronouncements or opinions of Heart Foundation. The Heart Foundation cannot guarantee that the e-mail or any attachments are free from viruses.

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**Australian Government**  
**Department of Health and Aged Care**

Meeting Brief  
MB23-000816  
Version (1)

Date sent to MO: 17/03/2023

To: Minister Butler

Subject: Heart Foundation meeting with Minister Butler

Comments:			
Contact Officer:	Chris Carlile	Assistant Secretary Hearing Services and Chronic Conditions Branch	s22 [Redacted]
Clearance Officer:	Lisa Schofield	First Assistant Secretary Cancer, Hearing and Chronic Conditions Division	s22 [Redacted] s22 [Redacted]

Date / Time: Wednesday, 22 March 2023, 4:00-4:30pm

Meeting Type/Location: Parliament House

Traditional Custodians: Ngunnawal and Ngambri

Purpose: Meeting with the National Heart Foundation Australia (NHFA). Proposed Agenda:

s22 [Redacted]  
s22 [Redacted]

3. Request for NHFA representation on the E-cigarettes Working Group

Desired Outcomes: To establish a relationship with the NHFA and discuss their priorities

Key Attendees/Speakers:	Title:	Organisation:	Mobile No:
s22 [Redacted]	s22 [Redacted]	National Heart Foundation Australia	s22 [Redacted]
s22 [Redacted]	s22 [Redacted]	National Heart Foundation Australia	s22 [Redacted]

Key Matters/Issues:

- s22 [Redacted]
- Request for NHFA representation on the E-cigarettes Working Group

**Discussion Guide:**

- s22 [REDACTED]
- s22 [REDACTED]
- Re-affirm the Australian Government is concerned about the increased marketing and use of e-cigarettes, particularly among young people, and is working with the states and territories to strengthen the regulatory framework governing these products.

- s22 [REDACTED]
- s22 [REDACTED]

**Stakeholder information:**

- The NHFA is a National Health Promotion Charity which, for over 60 years, has worked to improve heart disease outcomes through the prevention, detection and support for Australians impacted by heart disease and their families and carers. Activities include:
  - Funding research, and supporting heart health researchers
  - Working to improve heart disease prevention, detection, care, and support for all Australians
  - Advocating to governments and industry for investment in initiatives and resources for heart health
  - Building community awareness about living a heart-healthy lifestyle, through public health awareness campaigns, accessible information, and resources; and
  - Supporting health professionals in their work to prevent, diagnose, treat, and manage heart disease.
- The NHFA receives funding under the Action Plan for four projects (Attachment C refers).

s22 [REDACTED]

[REDACTED]

[REDACTED]

s22 [REDACTED]

[REDACTED]

[REDACTED]



**Stakeholder Objective:**

- s22 [REDACTED]
- s22 [REDACTED]
- The NHFA is seeking representation on the Australian Government's E-cigarette's Working Group.

**Sensitivities or Contentious Issues:**

- s22 [REDACTED]
- s22 [REDACTED]
- The NHFA has a zero-tolerance approach to E-cigarettes. Other key bodies including the Royal Australian College of General Practice (RACGP) support the use of E-cigarettes as a transitional device from tobacco.
- On 30 September 2022, you convened a Tobacco Control Roundtable, which brought together experts in tobacco control in Australia and included discussion on options to reduce e-cigarette marketing, promotion and use. The NHFA did not attend the Tobacco Control Roundtable in September 2022 and is not on the invite list for the upcoming roundtable in April 2023.

s22 [REDACTED]

**Background:**

- Relevant government initiatives are included at [Attachment C](#).

**Attachments:**

s22 [REDACTED]

C. Relevant Government Initiatives

s22

# s22

Relevant Government Initiatives

s22 [Redacted text block]

[Redacted text block]

[Redacted text block]

[Redacted text block]

factors s22 [Redacted text block]

[Redacted text block]

[Redacted text block]

s22





s22



[REDACTED]

***E-cigarettes and Vaping Products***

- At the Health Ministers’ Meeting on 24 February 2023, Ministers endorsed the National Tobacco Strategy 2023-2030. The Strategy includes targets to reduce daily smoking prevalence in Australia to below 10% by 2025 and to 5% or less by 2030. The Strategy also includes a number of actions to address e-cigarettes. The Strategy will be made publicly available shortly.
- To support action related to e-cigarettes and vaping, Ministers also agreed to establish a national E-cigarette Working Group aimed at reviewing and advising on measures to protect young people from the harms of e-cigarettes by addressing the increasing availability, appeal, and uptake of vaping products.
- The TGA has recently undertaken a public consultation on nicotine vaping products. Almost 4,000 submissions were received, including from the NHFA. Options for strengthening border controls for nicotine vaping products (NVPs) were among the topics of the consultation. The Government is actively considering the submissions to inform reform of the regulatory framework surrounding NVPs
- The Department has commissioned a tobacco control and e-cigarette research program to inform strategic communication activities aimed at motivating quit attempts, promoting the use of smoking cessation resources, and preventing e-cigarette uptake. The outcomes of this work will be used to inform future communication activities related to tobacco and e-cigarette products.
- The Department has also commissioned the Cancer Council NSW to expand their Generation Vape study to a national cohort. This study aims to understand the perceptions, attitudes, related knowledge and behaviours of e-cigarette use among 14–17-year-olds and 18–24-year-olds.
- In 2022, researchers from the ANU published a systematic review of global evidence on the health effects of e-cigarettes, which found indirect evidence of adverse effects of e-cigarettes on cardiovascular health markers, including blood pressure and heart rate. The report is available at [https://nceph.anu.edu.au/files/E-cigarettes health outcomes review summary brief 2022.pdf](https://nceph.anu.edu.au/files/E-cigarettes%20health%20outcomes%20review%20summary%20brief%202022.pdf)

OFFICIAL

<b>Minister</b>	<b>Minister Butler</b>
<b>PDR Number</b>	<b>MB23-000816</b>
<b>Subject</b>	<b>Meeting brief - Heart Foundation   Meeting with Minister Butler</b>
Contact Officer	Chris Carlile s22 s22
Clearance Officer	Lisa Schofield s22 s22
Division/Branch	Primary and Community Care   Cancer Hearing and Chronic Conditions

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
-----------------------	---



**The Hon Mark Butler MP**  
**Minister for Health and Aged Care**

Ref No: MC23-004200

s22

The National Heart Foundation

s22 @heartfoundation.org.au

Dear s22

Thank you for your correspondence of 22 February 2023 regarding tobacco and e-cigarettes.

At the Health Ministers' Meeting on 24 February 2023, Ministers endorsed the National Tobacco Strategy 2023-2030 (Strategy). The Strategy includes targets to reduce daily smoking prevalence in Australia to below 10% by 2025 and to 5% or less by 2030. It prioritises addressing smoking among First Nations people and the importance of Closing the Gap. The Strategy also includes a number of actions to address e-cigarettes. The Strategy will be made publicly available shortly.

To support action related to e-cigarettes and vaping, Ministers also agreed to establish a national E-cigarette Working Group aimed at reviewing and advising on measures to protect young people from the harms of e-cigarettes by addressing the increasing availability, appeal, and uptake of vaping products.

Almost 4,000 submissions were made to the recent public consultation on nicotine vaping products (NVPs) conducted by the Therapeutic Goods Administration (TGA), and I thank the Heart Foundation for its contribution. Options for strengthening border controls for NVPs were among the topics of the consultation. The Australian Government is actively considering the submissions which, together with the Working Group, will inform reform of the regulatory framework surrounding NVPs.

In the meantime, the TGA, in conjunction with Australian Border Force and state and territory agencies, is continuing to take action to enforce the current laws, and to educate the public on issues relating to nicotine vaping. Information about enforcement activities, including ongoing Federal Court proceedings against two companies and their directors who are alleged to have illegally advertised NVPs, is available on the TGA's website at [www.tga.gov.au/nicotine-vaping-products-news-and-updates](http://www.tga.gov.au/nicotine-vaping-products-news-and-updates).

Thank you for writing on this matter.

Yours sincerely

s22

Mark Butler

15 / 33 / 2023



**The Hon Mark Butler MP**  
**Minister for Health and Aged Care**

Ref No: MC23-004262

s22

Lung Foundation Australia  
[markb@lungfoundation.com.au](mailto:markb@lungfoundation.com.au)

Dear

Thank you for your correspondence of 22 February 2023 regarding the National Tobacco Strategy and urgent need for e-cigarette and tobacco control.

Thank you also for sharing the outcomes of your survey on community and health professional views on vaping in Australia, and your Pre-Budget submission.

May I express my appreciation of your attendance at the Tobacco Control Roundtable on 30 September 2022 and the support of Lung Foundation Australia at the 10th anniversary of tobacco plain packaging event on 30 November 2022. I valued the opportunity to hear directly from experts in the field. I agree with you that tobacco and e-cigarette control is vitally important, and I intend to continue engaging with key stakeholders to progress action and reform in Australia.

At the Health Ministers' Meeting on 24 February 2023 Ministers endorsed the National Tobacco Strategy 2023-2030 (Strategy). The Strategy includes targets to reduce daily smoking prevalence in Australia to below 10% by 2025 and to 5% or less by 2030. It prioritises addressing smoking among First Nations people and the importance of Closing the Gap. The Strategy also includes a number of actions to address e-cigarettes. The Strategy will be made publicly available shortly.

To support action related to e-cigarettes and vaping, Ministers also agreed to establish a national E-cigarette Working Group (Working Group) aimed at reviewing and advising on measures to protect young people from the harms of e-cigarettes by addressing the increasing availability, appeal, and uptake of vaping products.

Almost 4,000 submissions were made to the recent public consultation on nicotine vaping products (NVPs) conducted by the Therapeutic Goods Administration (TGA), and I thank the Lung Foundation Australia for its contribution. Options for strengthening border controls for NVPs were among the topics of the consultation. The Australian Government is actively considering the submissions which, together with the Working Group, will inform reform of the regulatory framework surrounding NVPs.



In the meantime, the TGA in conjunction with Australian Border Force and state and territory agencies, is continuing to take action to enforce the current laws, and to educate the public on issues relating to nicotine vaping. Information about enforcement activities, including ongoing Federal Court proceedings against two companies and their directors who are alleged to have illegally advertised NVPs, is available on the TGA's website at [www.tga.gov.au/nicotine-vaping-products-news-and-updates](http://www.tga.gov.au/nicotine-vaping-products-news-and-updates).

Thank you for writing on this matter.

Yours sincerely <sup>s22</sup>



Mark Butler

15 / 93 / 2023



**The Hon Mark Butler MP**  
**Minister for Health and Aged Care**

Ref No: MC23-005309

s22

Australian Council on Smoking and Health

s22@acosh.org

s22

Australian Council on Smoking and Health

s22@acosh.org

s22

Australian Council on Smoking and Health

s22@health.wa.gov.au

Dear s22 and s22

Thank you for your correspondence of 8 March 2023 regarding e-cigarette and tobacco control.

I would like to congratulate you all on your new appointments in the Australian Council on Smoking and Health (ACOSH). Thank you also for sharing your insight regarding the concerns of the Parents and Citizens' Associations and WA Aboriginal Tobacco Control Strategic Leadership Team.

May I express my appreciation for ACOSH and its input in the tobacco control roundtable on 30 September 2022. I valued the opportunity to hear directly from experts in the field and appreciated the robust discussion of options to reduce e-cigarette marketing, promotion and use. I look forward to meeting with s22 at the upcoming roundtable focusing on e-cigarettes on 17 April.

Ministers endorsed the National Tobacco Strategy 2023-2030 (Strategy) at the Health Ministers' Meeting on 24 February 2023. The Strategy includes targets to reduce daily smoking prevalence in Australia to below 10% by 2025 and to 5% or less by 2030. It prioritises addressing smoking among First Nations people and the importance of Closing the Gap. The Strategy also includes a number of actions to address e-cigarettes. The Strategy will be made publicly available shortly.

Ministers also agreed to establish a national E-cigarette Working Group (Working Group) aimed at reviewing and advising on measures to protect young people from the harms of e-cigarettes by addressing the increasing availability, appeal, and uptake of vaping products. Work is currently under way to determine the next steps to progress this initiative.

Almost 4,000 submissions were made to the recent public consultation on nicotine vaping products (NVPs) conducted by the Therapeutic Goods Administration (TGA), and I thank ACOSH for its contribution. Options for strengthening border controls for NVPs were among the topics of the consultation. The Australian Government is actively considering the submissions which, together with the Working Group, will inform reform of the regulatory framework surrounding NVPs.

In the meantime the TGA, in conjunction with Australian Border Force and state and territory agencies, is continuing to take action to enforce the current laws and to educate the public on issues relating to nicotine vaping. Information about enforcement activities, including ongoing Federal Court proceedings against two companies and their directors who are alleged to have illegally advertised NVPs, is available on the TGA's website at [www.tga.gov.au/nicotine-vaping-products-news-and-updates](http://www.tga.gov.au/nicotine-vaping-products-news-and-updates).

Thank you for writing on this matter.

Yours sincerely

s22  


Mark Butler

23/03/2023



**Australian Government**  
**Department of Health and Aged Care**

**Ministerial Submission – Standard**  
**MS23-000298**  
**Version (1)**  
**Date sent to MO: 28 February 2023**



To: Minister Butler

Subject: Upcoming Australian National Advisory Council on Alcohol and Other Drugs (ANACAD) meeting: 6-7 March 2023

Critical date: 3 March 2022, to allow time to make arrangements prior to the meeting.

**Recommendation/s:**

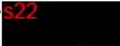

<p>1. Note the upcoming Australian National Advisory Council on Alcohol and Other Drugs (ANACAD) meeting to be held on 6 and 7 March 2023.</p>	<p>1. <b>Noted</b></p>
<p>2. Agree to attend part of the upcoming ANACAD meeting.</p>	<p>2. <b>Agreed/Not agreed/Please discuss</b></p>
<p>OR</p> <p>3. Agree to meet with the ANACAD Interim Chair.</p>	<p>3. <del>Agreed/Not agreed/Please discuss</del> <b>MR.</b></p>

Signature .....  *Minister will meet with new on going chair in due course. Ok to *

Comments: *Date: 7/3 / 2023*  
*Interim chair on 7/3 @chap in.*

Contact Officer:	Celia Street	First Assistant Secretary, Population Health Division
Clearance Officer:	Tania Rishniw	Deputy Secretary, Primary and Community Care Group

**Issues:**

- The Australian National Advisory Council on Alcohol and Other Drugs (ANACAD) will be holding its first meeting of the year in Canberra on Monday 6 and Tuesday 7 March. This will be the first face to face meeting of the Council following a refresh of the ANACAD structure and removal of COVID-19 restrictions. A key focus of the meeting will be on developing priorities and a forward work program.
- A process is underway to appoint a new Chair following the resignation of  in December 2022 (MS23-000037 refers).  was appointed interim Chair on 1 January 2023 and will Chair the upcoming meeting.



3. Your attendance at the meeting would provide an opportunity to meet ANACAD and share your views on Government priorities with regards to alcohol and other drugs.
  - a. If you are available, we will work with your office to facilitate your attendance, either in person or virtually.
  - b. Alternatively, you may wish to separately meet with s22 the Interim ANACAD Chair, to discuss your priorities.
4. The meeting agenda is at Attachment A. The meeting will include:
  - a. A presentation on Nicotine Vaping Product Reform by Adjunct Professor John Skerritt from the Therapeutic Goods Administration.
  - b. Standard agenda items, including updates on the National Preventative Health Strategy, and addiction medicine and related workforce issues.
  - c. A facilitated workshop planning session on day two of the meeting to determine ANACAD priorities and development of ANACAD's ongoing workplan. A facilitator with significant alcohol and other drug experience will run the planning session. A copy of a ANACAD's existing priorities and previous workplan is provided for your information at Attachment B.

**Background:**

ANACAD is the principal alcohol and other drugs expert advisory body to the Australian Government. ANACAD reports to you as the Minister responsible for drugs and alcohol policy within the Health portfolio, providing confidential, strategic, evidence-based advice on drug and alcohol policy. The Council brings together experts with leading expertise in a range of areas, including research, prevention and treatment. ANACAD meets up to four times per year and provide advice on new and emerging polices, ideas or issues relating to alcohol and other drugs.

In 2021-22, the operation and structure of ANACAD was revised and refreshed. The size of the Council was reduced from 16 members and one observer, down to a total of ten members.

**Attachments:**

- A: ANACAD Agenda: 6-7 March 2023
- B: ANACAD priorities workplan 2017-2020

**Sensitivities:**

You may be asked about the process and timing for appointment of the Chair of ANACAD. Final arrangements are being made following your indication of a preferred candidate, however, it is likely to be too early to discuss this with ANACAD.

**Consultations:**

Nil