

# Therapeutic vapes

## Medicines and Poisons Act 2019

### Background and purpose

On 1 July 2024, the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (Commonwealth vaping reforms) came into effect. Therapeutic vapes (which include nicotine and zero-nicotine vapes) are only available in pharmacies for the purposes of smoking cessation or managing nicotine dependence. It is illegal for any other retailer—including tobacconists, vape shops and convenience stores—to sell any type of vaping goods.

The Commonwealth vaping reforms further amend the [Poisons Standard](#) to 'down-schedule' nicotine in some therapeutic vapes from a schedule 4 (S4) medicine to a schedule 3 (S3) medicine from 1 October 2024.

### What do these changes mean?

#### S3 therapeutic nicotine vapes and unscheduled zero-nicotine vapes

From 1 October 2024, under the Commonwealth vaping reforms, persons 18 years or over can access therapeutic vapes containing 20 mg/mL of nicotine or less from pharmacies, without a prescription, for smoking cessation or management of nicotine dependence.

Prior to supplying an S3 therapeutic nicotine vape or an unscheduled zero-nicotine vape, the Commonwealth vaping reforms require that a pharmacist must ensure:

- supply is to persons aged 18 years or over, including requesting and sighting evidence of the patient's identity and age; and
- professional advice is provided to the patient on alternative cessation supports and therapies, appropriate dose and frequency depending on age, weight and severity of condition, length of treatment, suitable titration, and interactions with other medicines; and
- contact details about smoking cessation support services are provided to the patient; and
- the quantity of the therapeutic vape does not exceed 1 month supply and that total quantity is only supplied to the patient once per month; and
- that the nicotine concentration does not exceed 20 mg/mL, or contains zero-nicotine.

If the request for supply does not meet the above requirements, a prescription from an authorised prescriber will be required.

Pharmacists are required to submit a Special Access Scheme (SAS) C notification to the Therapeutic Goods Administration (TGA) within 28 days of supplying an S3 therapeutic vape or zero-nicotine vape.

Further information for pharmacists supplying S3 therapeutic nicotine vapes and zero-nicotine vapes can be found [here](#).

## S4 therapeutic vapes

Therapeutic vapes will remain S4 medicines in certain circumstances and will require a prescription from an authorised prescriber.

**A prescription is required** for persons under 18 years of age, to ensure they receive appropriate medical advice and supervision. Persons who require a therapeutic vape with more than 20 mg/mL of nicotine will also need a prescription.

As therapeutic vapes are unapproved medicines, prescribers must use either the TGA Authorised Prescriber (AP) scheme or SAS to access these medicines. No additional approval from the Queensland Department of Health is required. The written prescription must comply with the requirements for a lawful prescription in Queensland.

Currently, only medical practitioners and nurse practitioners are authorised to prescribe therapeutic vapes as they are the only prescribers who can utilise the TGA special access pathways. Medical practitioners can either obtain an AP or SAS approval, however nurse practitioners can currently only obtain an SAS approval.

Further information about prescribing therapeutic vapes and TGA special access pathways can be found [here](#).

## List of notified vapes

There are currently no therapeutic vapes for smoking cessation or management of nicotine dependence included in the Australian Register of Therapeutic Goods (ARTG). Instead, the TGA maintains a [list of notified vapes](#) that sponsors have provided to the TGA as complying with applicable standards for supply in Australia. This includes complying with requirements (such as flavours and nicotine concentrations) in the *Therapeutic Goods (Standard for Therapeutic Vaping Goods) (TGO 110) Order 2021* (TGO 110), which apply to therapeutic vapes that are intended to be used for smoking cessation or management of nicotine dependence.

Only therapeutic vapes on the TGA list of notified vapes can be lawfully prescribed or supplied. This means that even with a prescription, patients can only access therapeutic vapes that are on the TGA list.

## Compounding therapeutic vapes

Pharmacists wishing to extemporaneously compound therapeutic vapes will require approval from the TGA. This is a requirement unique to therapeutic vapes and overrides the authority a pharmacist would otherwise have to compound these products. Additionally, the pharmacist will be considered the Australian sponsor for the compounded therapeutic vape and will therefore need to ensure that the compounded product meets all the requirements outlined in TGO 110, including maintaining adequate records. Pharmacists must also adhere to requirements in relevant standards and guidelines such as the Pharmacy Board of Australia's [Guidelines on compounding of medicines](#).

# Changes to Queensland legislation

Further amendments have been made to the [Medicines and Poisons \(Medicines\) Regulation 2021](#) (MPMR) to ensure that additional controls and safeguards are in place when S3 therapeutic nicotine vapes can be sold over the counter by pharmacists. These changes will commence from 1 October 2024 to align with the Commonwealth vaping reforms.

## Therapeutic nicotine vapes as diversion-risk medicines

Schedule 2, part 3 of the MPMR has been amended to classify nicotine in therapeutic vaping substances as a diversion-risk medicine. Diversion-risk medicines present a higher risk of diversion and may have value as an illicit substance. As diversion-risk medicines, therapeutic nicotine vapes have additional controls placed on them, including obligations to report lost or stolen goods, to report attempts to obtain excessive supply, and requirements relating to the disposal and destruction of waste.

## Sale of therapeutic nicotine vapes

Schedule 9, part 1, division 1 of the MPMR has been amended to provide that therapeutic nicotine vapes can only be sold at a community pharmacy by a pharmacist. Pharmacists are not required to hold a licence under the *Tobacco and Other Smoking Products Act 1998* (TOSPA) to sell therapeutic vapes.

The amendment ensures that a pharmacist cannot sell therapeutic nicotine vapes from other retail environments and limits the sale of therapeutic nicotine vapes, without a prescription, to a community pharmacy.

## Display of therapeutic vapes

Section 199 of the MPMR has been amended to provide that therapeutic nicotine vapes, stored at a place, must be kept out of sight from members of the public. The amendment aims to reduce the risk of theft, and to ensure therapeutic nicotine vapes are not being displayed or promoted. Failure to store therapeutic nicotine vapes in a manner compliant with the MPMR is an offence which carries a maximum of 40 penalty units. Display of zero-nicotine vapes is already similarly restricted under TOSPA.

## Disposal of therapeutic nicotine vapes

As therapeutic nicotine vapes are diversion-risk medicines, disposing of and destroying waste from a diversion-risk medicine should be done in accordance with section 148 of the MPMR. A medicine is destroyed when it has been rendered unusable and unidentifiable.

The [Disposal and destruction of diversion-risk medicine waste](#) factsheet contains more information.

## Reporting matters to the chief executive

There are reporting obligations if a pharmacist reasonably suspects therapeutic nicotine vapes have been lost or stolen. Section 226(1)(c) of the MPMR has been amended to provide that the pharmacist must, as soon as possible, and no later than the end of the next business day, notify the chief executive and the police service.

When selling S3 therapeutic nicotine vapes, pharmacists have a professional responsibility to make a clinical judgement based on the information presented to them. If the pharmacist reasonably suspects that the amount of medicine being sought is excessive, the pharmacist has obligations to report this to the chief executive under section 233 of the MPMR.

The Queensland Health web page [Reporting medicines matters to the chief executive](#) contains the specific forms that must be used for the purposes of notification to the chief executive.

## Do smoke-free laws apply to therapeutic vapes?

Therapeutic vapes are subject to Queensland's smoke-free laws.

Under TOSPA, the definition of smoking applies to all vaporiser devices. This includes therapeutic vapes that have been obtained from a pharmacy. Persons using vaporiser devices need to observe smoke-free requirements; penalties apply for non-compliance.

Information on smoke-free laws is available on the [Smoking laws in Queensland website](#) or by calling 13 QGOV (13 7468).

## Additional resources

- [Vaping hub | Therapeutic Goods Administration \(TGA\)](#)

## For further information

Contact the Medicines Approvals and Regulation Unit

[MARU@health.qld.gov.au](mailto:MARU@health.qld.gov.au)

## Version control

Version	Date	Comment
1	September 2024	New document.
2	October 2024	Minor wording amendments to provide clarification