

# Understanding what the vaping reforms mean for GPs



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# Acknowledgement of Country

I acknowledge the traditional custodians of this land and pay my respects to the Elders both past, present and emerging.

I acknowledge and respect their continuing culture and the contribution they make to the life of this city and this region.

I also acknowledge and pay my respects to our Aboriginal and Torres Strait Islander people joining us today.



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**Department of Health and Aged Care**

Therapeutic Goods Administration

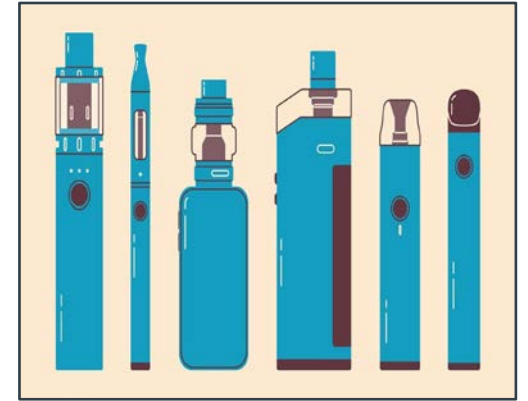
# What we'll cover today

- What are vapes?
- How are vapes regulated?
- Reforms to the regulation of vapes
- Prescribing therapeutic vapes
- Frequently asked questions
- Focus is on nicotine vapes and vapes for smoking cessation or the management of nicotine addiction – not cannabis vapes



# What are vapes?

- Vapes are products designed or intended to vaporise and administer the e-liquid component by inhalation, using electronic means, in a manner that replicates, or produces an experience similar to, smoking.
- Vapes generally comprise a **vaping substance** (e.g. e-liquid) and a **device** (including device components):



## Vaping substance

- May or may not contain nicotine
- May be present in pods, cartridges or refillable liquids

## Vaping device (inc. device components)

- A device designed to generate or release, by electronic means, an aerosol or vapour (i.e. mist or emission) for inhalation
- Can be a disposable or refillable system
- Refillable systems include, pods, cartridges and refillable chambers



# Regulation under the Therapeutic Goods Act 1989

- Nicotine vaping substances, and zero-nicotine vaping substances for which therapeutic claims are made, are regulated as medicines under the *Therapeutic Goods Act 1989* (the TG Act).
- Vaping devices are regulated as medical devices under the TG Act where they are for therapeutic use.
- Generally, therapeutic goods must be included on the ARTG to be introduced to the Australian market.
- There are currently no therapeutic vapes for smoking cessation or the management of nicotine dependence included in the ARTG.
- Therapeutic goods that are not included in the ARTG are known as unregistered or 'unapproved' goods.
- There are established pathways for consumers to lawfully access unapproved goods.



# Requirements for unapproved therapeutic goods

- The *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110) sets out minimum safety and quality requirements for unapproved therapeutic vapes that are imported into or supplied in Australia.
- For example: prohibited ingredients, maximum nicotine concentration, packaging, permissible flavours etc.
- Importers and domestic manufacturers are required to submit pre-market notifications to the TGA declaring compliance with the relevant product standards (TGO 110), prior to the import or supply of those goods.
- Other product standards apply to vaping devices.



# State and territory requirements

- The supply of vapes is partially regulated under state and territory legislation.
- Vapes that contain nicotine are Schedule 4 medicines.
- State and territory medicines and poisons laws require a valid prescription before a pharmacist can supply an unapproved therapeutic vaping substance containing nicotine to a patient.
- State and territory laws also regulate vapes under tobacco laws.



# Vaping landscape

- The marketing and use of vapes has rapidly increased in Australia and internationally over the past few years, particularly among young people.
- Recent data shows that among people aged 14 years and over, current use of vaping goods nearly tripled between 2019 (2.5%) and 2022–2023 (7.0%).
- The increase was even more marked among young people, with current use of vaping goods increasing from 5.3% to 21% among people aged 18 - 24, and from 1.8% to 9.7% among people aged 14 -17.
- This growth in vaping and the unknown quality and safety of vapes represent an unacceptable population health risk, particularly in light of the unfortunate lessons we have learnt from tobacco use.
- Vape use is associated with a number of health risks, including nicotine addiction and the long-term risks are still emerging.





# Reforms to the regulation of vapes

“Vaping was sold to governments and communities around the world as a therapeutic product to help long-term smokers quit. It was not sold as a recreational product - especially not one targeted to our kids but that is what it has become.”

The Hon Mark Butler MP, Minister for Health and Aged Care  
2 May 2023



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# Reforms to the regulation of vapes

- The Australian Government announced reforms, being implemented in three stages, to progressively restrict access to vapes within Australia, unless they are non-disposable therapeutic vapes that comply with the *Therapeutic Goods Act 1989*.
- The reforms are needed to address the harms of all vapes, to close regulatory loopholes that frustrate current compliance efforts, to heighten the quality of therapeutic vapes and make vapes less attractive to young people.
- Prior to these reforms, therapeutic vapes containing nicotine could only be legally purchased from pharmacies or through the Personal Importation Scheme by a patient with a valid prescription.
- However, zero-nicotine vapes and vaping devices were subject to limited regulation and could be legally sold by non-pharmacy retailers to people without a prescription. This created opportunities for retailers to circumvent the rules. Highly attractive and addictive products – often marketed towards young people – remained readily available.
- Once the changes are complete, tobacconists, vape shops and convenience stores will no longer be able to lawfully sell any type of vape, and the Personal Importation Scheme for vapes has ceased.



*"These changes will protect Australians, particularly young people, from the harms of vaping and nicotine dependence, while ensuring those with a legitimate need to access therapeutic vapes can continue to do so, where clinically appropriate."*

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



# Reforms to the regulation of vapes (cont'd)

## Stage 1

- Regulations beginning on 1 January 2024 (and 1 March 2024) has resulted in:
  - a ban on the import of disposable and non-therapeutic vapes.
  - preventing the importation of therapeutic vapes without an import licence and permit.
  - closure of the Personal Importation Scheme, which previously allowed individuals to import nicotine vapes for personal use with a prescription.
  - introduction of a pre-market notification process for therapeutic vapes – importers and manufacturers must notify the TGA that products meet the minimum standards.
  - strengthening of product standards for therapeutic non-nicotine vapes and devices imported or manufactured from 1 March 2024.
  - restrictions on flavours to mint, menthol and tobacco.



# Reforms to the regulation of vapes

## Stage 2 - Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024

- The next stage of reforms is subject to the passing of the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Bill 2024*.
- Under this Bill:
  - therapeutic vapes that meet TGA requirements will remain available – a prescription will continue to be required for nicotine vapes.
  - the domestic manufacture, supply, and commercial possession of all non-therapeutic vapes and disposable single use vapes will be banned.
  - most advertising of vapes will be prohibited – the intention is that some advertising to health practitioners will be permitted.
  - vapes will only be available through pharmacies.

“This Bill ensures people can continue to access therapeutic vapes to stop smoking on the advice of their doctor, while putting in place comprehensive laws to control the manufacture, supply and commercial possession of illegal vapes.”

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

Introduction of the *Therapeutic Goods and Other Legislation Amendment*

*(Vaping Reforms) Bill 2024* to Parliament



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[tga.gov.au](https://tga.gov.au)

# Reforms to the regulation of vapes

## Stage 3 – Strengthened product standards

- Likely publication in May or June 2024
- Anticipated commencement late 2024

### Proposed changes to be implemented:

- **Changes to packaging and labelling**
  - pharmaceutical like packaging and labelling.
  - restrictions on appearance of vapes.
  - new warning statements.
- **Restrictions on ingredients**
  - vapes can only contain a few permitted ingredients.
  - reduction of maximum concentration nicotine.
  - new maximum limit for menthol contents.
- **Restrictions on container volume**
- **Other changes to vaping device requirements**



# Prescribing vapes

“For people who have tried to achieve smoking cessation with approved pharmacotherapies but failed, but who are still motivated to quit smoking and have brought up e-cigarette usage with their healthcare practitioner, nicotine containing e-cigarettes may be a reasonable intervention to recommend.”

*Supporting smoking cessation: A guide for health professionals*  
Royal Australian College of General Practitioners



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Therapeutic Goods Administration



# RACGP smoking cessation: A guide for health professionals

## Scope of the Guide:

- **2011** - first published.
- **2012 & 2014** - minor updates.
- **2020** - new topics including more sophisticated pharmacotherapy (combination NRT), technology (eg quitting apps) and controversial nicotine delivery modalities, **in particular nicotine vapes / e-cigarettes.**
- **2021** – the first of a series of regulatory changes to a prescription only / medical framework for nicotine vaping products or therapeutic vapes.
- **2023** – present - further regulatory changes announced in May 2023, and updates are currently underway.



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# Why prescribe therapeutic vapes: evidence on efficacy of nicotine e-cigarettes in smoking cessation

- 2022: Cochrane review, which included 17 new studies with 78 studies in total.<sup>1</sup> It found there :
  - high-certainty evidence that e-cigarettes with nicotine increase quit rates compared with nicotine replacement therapy,
  - moderate-certainty evidence that e-cigarettes with nicotine increase quit rates compared with e-cigarettes without nicotine, and
  - no clear evidence of harm from nicotine e-cigarettes when used to quit smoking was detected (however, the longest follow-up was two years and the overall number of studies was small).
- 2023: RACGP Smoking Cessation Expert Advisory Group reviewed the existing GRADE evidence. This review included examination of study biases in the 2022 Cochrane review that were relevant to clinical decision-making.

1. Hartmann-Boyce J, Lindson N, Butler A, et al., 2022 Electronic cigarettes for smoking cessation. Cochrane Database of Systematic Reviews Issue 11. Art.No.:CD010216 DOI: 10.1002/14651858.CD010216.pub7.



# Vaping to support smoking cessation

**Recommendation 15** – For people who want to quit but have failed to achieve smoking cessation with first-line therapy (combination of behavioural support and TGA-approved pharmacotherapy), it may be reasonable to recommend nicotine vaping products in conjunction with behavioural support. The decision to proceed with this treatment must be part of an evidence-informed shared-decision making process, where the patient is aware of the following:

- Due to the lack of available evidence, the long-term health effects of nicotine vapes are unknown.
- NVPs are not registered therapeutic goods in Australia and therefore their safety and quality have not been established.
- The lack of uniformity in vaping devices and nicotine vaping goods (e.g. in ingredients and dosage) increases the uncertainties and risks associated with their use.
- To maximise possible benefits and minimise risk of harms, dual use (tobacco and e-cigarettes) should be avoided and the duration of nicotine vape use should be minimised.
- The importance of the patient returning for regular review and monitoring.

Conditional recommendation for intervention, **moderate** certainty (previously **low** certainty).



# When to prescribe: smoking cessation

- Adults who want to quit but have failed to achieve smoking cessation with first-line therapy.
- Adult dual users who want to transition onto therapeutic vapes only and cease combustible tobacco use.
- There is no requirement for medical or nurse practitioners to prescribe therapeutic vapes, even if their patient requests a prescription.
- Therapeutic goods registered by the TGA for smoking cessation, along with follow-up and behavioural support, are the first-line therapies for smoking cessation.



# When to prescribe: to support vaping cessation

- Provisional draft of RACGP Guidelines, first published in December 2023, includes a new section on vaping cessation.
- Currently there is a lack of research on interventions specifically targeting vaping cessation.

“In the absence of evidence specific to vaping, strategies shown to be effective for smoking cessation – behavioural support and pharmacotherapy - may be considered to support vaping cessation.”

“However, in some patients dependent on nicotine, it may be reasonable to prescribe them a NVP for a limited time, with the aim of titrating down to become nicotine free. In considering this option the person’s vaping and smoking history is relevant. While the objective is to reduce patients’ dependence on nicotine in any format, a key consideration is to minimise the chance of the patient relapsing to, or initiating, cigarette smoking.”



# Prescribing to under 18s

- The prevalence of people under 18 years old who vape (and may have never previously smoked) is rising.
- There is a currently a lack of evidence on the effectiveness and safety of medicines for smoking cessation in this group.
- There are differences across jurisdictions about the legality of supplying a young person with a therapeutic vape even if it is on prescription.
- The RACGP Guidelines do not currently recommend prescription of nicotine vapes to under 18s – but are being updated.



# Further guidance

- The RACGP Guidelines contains more detail on managing smoking cessation and vape addiction and deciding the best treatment options for particular patients.
- The Guidelines include information about how to write a prescription for a vaping good and how to determine appropriate dosage.
- They also include guidance about duration of scripts and titration of dosage.
- If a vape is prescribed the aim should be to titrate dosage down to facilitate the patient ceasing to be nicotine dependent.



# 1

## Consultation

A medical or nurse practitioner determines the appropriateness of prescribing therapeutic vapes through consultation with a patient.

The decision to prescribe an unapproved therapeutic good is a clinical decision made at the discretion of the prescriber.

The prescriber must ensure that all therapies included in the ARTG have been considered prior to prescribing an unapproved good.

The prescriber is responsible for ensuring that the patient or patient's guardian has given their informed consent.



# 2

## TGA notification or approval

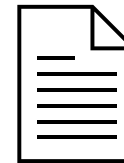
Notify or apply via the SAS or AP Online System.



# 3

## Prescription

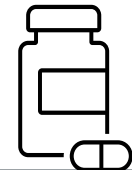
Prescription, where required, should be written in accordance with relevant state or territory legislation and be for products that meets TGA requirements.



# 4

## Pharmacy

Pharmacists should dispense the prescription in accordance with their state and territory drugs and poisons legislation and TGA requirements.





# How to prescribe vapes

Medical practitioners prescribing to high numbers of patients can apply and be authorised as **Authorised Prescribers**

Established history of use pathway  
or  
Standard pathway  
(Can be used for under 16s)

**Don't** need to notify TGA for each prescription  
**Do** need to report numbers in July and January of each year

- Pharmacists need evidence of a prescriber's AP status to fill scripts for unapproved goods
- Pharmacists can use online tool to check AP status
- Pharmacists may or may not keep records of Authorised Prescribers

- For the smoking cessation and treatment of nicotine addiction; and
- To patients 16+

Medical and nurse practitioners prescribing to individual patients

**SAS C**

**Do** need to notify TGA for each patient  
**Don't** need to notify TGA before issuing script

- 28-day window for notifications
- Online validation tool shows active notifications only
- Pharmacists will need reference number to use online tool

- For indications other than smoking cessation / treatment of nicotine addiction; and/or
- To patients under 16

**SAS B**

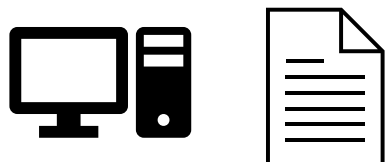
In accordance with State and Territory law

**Do** need to apply to the TGA for each patient  
**Do** need approval letter before issuing script

- Online validation tool shows active approvals only
- Pharmacists will need reference number to use online tool

# Prescribing nicotine vaping substances, packs and devices

## Requires an approval under AP or approval/notification under SAS



- **Therapeutic vaping substances** (including filled pods and cartridges).
- **Therapeutic vaping packs** (including substances, accessories and devices).
- **Zero nicotine vaping substances** (only accessed via SAS at present).
- From 1 March 2024, must only be supplied by a registered pharmacist or person authorised under state/territory legislation to supply prescription medicines.

## Does not require an approval under AP or approval/notification under SAS

- **Vaping devices without substances** (including unfilled cartridges, capsules, pods or other vessels).
- From 1 March 2024, must only be supplied by a registered pharmacist or person authorised under state/territory legislation to supply prescription medicines.



# List of notified vapes

- Manufacturers and suppliers must notify the TGA with a declaration that their products comply with TGO110 and other relevant standards, before importation and supply in Australia.
- These therapeutic vapes, called **notified vapes**, are included on the TGA's *List of notified vapes*.
- Prescribers can refer to the notified list to determine what therapeutic vapes are available for lawful supply.
- A transition period exists for vapes imported or manufactured before 1 March 2024.
- This means some other products not on the list may be lawfully prescribed until the Bill commences, including vapes with flavours that are no longer allowed.

[Home](#) > [Products we regulate](#) > [Unapproved therapeutic goods](#) > [Vaping hub](#)

## List of notified vapes

This page contains a list of vapes (including vaping substances, vaping accessories and vaping devices) that sponsors have provided to the TGA stating that the goods comply with applicable standards for supply in Australia and are only indicated for smoking cessation or the management of nicotine dependence. The listed vapes have not been assessed by the TGA for quality, safety and efficacy or performance.

Last updated: 14 March 2024

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This is not a complete list of vapes that may be lawfully supplied in Australia at this time, only those that are imported or manufactured on or after 1 March 2024. Certain other vapes containing nicotine that have been imported or manufactured prior to 1 March 2024 can continue to be lawfully supplied in Australia for a period where those vapes comply with previous standards and state and territory laws relating to the supply of prescription medicines.

The notifications by vape sponsor are made under the:

- [Therapeutic Goods Regulations 1990 \(the TG Regulations\)](#) <sup>EG</sup> Schedule 5A: items 15 and 16
- [Therapeutic Goods \(Medical Devices\) Regulations 2002 \(the MD Regulations\)](#) <sup>EG</sup> Schedule 4, Part 2: items 2.17 and 2.18.

Search:  Show 10 entries

Product name	Supplier Name	Vaping good type	Nicotine concentration (mg/mL)	Flavour	Volume (mL)	Notification number
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# Interactions with pharmacists

- Pharmacists must only dispense therapeutic vapes that conform with TGA requirements, including those in TGO 110.
- Pharmacists may dispense therapeutic vapes with evidence of an AP approval, SAS B approval or SAS C notification and a prescription, where required.
- A new validation tool has been developed for pharmacists to confirm the validity of AP and SAS approvals and notifications:
  - To use this tool, pharmacists need to know the notification reference number.
  - Prescribers should include this number on prescriptions to enable pharmacists to verify notification without needing to contact the prescriber.



# The Special Access Scheme and Authorised Prescriber portal – video available on YouTube

[How to use the Special Access Scheme and Authorised Prescriber portal to access vapes \(youtube.com\)](#)



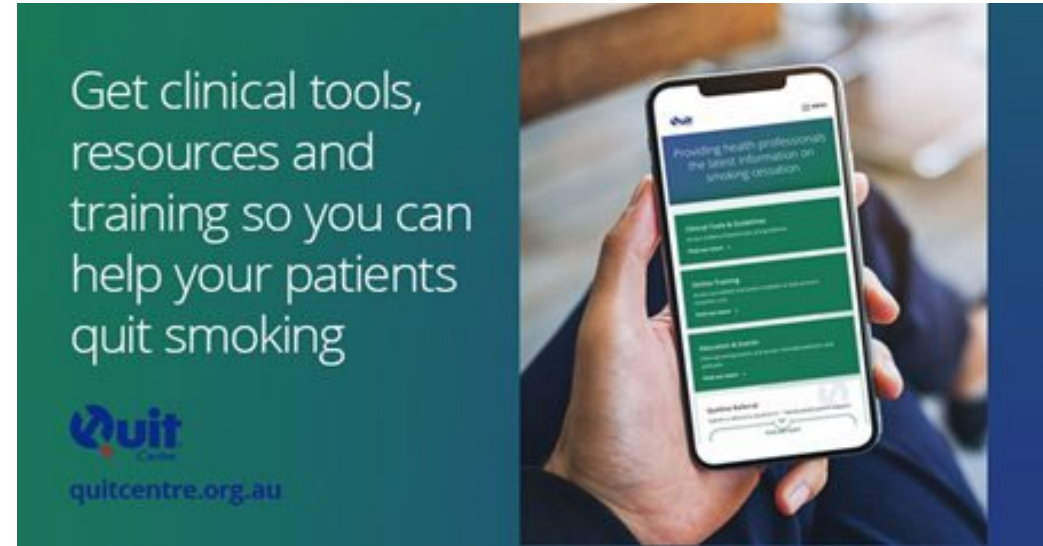
# Additional support

## Quit Centre ([www.quit.org.au](http://www.quit.org.au)):

- **For prescribers:** The Quit Centre has a range of clinical tools, resources and training available to support your care of patients wanting to quit.
- **For patients:** Patients can contact the Quitline on 13 7848 or visit the website to discuss the various options available to help them quit smoking or to manage nicotine dependence,. This includes information about prescription medicines, nicotine replacement therapies and support services.

## TGA Vaping Hub:

- Information about the regulation of vapes, and the implementation of the reforms:
- [Vaping hub | Therapeutic Goods Administration \(TGA\)](#)



# Frequently asked questions



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**Department of Health and Aged Care**  
Therapeutic Goods Administration

[tga.gov.au](http://tga.gov.au)

## Are medical appointments relating to prescribing therapeutic vapes or supporting vape cessation included in the Medicare Benefits Scheme?

- There are a range of general MBS consultation items that service providers may use to support patients seeking to cease or reduce their nicotine dependence
- Patients seeking support to quit smoking or vaping use are also encouraged to contact the Quitline, on 13 QUIT (13 7848)





## Will therapeutic vaping goods be included in the Pharmaceutical Benefits Scheme?

- At present, there are no therapeutic vaping goods subsidised under the Pharmaceutical Benefits Scheme (PBS).
- Medicines are not generally made available on the PBS to treat conditions for which they have not been registered on the Australian Register of Therapeutic Goods (ARTG).
- There are smoking cessation medicines subsidised through the PBS that are included on the ARTG and that have an established quality, safety and efficacy profile:
  - These medicines are accessible to patients through medical practitioners and nurse practitioners and include nicotine replacement therapy (NRT) patches, bupropion (Zyban) and varenicline (Champix, Varenapix).



## Can PBS-subsidised NRTs be prescribed for vaping cessation?

- A patient may be eligible for PBS subsidised NRTs, including smoking cessation medicines, if the patient has become nicotine dependent from the inhalation of a nicotine containing product (e.g. vapes), and where prescribing NRTs is clinically appropriate.
- The PBS restrictions for NRTs aim to provide an affordable intervention to support nicotine cessation.
- The Department has [published](#) advice for health professionals to assist with determining whether their patients are eligible for subsidised therapies under the PBS.



## How do State and Territory regulations apply when prescribing therapeutic vapes?

- The regulatory settings governing the domestic supply of vaping products is shared between the Commonwealth, states and territories, and there is some variation in the restrictions that apply.
- The TGA's requirements governing the supply of therapeutic vapes do not override state and territory legislation:
  - It is the responsibility of prescribing practitioners engaged in this practice to ensure all relevant state and territory regulations and requirements are met.
  - The Department is working in collaboration with the RACGP and state and territory health departments to provide further guidance in this area.
- See: [RACGP - Supporting smoking cessation: A guide for health professionals.](#)



## Can therapeutic vapes be prescribed long term?

- Unapproved therapeutic goods have not been evaluated for safety, quality and efficacy. The long-term health effects of vaping are unclear.
- In accordance with good medical practice, it is critical that medical practitioners regularly monitor and review the clinical suitability of the ongoing use of an unapproved vape for their patients.
- The RACGP Guidelines recommend prescribing a maximum of 3 months' supply, with a maximum of 12 months of use.



## Can therapeutic vapes be prescribed to under 18s?

- Before assessing any clinical considerations, prescribers should be aware that:
  - The regulatory settings governing the supply of vaping products are shared between the Commonwealth, states and territories, and there is variation in restrictions that apply to the supply of therapeutic vaping products to minors.
  - Vapes containing nicotine can be supplied to under 18s in New South Wales, Western Australia, South Australia, and the Northern Territory.
  - Supply to under 18s is prohibited in Victoria, Queensland, Tasmania and the ACT.
- Prescribers are encouraged to contact their local state or territory health department regarding the requirements that apply in their jurisdiction.
- The Department is working in collaboration with the RACGP and state and territory health departments to provide further guidance to prescribers in this area.
- See: [RACGP - Supporting smoking cessation: A guide for health professionals](#)



# Questions?



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Therapeutic Goods Administration

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# Therapeutic Goods Administration (TGA)

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