



Australian Government

Department of Health and Aged Care

Information Brief

MB23-000824

Version (1)

Date sent to MO: 14/03/2023

To: Minister Butler

Subject: DEPT INITIATED BRIEF - POTENTIAL REFORMS TO THE REGULATION OF NICOTINE VAPING PRODUCTS (NVP) – PUBLICATION OF RESPONSES TO CONSULTATION

Comments:			
Contact Officer:	<i>Dr Bridget Gilmour-Walsh</i>	<i>Principal Legal and Policy Adviser, Health Products Regulation Group</i>	Ph: (02) 6289 4290 M: S22
Clearance Officer:	<i>Adj Prof John Skerritt</i>	<i>Deputy Secretary, Health Products Regulation Group</i>	Ph: (02) 6289 4200 M: [Redacted]

Key Issues:

1. The TGA undertook to publish all appropriate responses received to the Consultation Paper—'Potential reforms to the regulation of nicotine vaping products' and proposes to publish the almost 4,000 submissions received in the week beginning 20 March 2023.
2. Each submission has been reviewed to ensure that it does not contain any material that is unsuitable for publication (such as personal information for which there is no consent to publish, and offensive or defamatory material). All submissions will be published other than a few that contained defamatory or offensive material.
3. The submissions will be published on the TGA website accompanied by our usual 'We asked, you said, we did' summary. The summary is set out in Attachment A. As the reform options are still under active consideration, we have limited the 'We did' part of the summary to a status update.

Background:

In November 2022, you approved the release of a public consultation paper on proposed reforms to the regulation of NVPs (MB22-001578). The consultation period began on 30 November 2022 and concluded on 16 January 2023.

The TGA briefed you on the results of the consultation and options for reform in MS23-900067 and MB23-000577.

To comply with obligations in the WHO Framework Convention on Tobacco Control to protect public health policies from the commercial and vested interests of the tobacco industry, submitters consented to their submissions being published, subject to the

removal of personal information on request. The TGA also reserved the right not to publish submissions containing defamatory or offensive removal or that were outside the scope of the consultation.

Attachment:

A. Potential reforms to the regulation of nicotine vaping products - Consultation summary

Attachment A

Potential reforms to the regulation of nicotine vaping products - Consultation summary**We asked**

We asked for feedback on potential reforms to the regulation of nicotine vaping products (NVPs) in Australia. Feedback was sought on:

- changes to border controls for NVPs
- pre-market TGA assessment of NVPs against minimum quality and safety standards
- minimum quality and safety standards for NVPs
- clarifying the status of NVPs as 'therapeutic goods'.

You said

We received almost 4,000 submissions in response to the consultation. The respondents were:

- State and Territory Health and Education Departments
- health professional bodies
- public health associations
- university researchers
- pharmaceutical industry and peak bodies
- vaping manufacturers/importers
- vaping retailers, including convenience stores and petrol stations
- pro-vaping associations
- individual healthcare professionals
- the general public, including individual vapers, smokers and ex-smokers.

A large number of the submissions from the general public appeared to be campaign responses that advocated changing the current regulatory framework in which NVPs are regulated as prescription medicines (which was outside the scope of the consultation).

Changes to border controls

- TGA's preferred option was to strengthen border controls by requiring importers to obtain an import permit and by closing off the personal importation scheme.
- All State and Territory governments supported tightening border controls for NVPs, with most also supporting closing the personal importation scheme and requiring import permits.
- Health professional bodies, public health associations, individual health professionals, university researchers and companies marketing prescription NVPs to Australian pharmacies overwhelmingly supported tightening border controls for NVPs.
- Many (but not all) of these groups also submitted that border controls should be placed on non-nicotine vaping products (which went further than the proposed option in the consultation paper).
- Individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations did not generally support any import controls.

Pre-market TGA Assessment of NVPs against a product standard

- TGA's preferred option was to require pre-market TGA assessment of NVPs against a product standard specifying certain quality and safety requirements.
- Companies supplying to the prescription pharmacy market supported this approach, as did about half of State and Territory governments, half of health professional bodies and nearly half of individual health professionals.
- Nearly half of public health associations and health professional bodies proposed instead that all NVPs be registered in the Australian Register of Therapeutic Goods and opposed pre-market assessment as they were concerned it could be misinterpreted as TGA approval.
- A large number of individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations supported at least some regulation to ensure NVP quality and safety (but with NVPs regulated as consumer goods, instead of as prescription medicines).

Strengthening quality standards for NVPs

- There was strong support for TGA's preferred option from State and Territory governments, health professional bodies, individual health professionals, public health associations and university researchers to strengthen Therapeutic Goods (Standard for Nicotine Vaping Products) (TGO 110) Order 2021 to introduce warning statements (although this was opposed by some), require pharmaceutical-like packaging, lower the maximum allowable nicotine concentrations, prohibit/restrict flavours and certain other ingredients and limit NVP volume and overall nicotine content.
- Many of these submissions also called for the imposition of similar controls on non-nicotine vaping products (this was outside the scope of the consultation).
- Many individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations proposed abandoning the prescription model and the TGO 110 (also outside the scope of the consultation), but nonetheless many in this category supported some regulation to ensure NVP quality and safety.
- There was significant support for banning disposable NVPs from all categories of submitters (including individual vapers), but some opposed this because of concerns a ban could affect accessibility for smoking cessation and because of the risks of using some alternative products.

Clarifying the status of NVPs as 'therapeutic goods'

There was general support for the proposal to clarify that all vaping products containing nicotine are therapeutic goods from all categories of submitters except individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations.

We did

The Government is actively considering the submissions and possible options for reform. No decisions have yet been made on preferred options.

Published responses

View submitted responses [insert hyperlink].

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Australian Government
Department of Health and Aged Care

Meeting Brief
MB23-001225
Version (1)
Date sent to MO: 14/04/2023

To: Minister Butler

Subject: TOBACCO AND E-CIGARETTE CONTROL ROUNDTABLE

Comments:			
Contact Officer:	s22	A/g Assistant Secretary Tobacco and E-cigarette Control Branch	Ph: s22 Mobile: s22
Clearance Officer:	Tiali Goodchild	Assistant Secretary Population Health Division	Ph: (02) 6289 7318 Mobile: s22

Date / Time: Monday 17 April 2023 / 2:30PM to 5:30PM
Some attendees may need to leave early to catch 7pm flights

Meeting Type/Location: In person / Parliament House Canberra, Reps Committee Room 1R1 (map at **Attachment A**)

Traditional Custodians: Ngunnawal and Ngambri people

Purpose: Public health stakeholder engagement on future direction and priority setting for tobacco control including e-cigarettes. (Agenda at **Attachment B**)

Desired Outcomes: Engage with key public health stakeholders on tobacco control and e-cigarette reform options and priorities.

Key Attendees/Speakers:	Title:	Organisation:
S22		Cancer Council Australia
		Australian Council on Smoking and Health
		Lung Foundation Australia
		Australian Council of Smoking and Health
		Monash Addiction Research Centre The Royal Australian and New Zealand College of Psychiatrist
		National Best Practice Unit for Tackling Indigenous Smoking
		VicHealth
		School of Public Health, University of Sydney
		National Centre for Epidemiology and Population Health, Australian National University
		Faculty of Health Sciences, Curtin University
		School of Public Health, University of Sydney
		National Centre for Epidemiology and Population Health, Australian National University
		Centre for Research Excellence on Achieving the Tobacco Endgame
		Alcohol and Drug Foundation
		Public Health Association of Australia
		Australian Medical Association
		Tobacco in Australia: Facts and Issues
Royal Australian College of General Practitioners		
Departmental Attendees		
<ul style="list-style-type: none"> • Tania Rishniw, Deputy Secretary, Primary and Community Care Group • Adjunct Professor John Skerritt, Deputy Secretary, Health Product Regulations Group • Celia Street, First Assistant Secretary, Population Health Division • Dr Bridget Gilmour-Walsh, Principal Legal and Policy Adviser, Therapeutic Goods Administration (TGA) • s22, A/g Assistant Secretary, Tobacco and E-Cigarette Control Branch (observer) • s22, A/g Assistant Director, Tobacco Control Policy Section (observer) 		

Brief biographies of attendees are at Attachment C

Minister's Talking Points

Agenda item 1: Opening remarks and focus of meeting

Tobacco Control

- s22 [REDACTED]
- s22 [REDACTED]
- I am aware there is concern among the tobacco control community that the increasing attention to e-cigarettes may detract focus from the ongoing harms that tobacco use poses to the community.

E-cigarettes

- Australian governments have taken a precautionary approach to the marketing and use of e-cigarettes in view of the risks these products pose to tobacco control and population health.
- The Therapeutic Goods Administration (TGA) prescription model aims to balance the option to use nicotine vaping products as a smoking cessation aid where clinically appropriate, with the need to ensure these products are not ending up in the hands of young people and people who do not smoke.
- E-cigarette regulation is shared between the Commonwealth, state and territory governments and draws on laws that apply to poisons, therapeutic goods, tobacco products, consumer goods and industrial chemicals.
- There is no Commonwealth legislation that specifically regulates non-nicotine e-cigarettes.

Focus of today's meeting

- Today, I am particularly keen to discuss the outcomes of the recent TGA consultations and hear your views about the next steps in regulation of e-cigarettes in Australia.
- Tobacco regulators worldwide continue to struggle with how best to respond to the growing presence of e-cigarettes, and a wide range of other new products, which are clearly designed and marketed to appeal to young people and addict a new generation of users to nicotine.
- Australia is the only jurisdiction to have a prescription model for e-cigarettes, so there's no international precedent.
- The regulatory arrangements applicable to e-cigarettes vary considerably within and across countries, ranging from prohibition to minimal or no regulation.
- This is our opportunity to create an international precedent on best practice, evidence-based approaches.

Agenda item 2: Outcomes of previous roundtable and Government progress

- In September 2022, many of you attended a roundtable meeting with me and shared your views on tobacco control and e-cigarettes.
- At that meeting, I heard that stakeholders were keen for the Government to finalise the National Tobacco Strategy, undertake a review of TGO110 regulation of Nicotine Vaping Products, and progress the tobacco control thematic review.
- Since that meeting, we have progressed these items.
- In February, all Health Ministers agreed to endorse the new National Tobacco Strategy 2023-2030.
- The new Strategy commits to 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.
- s22 [REDACTED]
- s22 [REDACTED]
- As you are aware the TGA recently undertook a public consultation on potential reforms to the regulation of nicotine vaping products, with almost 4,000 submissions received in response to this consultation, including from state and territory health departments and health professional bodies and health practitioners, as well as vaping retailers and importers and the public, including individual vapers, smokers, and ex-smokers.

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Agenda item 4: Nicotine Vaping Product regulation reform

- **Handling note:** Professor John Skerritt and Dr Bridget Gilmour-Walsh will lead this item providing a summary of what was learnt from the public consultation on potential reforms to the regulation of nicotine vaping products.

Agenda item 5: Options to protect Australians from e-cigarette harms

- The Government is considering the option that many of you supported of prohibiting access to all vaping products other than through approved TGA pathways.
- As we've just heard from Professor Skerritt, this might be implemented by:

- s47C(1) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

- The Government is carefully considering the potential impact of such an approach on product accessibility and doctors' heavy workloads.
- In terms of non-regulatory measures, the Government is also investing in further research and exploring approaches to public education campaigns.

- s47C(1) [Redacted]
 - [Redacted]
 - [Redacted]
 - educating pharmacists and others to support nicotine vaping products and smoking cessation more broadly

- s47C(1) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

Agenda item 6: Next Steps

- **Handling note:** you may wish to summarise action items prior to meeting close.

Proposed Objective and/or Desired Outcomes:

- Determine stakeholder views on regulatory options for vaping products and e-cigarettes.
- s47C(1) [REDACTED]
- The Government is supportive of work to strengthen regulations on e-cigarettes. This is consistent with the objectives outlined in the National Tobacco Strategy 2023-2030 including to prevent the uptake of e-cigarettes by young people, and to de-normalise and limit the marketing of e-cigarettes.

Sensitivities or Contentious Issues:

Roundtable stakeholders may raise the following concerns during the discussion:

- Stakeholders have expressed concern that the vaping epidemic has taken policy and regulatory focus away from tobacco control efforts, which must remain a priority.
- Regulatory reform for e-cigarettes has not achieved the desired outcome of restricting access to these products by children and young Australians.
- Stakeholders would welcome the release of the new National Tobacco Strategy 2023-2030 following its endorsement at the Health Ministers’ Meeting in February 2023. Some public health stakeholders may raise the need for dedicated funding to support implementation of the National Tobacco Strategy.
- Many of the invitees opposed the proposal in the TGA consultation paper for the TGA to conduct a pre-market assessment of nicotine vaping products against the TGA standard as they felt this was lowering standards for a TGA approval. s47C(1) [REDACTED]
- s47C(1) [REDACTED]
- [REDACTED]
- [REDACTED]
- s47C(1) [REDACTED]
- The Department commissioned the Centre for Behavioural Research in Cancer (CBRC), Cancer Council Victoria to provide more current data on smoking and vaping prevalence in Australia, using data collected by the Roy Morgan Research company. The data rely

on a smaller sample size than the national surveys conducted by ABS and AIHW. The study finds a marked increase in the six-monthly population prevalence of current vapers that began in the last 6 months of 2020 and continued throughout 2022. Smoking prevalence was fairly stable overall but, concerningly, increased between 2020 and 2022 among those aged under 25 years. The Department will prepare a brief on this report and seek your views on its publication.

Stakeholder Views on nicotine vaping products and e-cigarette regulatory reform options:

- **Strengthening border controls:** All state and territory governments, health professional bodies and associations, individual health professionals, university researchers and companies marketing prescription nicotine vaping products supported tightening border controls. Many of these groups also submitted that border controls should be placed on non- nicotine vaping products (although this was outside the scope of the TGA consultation). In contrast, individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping associations did not generally support any import controls.
- **Strengthening quality standards for nicotine vaping products:** There was strong support for these proposed regulatory changes from state and territory governments, health professional bodies and associations, individual health professionals, and university researchers. Many of these submissions also called for the imposition of similar controls on non- nicotine vaping products. Many individual vapers, vaping retailers, vaping manufacturers/importers, and pro-vaping bodies also supported some regulation to ensure nicotine vaping products quality and safety (albeit with nicotine vaping products regulated as consumer goods and not medicines).
- **Pre-market TGA assessment against a product safety and quality standard:** Companies supplying to the prescription pharmacy market supported this approach, as did about half of State and Territory governments, half of health professional bodies and nearly half of individual health professionals. Many individual vapers, vaping retailers, vaping manufacturers/importers and pro-vaping associations supported at least some regulation to ensure nicotine vaping products quality and safety (but with nicotine vaping products regulated as consumer goods, instead of as prescription medicines).
- **Ban on all disposable nicotine vaping products:** There was significant support for banning disposable nicotine vaping products from all categories of submitters (including individual vapers).

Consultation

- This meeting brief has been prepared by Population Health Division and Health Products Regulations Group, Regulatory Legal Services.

Attachments:

- A. Map
- B. Meeting agenda and key points
- C. Attendee biographies
- D. Summary of e-cigarette laws at state/territory level
- E. Principles that underpin the policy and regulatory approach to e-cigarettes
- F. Key figures: Smoking and e-cigarette use data

Background:*E-cigarette regulation in Australia*

- E-cigarette regulation is a shared responsibility between the Commonwealth, state and territory governments. The current regulatory framework draws on existing laws that apply to tobacco products, poisons, therapeutic goods, consumer goods and industrial chemicals.
- Australian governments have taken a precautionary approach to the marketing and use of e-cigarettes in view of the risks these products pose to tobacco control and population health. A summary of state and territory legislation relating to e-cigarettes is at **Attachment D**.
- All Australian governments have agreed to a set of principles that underpin the policy and regulatory approach to e-cigarettes (**Attachment E**). The principles emphasise that any change to the regulation of e-cigarettes in Australia should ensure protecting the health of children and young people as its primary focus and goal.
- The National Tobacco Strategy 2023-2030 includes measures to strengthen regulations for e-cigarettes, with the objective of preventing the uptake of e-cigarettes by young people, and to denormalise and limit the marketing of e-cigarettes. The Strategy provides a broad framework with suggested actions for implementation but does not commit any jurisdiction to a specific course of action.
- Nicotine vaping products are also regulated under the Commonwealth therapeutic goods framework as prescription medicines (the 'prescription model'), namely:
 - (a) the *Therapeutic Goods Act 1989* prohibits the import, manufacture and supply of therapeutic goods unless the goods are entered on the Australian Register of Therapeutic Goods or an exception to registration applies. There are no registered nicotine vaping products, but they can be lawfully imported, manufactured and supplied through established exceptions to registration;
 - (b) A person can obtain a nicotine vaping products domestically if they have a prescription from a doctor approved by the TGA under what is known as the Authorised Prescriber or Special Access Schemes. Commercial importers and manufacturers can import/manufacture where they reasonably believe products will be supplied under one of these approvals;
 - (c) A person can also import a limited quantity of nicotine vaping products for personal use with a prescription from any doctor, under what is known as the personal importation scheme;
 - (d) Nicotine vaping products must also meet some minimum safety and quality standards set out in Therapeutic Goods Order 110 (TGO 110) to be lawfully supplied under these mechanisms, including relating to nicotine concentration, packaging and ingredients.

Non-regulatory e-cigarette control measures

- Campaigns: The Department has commissioned Cancer Council Australia to undertake 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.
- Cessation services: The Government funds the National Quit Centre at Cancer Council Victoria to support national best practice approaches for nicotine cessation. The Quit Centre has been developed to upskill frontline health professionals to support their patients to quit tobacco and the use of e-cigarettes as part of their routine care.
- Research, monitoring and surveillance: The Department is monitoring evidence on the marketing, use and health impacts of e-cigarettes, including among young people.
 - Cancer Council NSW has been commissioned to expand their Generation Vape study to better understand perceptions, attitudes, related knowledge and behaviours of e-cigarette and tobacco use among young people nationally.
 - The Department participates in an e-cigarette monitoring consortium led by s22. The consortium consists of experts in tobacco and e-cigarettes from health, policy and research sectors. The purpose of this group is to generate ideas for e-cigarette monitoring and maximise evidence for decision making.

E-cigarette use in Australia

- In 2019, 2.5% of Australians aged 14+ reported current e-cigarette use (daily, weekly, monthly, or <monthly).
 - between 2016 and 2019, the rate of people aged 18-24 who reported using e-cigarettes nearly doubled, from 2.8% in 2016 to 5.3% in 2019.¹
- Findings from a Cancer Council Victoria report show that in 2022 in Australia:
 - 7.7% of people aged 14+ currently used e-cigarettes.
 - 18-24 year olds reported the highest prevalence of e-cigarette use (25.1%), followed by 14-17 year olds (15.8%), the 50+ years age group reported lowest prevalence (1.4%).²
- Note: These surveys did not distinguish between use of nicotine and non-nicotine e-cigarettes.
- Further detail on smoking and e-cigarette use data is at **Attachment F**.

¹ AIHW, 'National Drug Strategy Household Survey, 2019'

² Cancer Council Victoria, 'Current vaping and current smoking in the Australian population aged 14+ years: February 2018-September 2022'. Prepared for the Department of Health and Aged Care. January 2023

MBS items for smoking and nicotine cessation

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- MBS items that may be claimed for nicotine cessation consultations, be they general or specific, may be suitable for tobacco smoking and e-cigarettes. The relevance of nicotine counselling and suitability of nicotine cessation therapies in the context of any consultation are at the clinical discretion of providers.

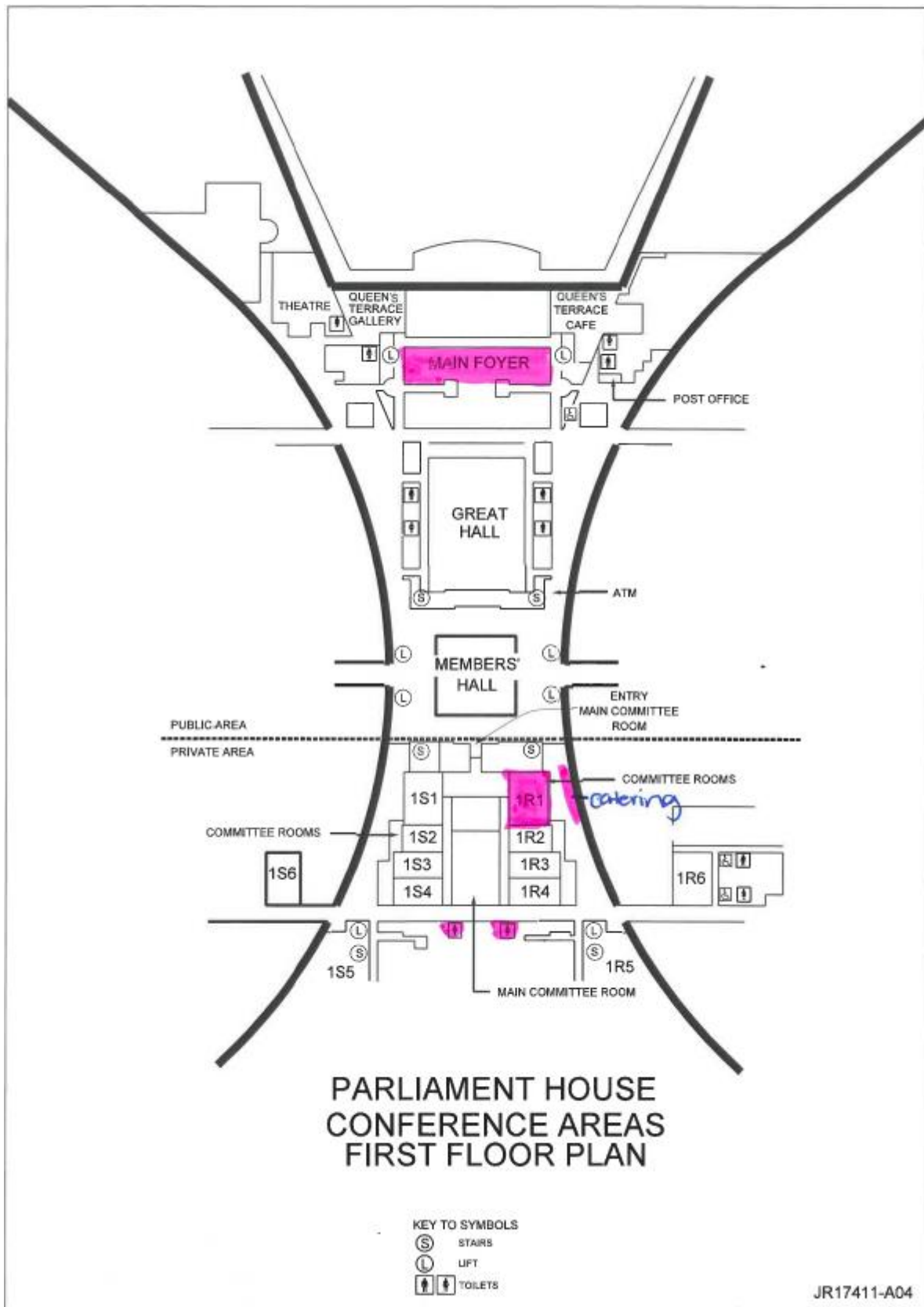
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Minister	Minister Butler
PDR Number	MB23-001225
Subject	Tobacco and E-Cigarette Roundtable 17 April 2023
Contact Officer	s22 [REDACTED] Ph: s22 [REDACTED] Mobile: s22 [REDACTED]
Clearance Officer	Celia Street Ph: (02) 6289 3694 Mobile: s22 [REDACTED]
Division/Branch	Population Health Division / Tobacco and E-cigarette Control Branch

Adviser/DLO comments:	Returned to Dept for: REDRAFT <input type="checkbox"/> NFA <input type="checkbox"/>
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Attachment A – Map



ATTACHMENT B – Agenda and key points**Date:** 17 April 2023**Time:** 2:30PM to 5:30PM AEST**Location:** Parliament House Canberra**Meeting Chair:** The Hon Mark Butler MP

No	Item	Time	Lead	Key points (Internal use only)
1.	Welcome/ Acknowledgement of Country / Introduction/ Format and Objectives	2:30pm to 2:40pm (10 -20 mins)	Minister Butler	<ul style="list-style-type: none"> - Outline purpose of meeting: to engage with public health stakeholders on e-cigarettes with a focus on potential reform priorities. - Outline structure of meeting and note that a summary of outcomes will be prepared after the meeting. - Opening remarks from Minister.
2.	Outcomes of previous roundtable	2:40pm – 2:50pm (10 mins)	Minister Butler	<ul style="list-style-type: none"> - Summary of outcomes from September 2022 roundtable - Brief overview of what has been done since then

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No	Item	Time	Lead	Key points (Internal use only)
4.	Nicotine Vaping Product (NVP) Regulation Reform	3:10pm – 4:10pm (60 mins)	Therapeutic Goods Administration (John Skerritt/ Bridget Gilmour-Walsh)	<ul style="list-style-type: none"> - Outcomes from TGA consultation - Introduce reform options - Invite discussion on proposed way forward to regulate vapes - Invite discussion on proposed ways to manage transition
Break (15-20 min)				
5.	Options to protect people from e-cigarette harms	4:30pm – 5:20pm (50 mins)	Minister	<ul style="list-style-type: none"> - Invite discussion on regulatory and non-regulatory options - Invite discussion on cessation support required for different populations - Invite discussion on appropriate approaches to campaign options
6.	Next Steps	5:20pm – 5:30pm (10 mins)	Minister	<ul style="list-style-type: none"> - Closing remarks from Minister - Outline next steps and close meeting

Role	Attendees
Public health stakeholders (18)	<p>§22</p> <p>[Redacted]</p> <p>[Redacted]</p> <p>[Redacted]</p>

	§22 [Redacted]
Meeting Chair	Minister for Health and Aged Care, The Hon Mark Butler MP

ATTACHMENT C – Attendee biographies

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ATTACHMENT D – Summary of e-cigarette laws at state/territory level

Summary of e-cigarette laws at state/territory level¹

Nicotine is included in the Poisons Standard as a Schedule 4 medicine and is regulated in State and Territory legislation such that the supply, including wholesale supply, is controlled as a medicine. For example, in NSW nicotine is regulated as a medicine under the *Poisons and Therapeutic Goods Act 1966* and its Regulation. In addition to the controls under medicines and poisons legislation, the following legislation applies.

<p>Australian Capital Territory</p> <p>In the ACT, the sale of electronic cigarettes that do not contain nicotine is currently allowed provided the business holds a tobacco licence and the person purchasing the product is over 18 years of age. The advertising, display, and marketing of products are strictly regulated. Use of e-cigarettes (whether or not they contain nicotine) is banned in smokefree areas, at smokefree public events and at all underage functions.</p>
<p>Western Australia</p> <p>In Western Australia, products that resemble tobacco products, including vaping devices with or without nicotine, cannot be sold by tobacco or general retailers. However, registered pharmacists may supply a vaping device designed and intended for delivery of prescribed nicotine vaping products, as part of a medically supervised smoking cessation program.</p>
<p>New South Wales</p> <p>In NSW, the <i>Public Health (Tobacco) Act 2008</i> prohibits the sale or supply of e-cigarettes and accessories to minors; restricts vending machine locations for e-cigarettes; and provides NSW police with powers to seize e-cigarettes from minors. It also restricts the display of e-cigarettes and accessories and bans the use of electronic cigarettes in cars carrying children. The <i>Smoke-free Environment Act 2000</i> prohibits the use of e-cigarettes in smoke-free areas.</p>
<p>Queensland</p> <p>Queensland's <i>Tobacco and Other Smoking Products Act 1998</i> applies to e-cigarettes (referred to in the Act as personal vaporisers). These products may not be sold to minors, used in smoke-free areas, or advertised, promoted or displayed at retail outlets.</p> <p>On 12 March 2023, QLD Government announced a Parliamentary Inquiry to investigate the availability and prevalence of vaping devices, and the health risks associated with e-cigarettes. The Parliament's Health and Environment Committee will be directed to carry out the Inquiry which will also look at current measures being undertaken in schools to discourage vapers</p>
<p>South Australia</p> <p>The <i>Tobacco and E-Cigarette Products Act 1997 (SA)</i> prohibits the sale or supply of e-cigarettes to minors, the retail sale of e-cigarettes without a licence, the use of e-cigarettes in legislated smoke-free areas and the sale of e-cigarettes from temporary outlets and vending machines. In addition, retail advertising for e-cigarettes is regulated in a similar way to retail advertising for tobacco products. The sale of e-cigarettes by indirect orders (including internet sales) is also prohibited.</p> <p>In April 2023, The SA Government announced a proposal to extend smoke-free and vape-free laws to more public places such as near schools, shopping centres, beaches, building and sporting grounds.</p>
<p>Tasmania</p> <p>The <i>Public Health Act 1997 (TAS)</i> prohibits the sale of e-cigarettes to minors, the use of e-cigarettes in legislated smoke-free areas, the sale of e-cigarettes without a licence and the sale of e-cigarettes in specialist tobacconist stores. In addition, retail advertising of e-cigarettes is regulated in much the same way as for tobacco products.</p>

¹ Internal report for NSW Health 2022, 'Electronic Nicotine and Non-Nicotine Delivery Systems Policy Options', prepared by A/Prof B Freeman, University of Sydney.

Victoria

The *Tobacco Act 1987* (Vic) bans the sale of e-cigarettes to minors, the sale of e-cigarettes from vending machines, and the use of any e-cigarettes in legislated smoke-free areas. It also restricts the advertising and promotion of e-cigarette products in retail stores.

Northern Territory

The *Tobacco Control Act 2002* (NT) regulates the availability and promotion of e-cigarettes that do not contain nicotine. The sale of these products without a licence, and to or by minors, is prohibited, and they may not be used in smoke-free areas. Retail advertising and promotion are regulated in the same way as for tobacco products.

Attachment E - Principles that underpin the policy and regulatory approach to e-cigarettes

Policy and regulatory approach to electronic cigarettes (e-cigarettes) in Australia

Principles that underpin the current policy and regulatory approach:

Protecting the health of children and young people

The evidence is clear that e-cigarettes in Australia are increasingly marketed to appeal to children and young Australians.

The widespread marketing and use of e-cigarettes cause harms to the health of children and young people, including:

- e-cigarettes can provide a gateway/pathway to a lifetime of nicotine addiction and dependency;
- e-cigarettes can lead to an increased uptake of smoking among young people;
- e-cigarettes cause direct harms to users from inhalation of a range of chemicals;
- e-cigarettes also provide health risks to bystanders from exposure to exhaled aerosol from e-cigarette users; and
- the liquid nicotine in e-cigarettes is a poison and children and adults can be harmed by swallowing, breathing or absorbing e-cigarette liquid.

Australia's successful approach to tobacco control over many decades has seen substantial declines in tobacco use among young Australians, with current tobacco use among secondary school students aged 12-15 declining from 17% in 1996 to 3% in 2017. E-cigarettes expose a new generation of young Australians to an unacceptable risk to their current and future health.

Any change to regulation of e-cigarettes in Australia will have protecting children and young people as its primary focus and goal.

Protecting the health of current adult cigarette smokers

E-cigarettes have been marketed by the e-cigarette and tobacco industries to existing smokers as both a smoking cessation tool and as a less harmful alternative to cigarettes and tobacco smoking.

This marketing has been effective as surveys of adult cigarette smokers indicate quitting or reducing smoking as reasons for using e-cigarettes. However, at the population level there is no strong evidence that e-cigarettes assist smoking cessation and some evidence suggests the opposite effect: that overall they may be depressing smoking cessation.

E-cigarettes pose a range of harms to human health. Many e-cigarettes contain nicotine at higher concentrations than in cigarettes so may contribute to increasing rather than decreasing nicotine dependence. No studies have yet demonstrated the safety of e-cigarettes or efficacy of e-cigarettes as an effective smoking cessation tool at a population level. Governments continue to support a range of measures and services to help people quit smoking.

Any change to regulation of e-cigarettes in Australia will place protecting the health of existing adult cigarette smokers as its second key goal.

Evidence-based

The current evidence base supports maintaining and, where appropriate, strengthening the current controls that apply to the marketing and use of e-cigarettes in Australia.

MB23-001225 Attachments

Decisions should take into account the conclusions reached by credible health and scientific agencies in relation to the interpretation and advice about that evidence, including for example the WHO, the NHMRC and the US Surgeon General.²

A notable example is the Therapeutic Goods Administration's (TGA's) scheduling legislation and underlying decision making processes which are informed by relevant evidence and provide a robust mechanism to balance potential risks and benefits of substances such as nicotine for use in e-cigarettes.

The [TGA's consideration and final decision](#) on an application to allow nicotine for use in e-cigarettes to be commercially sold in Australia during 2016 and early 2017, provides a valuable analysis to guide action (Scheduling delegate's final decisions, March 2017).

Health claims for e-cigarettes, such as that they are effective smoking cessation aids or safe alternatives to conventional tobacco products, should be rejected by health authorities in the absence of robust supporting scientific evidence to substantiate these claims.

Relevant to Australia's national circumstances

The appropriate policy and regulatory response to e-cigarettes should take into account Australia's national circumstances, including in the context of the existing approaches taken by the Australian and state and territory governments to reduce tobacco smoking prevalence and its associated harms and costs. Australia's favourable progress in tobacco control to date is also an important factor.

Current and future approaches taken by other countries to e-cigarettes are relevant to the formulation of potential national policy and regulatory responses to these products. At present, there is no international consensus on the most appropriate policy response or regulatory framework for e-cigarettes. Current and planned regulatory approaches vary considerably and across countries, ranging from treatment as tobacco products, poisons, medicines (including medical devices), and consumer products. Additionally, in some countries, the sale of e-cigarettes is prohibited, while in many developing countries, it is likely that minimal or no regulatory controls apply.

Precautionary approach

This acknowledges the potential risks associated with the marketing and use of e-cigarettes.

The precautionary approach encourages action to prevent harm when there is scientific uncertainty and until a body of evidence establishes the requirement for alternative regulation. This includes the lack of conclusive evidence around the safety risks posed to users by the unknown inhalation toxicity of nicotine and other chemicals used with e-cigarettes, passive exposure to e-cigarette vapour, risks associated with child poisoning, and issues around quality control and efficacy.

The precautionary approach also takes into account the broader risks that e-cigarettes may pose to population health, namely their potential to disrupt the decline in tobacco use in Australia.

² In November 2016, the seventh session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control (WHO FCTC) invited Parties to consider applying regulatory measures to 'prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives'. Read the statement about [Electronic nicotine delivery systems and electronic non-nicotine delivery systems](#) on WHO's website.

Protecting public health gains

While there have been significant gains made in reducing smoking rates and reducing exposure to tobacco smoke and smoking culture in Australia, an increase in e-cigarette marketing and use may undermine tobacco control success by establishing new cohorts with nicotine dependence, renormalising smoking, encouraging dual use of tobacco and e-cigarettes, and discouraging quitting.

Policy and regulatory decisions on e-cigarettes should aim to minimise the proliferation of e-cigarette marketing and use, particularly among young people while maximising the impact of effective tobacco control measures.

Policy and regulation for e-cigarettes should aim to protect public health gains in relation to smoking prevalence as well as smoke-free culture, including smoke-free areas and other measures that have contributed to the continued denormalisation of smoking in Australia.

Protecting public health policy from all commercial and other vested interests related to e-cigarettes, including interests of the tobacco industry

This acknowledges Australia's obligations under [Article 5.3 of the WHO Framework Convention on Tobacco Control \(FCTC\)](#), to which Australia is a party. Under Article 5.3 of the WHO FCTC, parties are obliged to act to protect their public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry, in accordance with national law.

Legal clarity to the public

Information from a range of sources highlights that there may be some confusion to users, retailers, employers and the general public about the legality of e-cigarettes and/or nicotine, especially in terms of the regulations that apply to their importation, marketing (including sale) and use.

It is important that Governments provide clarity to the public about their legal obligations in relation to these products.

The commercial supply of nicotine for use in e-cigarettes is prohibited under all state and territory poisons legislation.

Complementary with jurisdictional regulation and existing health and social policy frameworks

National policy and regulation of e-cigarettes and nicotine should aim to complement jurisdictional legislation, to the greatest degree possible.

It is also important that any action taken at a national or jurisdictional level for e-cigarettes and nicotine supports existing health and social policy frameworks. These include but are not limited to the [WHO FCTC](#) (and also including recent decisions of the Conference of the Parties to the WHO FCTC as noted above) the [National Drug Strategy 2017–2026](#), the [National Tobacco Strategy 2012-2018](#) and the [Scheduling Policy Framework](#).

Attachment F - Key Statistics: Smoking and E-cigarette use**Smoking prevalence data**National daily smoking prevalence

Age data	2017-18 NHS	2019 NDSHS	2021-22 Smoker status	2022 CBRC
14 years +	-	11.0%	-	11.9%
15 years +	13.3%	-	-	
18 years +	13.8%	11.6%	10.1%	

Smoker Status Australia 2021-22 (includes National Health Survey)

National Drug Strategy Household Survey

Centre for Behavioural Research in Cancer, Roy Morgan Research “Single Source” survey

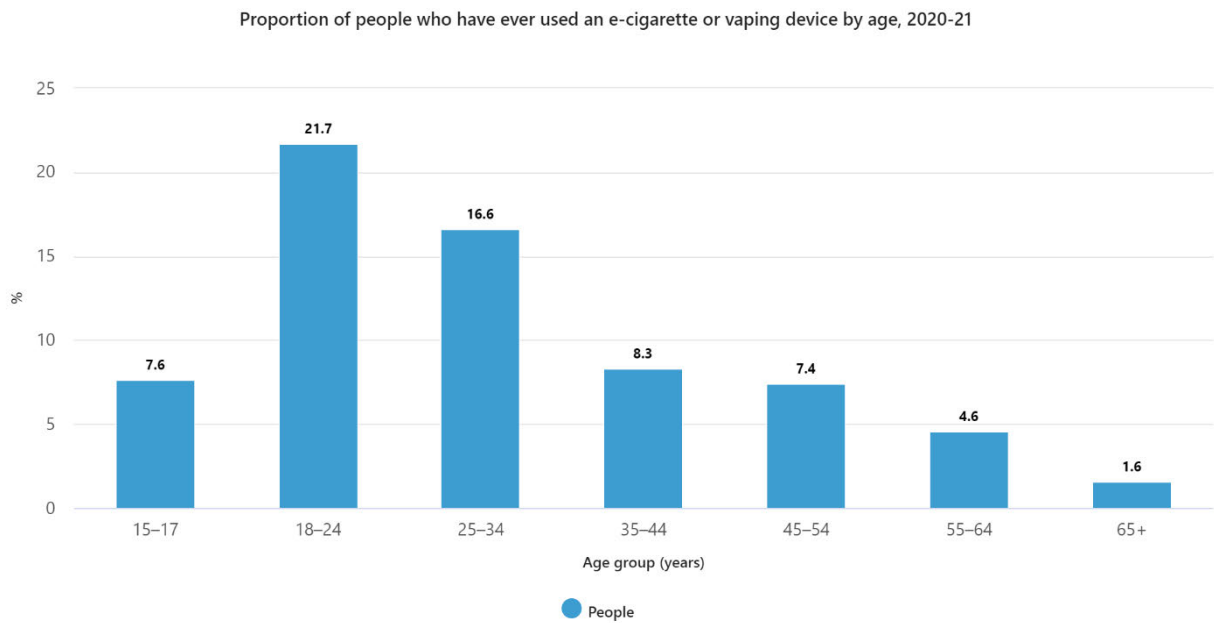
Smoking prevalence among priority populations

- **First Nations** - the proportion of First Nations people aged 15 years and over using tobacco has decreased from 41% in 2012–13 to 37% in 2018–19
- **Regional and remote** - Between 2011–12 and 2017–18, daily smoking prevalence among adults aged 18 years and over declined from 14.7% to 12.7% among those living in major cities, from 18.5% to 15.4% among those living in inner regional Australia, and from 22.4% to 19% in outer regional and remote areas
- **Social disadvantage** - In 2015, people living in the most disadvantaged socioeconomic areas experienced 2.6 times the rate of tobacco attributable death and disease compared to those living in the highest socioeconomic areas. As levels of social disadvantage accumulate, smoking prevalence increases. For example, in 2019, Australians living in the most disadvantaged socioeconomic areas were 3.7 times more likely than those in the most advantaged socioeconomic areas to smoke daily
- **Pregnant women** - In 2020, 9.2% of pregnant women who gave birth smoked at any time in their pregnancy, a decline from 14.6% in 2009
- **Mental illness** – In 2019, Australian adults who reported having been diagnosed or treated for mental illness in the past year were almost twice as likely to be a current smoker than those who had not been diagnosed or treated in the past year
- **Young people** – While smoking prevalence has remained relatively low among younger age groups in recent years, the CBRC report indicates a slight upwards trend in smoking prevalence among 18-24 year olds from 2019 to 2022. In 2022, dual use of smoking and vaping was also more common among 18-24 year olds (7.9%) compared to any other age group (range 0.7% to 4.6%).

E-cigarette use

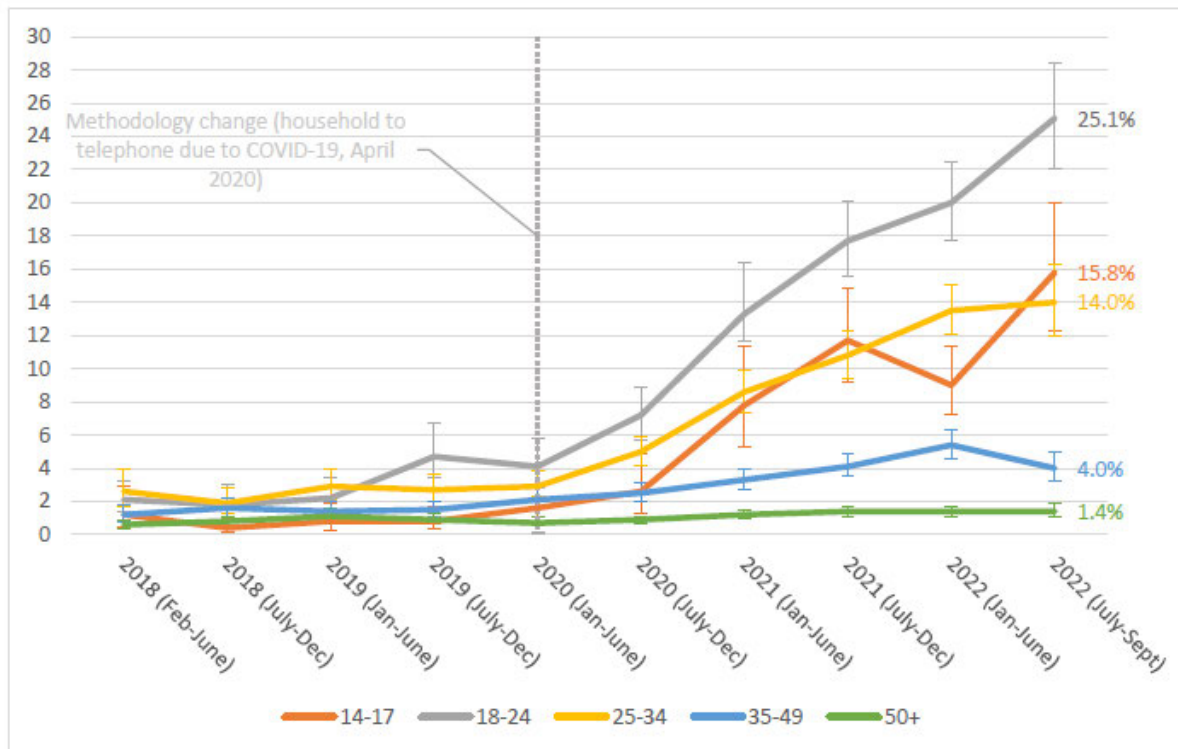
	2016 NDSHS	2019 NDSHS	2020-21 NHS	2022 CBRC
Lifetime use aged 14+	8.8%	11.3%		
Current use aged 14+	1.2%	2.5%		7.7%
Lifetime use aged 18+			9.3%	
Lifetime use 18-24 yrs	19.2%	26%		
Current use 18-24yrs			4.8%	25.1%

Use of e-cigarettes by age group



Source: Australian Bureau of Statistics, Smoking 2020-21 financial year

Figure 1. Proportion of people who have ever used an e-cigarette by age, 2020-21



Current vaping: used e-cigarettes in the past month. Error bars represent 95% confidence intervals around survey estimates.

Source: Centre for Behavioural Research, Cancer Council Victoria, Current vaping and current smoking in the Australian population aged 14+ years: February 2018-September 2022

Figure 2. Six-monthly prevalence of current vaping by age group 2018 to 2022 (weighted %)

Data sources

- The two key surveys that monitor smoking prevalence in the general population are the [ABS National Health Survey \(NHS\)](#) and the [AIHW National Drug Strategy Household Survey \(NDSHS\)](#).
- Both surveys provide a good snapshot of the smoking prevalence and characteristics of smokers at a point in time.
- The two surveys employ different methodology and therefore the results should not be directly compared to between different surveys.
- The Department commissioned the [Centre for Behavioural Research in Cancer \(CBRC\), Cancer Council Victoria](#) to provide more current data on smoking and vaping prevalence in Australia. This data has been collected by the Roy Morgan Research company with a monthly survey of Australians aged over 14 years old, and is a smaller sample size than the national surveys conducted by ABS and AIHW.
- Data on priority populations is collected from a range of different surveys.