Vaping Reforms – Implementation and Challenges

Chris Bedford
First Assistant Secretary
Regulatory Practice and Support Division
Department of Health, Disability and Ageing, TGA

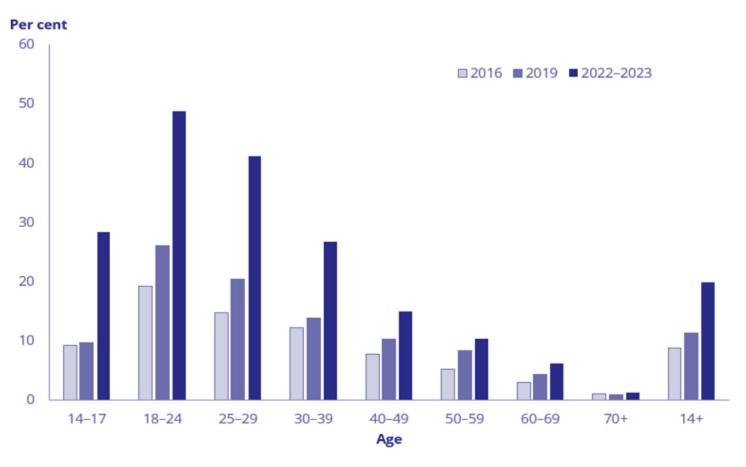
Session overview

- 1 Prevalence of vaping
- 2 Lead up and implementation of the reforms
- 3 Product standards and patient access
- 4 Enforcement and compliance
- 5 Engagement with the sector
- 6 Cessation support
- 7 Impact and next steps



Rise of vaping since 2016

Lifetime use of e-cigarettes by age, 2016 to 2022-23



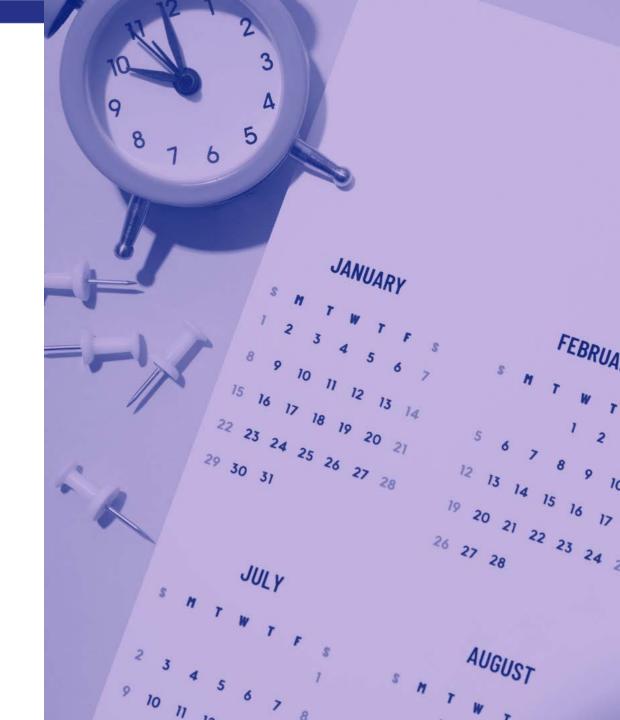
Source: National Drug Strategy Household Survey 2022–2023, AIHW

Cancer Council NSW Study

Adolescents who have vaped are **5 times** more likely to experiment with smoking

Lead up to the reforms

- The TGA has regulated vapes containing nicotine as a prescription medicine since 2021.
- **87%** of tested samples of vaping products contained undeclared nicotine.
- In 2023, the Minister for Health and Aged Care announced a commitment to introduce reforms to strengthen the regulation of vapes.
- In 2023 and 2024, the TGA worked closely with stakeholders to strengthen the regulation and enforcement of vaping products.



Timeline

Minister Butler's announcement of proposal to strengthen the regulation and enforcement of vapes.

Importation of all other vaping products was restricted and stronger controls on manufacturing introduced

Downscheduling of therapeutic vapes with a nicotine concentration of 20mg/ml or less. Only
therapeutic
vapes that
meet the
updated
product
standards can
be lawfully
supplied in
Australia.

2 May 2023 1 Jan 2024 1 March 2024 1 Jul 2024 1 Oct 2024 2 Mar 2025

1 Jul 2025

Importation ban on nontherapeutic vapes

Commencement
of the
Therapeutic
Goods and Other
Legislation
Amendment
(Vaping Reforms)
Act 2024 (Cth).

Only therapeutic vapes that meet the updated product standards can be imported into or manufactured in Australia.

Product standards and patient access

Key consideration of the reforms

- Preserving legitimate patient access to therapeutic vapes
- Ensuring product safety standards

Starting 1 July 2025: Strengthened product standards for therapeutic vapes

Introduction of product standards for therapeutic vapes and a sponsor notification compliance system



Labelling requirements



Packaging requirements



Flavour restrictions



Ingredient restrictions

Enforcement and compliance

From 1 January 2024 to 2 May 2025

- We participated in 28 significant joint enforcement operations with state and territory agencies across Australia.
- We issued 78 infringement notices, totalling \$1,326,552, in relation to unlawful activity regarding vaping goods.
- We requested the removal of over 8,600 unlawful advertisements for vaping goods from various digital platforms and blocked 271 websites.

TGA Therapeutic Goods Administration – tga.gov.au

TGA officers executing a warrant in Queensland, 2024

TGA organised for 900k vaping goods to be collected and removed under the Business Surrender Scheme

The Australian Government's Business Surrender Scheme was a time-limited scheme that allowed eligible businesses to surrender vaping goods to the TGA that would otherwise become unlawful to supply from 1 July 2024.

Legislation and process

The Scheme was legislated under the *Therapeutic Goods (Lawful Possession and Supply of Vaping Goods) Determination 2024.*

Businesses were required to notify the TGA of their intent to participate in the Scheme before 1 September 2024.

Approximately 900,000 vaping goods have been collected from businesses and removed from the community.



Surrendered goods collected by the Scheme's logistics provider.

Disposal of vapes

- Disposal of vapes is an internationally recognised challenge.
- Vapes have lithium batteries which are difficult to dispose of.
- There are different rules and regulations across Australia.
- Methods vary and can include separation, recycling and incineration.

What is being done to address this issue?

- A national panel of experts in transport, storage and disposal.
- Research on cost effective and environmentally sustainable methods to dispose of vaping goods.
- A community-based collection process for consumers.

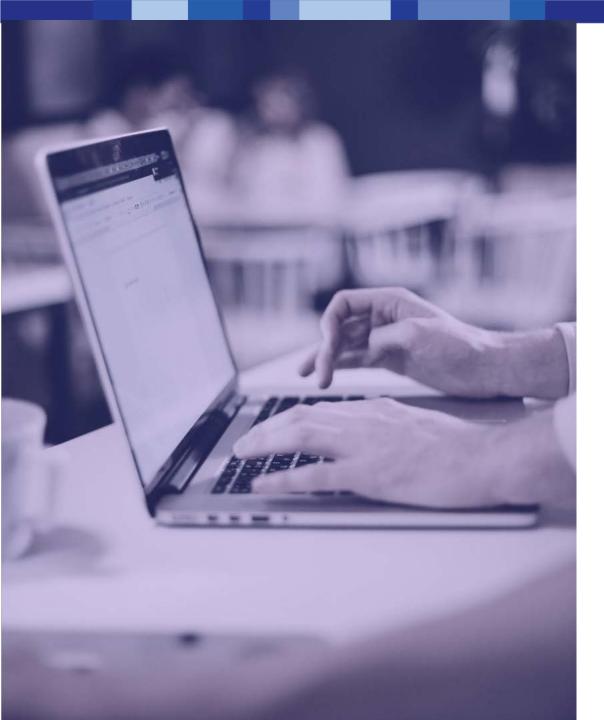


Support to the sector

Information and education for health professionals

- The Pharmaceutical Society of Australia updated <u>clinical</u> <u>guidelines</u> and provides ongoing education and information resources for pharmacists.
- The Royal Australian College of General Practitioners updated <u>guidance</u> on smoking and vaping cessation
- The National Best Practice Support Service for Nicotine and Smoking Cessation (the Quit Centre) provides training, information and resources for health professionals to help their patients to quit smoking and vaping.





Support to the sector

Engagement by the TGA

- Engaging with health professionals to ensure they are fully informed of the regulatory changes.
- Updating the sector on the reforms to support adoption across the supply chain.
- Providing the latest news on laws and regulations for stakeholders, sponsors, and consumers on the TGA's Vaping Hub website.

Cessation support initiatives

Cessation support

The Australian Government has committed a multi-year investment to discourage people from taking up smoking or vaping, and to support people to quit.

Funding

\$36.7 million from 21-22 to 27-28 for cessation programs and guidance

\$78.7 million from 23-24 to 27-28 for awareness campaigns

\$9.7 million from 24-25 to 27-28 for prevention programs

Public Health Campaigns and Prevention

- Launch of the Youth Vaping Campaign to discourage young people from vaping.
- Refresh of the National Tobacco Campaign, focusing on priority and at-risk groups.
 - This campaign will be expanded to include additional messaging on illicit tobacco.
- Investment into OurFutures a vaping prevention education program for Year 7 and 8 students.

Cessation supports for consumers

- Establishment of a national cessation platform at quit.org.au for easy digital access to information on quitting.
- Redevelopment and modernisation of the My QuitBuddy app.
- Scaling up state and territory Quitline and other quit services to meet increased demand.

Impact of the reforms

Early positive signals

 Recent Generation Vape research indicates an increased awareness of the harms of vaping among adolescents, parents and teachers is contributing to reduced vaping.

• **Decrease in vaping rates**: 85.7% of adolescents report they have never vaped.

- Decrease in smoking rates: 93.9% of adolescents report they have never smoked.
- **Increased awareness**: 87% of adolescents recognise the potential for addiction.

Key learnings and looking ahead

What's worked

- Need for a well-coordinated approach
- Working closely with states and territories and the ABF
- Commitment to ongoing compliance and enforcement activities
- Comprehensive sector engagement and education to support compliance

What's next

- Responding to new and emerging nicotine products in an agile environment
- Monitoring and assessing progress
- Implementation of \$92.6 million commitment to extend regulatory, compliance and enforcement action to address the illicit trade of vaping products



Therapeutic Goods Administration (TGA)

Exhibition booth No.60

Want to chat with me further? Come visit us.







Australian Government

Department of Health, Disability and Ageing

Therapeutic Goods Administration