

# Therapeutic Vaping Substances

Consultation Paper  
July 2024



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# Purpose

The purpose of this consultation paper is to seek stakeholder feedback on proposed changes to the *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) in relation to therapeutic vaping substances.

The consultation paper is for **consultation purposes only** and does not represent Queensland Government policy.

Your views are valuable and may be referred to in material provided to Government in considering this proposal. If legislative amendments are progressed, your feedback may be referred to in public documents, for example, as part of the Explanatory Notes.

Please provide any feedback on the proposed amendments by email to [legislationconsultation@health.qld.gov.au](mailto:legislationconsultation@health.qld.gov.au) by **5pm, 9 August 2024**.

If you have any questions or require further information, please email your queries to the email address above before the closing date and an officer from Queensland Health will contact you.

# Background

## Medicines legislative framework

The Medicines Regulation regulates medicines and complements the *Medicines and Poisons Act 2019* (Medicines and Poisons Act) by:

- ensuring medicines are used safely and effectively and to reduce public harm;
- setting out the ‘authorised way’ for a person to perform regulated activities with certain medicines; and
- providing flexible requirements for authorised activities, such as storage and disposal, that are commensurate with the approved person’s qualifications and activities and the public health and safety risk of the medicines.

Section 30 of the Medicines and Poisons Act specifies that the following persons may be authorised to deal with a regulated substance, such as a medicine, poison, or prohibited substance:

- an approved person who is a member of a ‘class of persons’, such as a pharmacist, dentist, doctor or nurse practitioner;
- a person acting under an emergency order, issued to deal with an event such as a declared public health emergency or disaster;
- a holder of a substance authority; or
- a person acting under a substance authority.

The proposed changes to the Medicines Regulation aim to address practical and operational issues that have been identified following passage of amendments at the Commonwealth level in relation to vaping and the down-scheduling of nicotine, and the introduction of a Queensland Bill which enforces the Commonwealth ban and takes strong action to address vaping in Queensland. The proposed changes will ensure the Medicines Regulation remains fit for purpose and allows health practitioners to practise to their full scope to help and support health consumers.

## Changes to vaping legislation at the Commonwealth level

On 1 July 2024, the *Therapeutic Goods and Other Legislation Amendment (Vaping Reforms) Act 2024* (Commonwealth Amendment Act) came into effect.

The Commonwealth Amendment Act puts in place nationally consistent rules on the importation, domestic manufacture, supply, commercial possession, and advertisement of all vaping goods (including vaping accessories, vaping devices and vaping substances). The intent of the Commonwealth Amendment Act is to address the increasing health risks of vaping while ensuring consumers who legitimately need access to vapes can still purchase them from pharmacies as a tool to help them quit smoking or manage nicotine dependence.

From 1 July 2024, all vapes, regardless of whether they contain nicotine, may only be sold by a pharmacist for the purpose of helping people to quit smoking or manage nicotine dependence. These changes mean it is illegal for any other retailer—including tobacconists, vape shops and convenience stores—to sell any type of vaping good.

The Commonwealth Amendment Act also amends the Standard for the Uniform Scheduling of Medicines (Poisons Standard) to ‘down-schedule’ nicotine in some therapeutic vaping goods (for example, liquid nicotine in certain concentrations) from a Schedule 4 (S4) to a Schedule 3 (S3) medicine.<sup>1</sup> The effect of these changes is that, from 1 October 2024, people 18 years or over will be able to buy therapeutic vaping goods with 20 mg/mL of nicotine or less from pharmacies without a prescription.

To do this, pharmacists will be required to provide professional advice 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. The person will need to provide identification before they purchase and will only be allowed to purchase one month’s supply once a month.

People under 18 years will still need a prescription to access vapes, to ensure they receive appropriate medical advice and supervision.

People who need a vape with more than 20 mg/mL of nicotine will still need a prescription.

## Changes to vaping legislation in Queensland

In 2023, the former Health and Environment Committee held an inquiry into vaping in Queensland. The Committee made 14 recommendations in its report *Vaping: An inquiry into reducing rates of e-cigarette use in Queensland*,<sup>2</sup> which were all accepted by the Queensland Government. In response to the Committee’s report, the Government committed to tackling the vaping crisis and supporting the implementation of the Commonwealth Government’s vaping amendments. This includes discontinuing the sale of vaping products in retail settings, bolstering Queensland’s resources and capabilities for compliance monitoring and enforcement activities, and progressing legislative amendments as necessary.

On 12 June 2024, the Tobacco and Other Smoking Products (Vaping) and Other Legislation Amendment Bill 2024 (Vaping Bill) was introduced in Queensland’s Legislative Assembly.

The Vaping Bill is currently before the Health, Environment and Agriculture Committee (Committee) for consideration. The Committee’s report on the Vaping Bill is due on 2 August 2024.

The Vaping Bill amends the *Tobacco and Other Smoking Products Act 1998* to ensure Queensland can effectively enforce the Commonwealth ban and take strong action to address vaping in Queensland. The Bill also gives effect to recommendations of the former Health and Environment Committee.

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<sup>1</sup> Commonwealth Amendment Act sch 4.

<sup>2</sup> Available at <https://documents.parliament.qld.gov.au/tableoffice/tabledpapers/2023/5723T1212-BEB3.pdf>.

The Vaping Bill provides that it is an offence to supply an illicit nicotine product (which includes vaping goods such as vaping devices, substances, and accessories) as part of a business activity. The offence does not apply if the conduct is authorised under Commonwealth legislation. As such, a pharmacist supplying vaping substances as an S3 medicine from 1 October 2024 would not be committing an offence under the Vaping Bill.

# Description of proposed amendments

## Amendments to the Medicines Regulation

It is proposed to make the following amendments to the Medicines Regulation:

- classify S3 and S4 nicotine in therapeutic vaping substances<sup>3</sup> as a diversion-risk medicine;
- provide that S3 and S4 nicotine in therapeutic vaping substances can only be sold at a community pharmacy;
- clarify that S3 and S4 medicines, other than nicotine in therapeutic vaping substances, can only be sold by a pharmacist at a pharmacy (community pharmacy or relevant institution);
- ensure therapeutic vaping substances stored at a community pharmacy must be kept in an area that is out of sight from members of the public; and
- ensure a pharmacist must notify the chief executive and the police service if they reasonably suspect therapeutic vaping substances have been lost or stolen.

## Diversion-risk medicine

Under the Medicines and Poisons Act, a medicine is a substance to which the following schedules in the Commonwealth Poisons Standard, applies:

- schedule 2 (an S2 medicine)
- schedule 3 (an S3 medicine)
- schedule 4 (an S4 medicine)
- schedule 8 (an S8 medicine)

The Medicines and Poisons Act describes new categories of medicines, such as restricted medicines, high-risk medicines, diversion-risk medicines and monitored medicines, to allow specific controls to be placed on specific categories of substances.

Diversion-risk medicines are those that present a higher risk for diversion and may have value as an illicit substance. Diversion-risk medicines have additional controls placed on them due to the risks associated with these medicines if they are diverted for uses other than their intended purpose, such as for illicit use which may result in serious harm to human health. They are listed in schedule 2, part 3 of the Medicines Regulation and include all S8 medicines, as well as medicines such as barbiturates, benzodiazepines, codeine, pseudoephedrine and ephedrine, anabolic and androgenic steroidal agents, growth hormone releasing hormones and peptides, and selective androgen receptor modulators.

The Medicines Regulation imposes additional controls on these medicines, including requirements to report attempts to obtain excessive supply, and requirements relating to disposal and destruction of waste.

The banning of the supply of vaping goods in retail environments other than pharmacies means some individuals may seek to obtain vaping goods from pharmacies and illegally divert or on-sell them, including to young people.

To address this risk, it is proposed to include S3 and S4 nicotine in therapeutic vaping substances as a diversion-risk medicine to ensure the diversion-risk controls apply.

## Sale of S3 and S4 medicines

Queensland Health considers the intent of the Medicines Regulation is that a pharmacist may only sell S3 and S4 medicines at a pharmacy (defined to mean a community pharmacy or relevant institution, such as a hospital or aged care facility) and has to date interpreted the Medicines Regulation accordingly. However, in light of the down-scheduling of nicotine in therapeutic vaping substances, it is proposed to put beyond doubt that a pharmacist cannot sell these or other S3 or S4 medicines from another retail environment such as a vape store.

It is therefore proposed to amend the Medicines Regulation to provide that:

- S3 and S4 nicotine in therapeutic vaping substances can only be sold at a community pharmacy; and
- consistent with the intent of the Medicines Regulation and established regulatory practice, all other S3 and S4 medicines can only be sold at a pharmacy, that is, a community pharmacy or relevant institution such as a hospital or aged care facility.

The proposed amendments will not prevent a general practitioner who prescribes an S3 or S4 medicine, including nicotine in a therapeutic vaping substance, from also dispensing the medicine. The amendment only limits the sale of S3 and S4 nicotine in therapeutic vaping substances to a community pharmacy and the sale of S3 and S4 medicines from a pharmacy.

## Display of therapeutic vaping substances

Section 199(2) of the Medicines Regulation provides that if pseudoephedrine is possessed at a place, the medicine store must also be kept in an area that is out of sight from members of the public. Failure to store pseudoephedrine out of sight from members of the public is an offence which carries a maximum penalty of 40 penalty units.

To reduce the risk of theft, and to ensure vaping goods are not being displayed or promoted to children or those who are seeking to cease vaping, it is proposed to amend section 199(2) to provide that a therapeutic vaping substance must also be stored out of sight from members of the public. This will also carry a maximum penalty of 40 penalty units.

## Reporting loss or theft of therapeutic vaping substances

Section 226(1)(c) of the Medicines Regulation provides that if a pharmacist reasonably suspects pseudoephedrine has been lost or stolen, 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 of the missing medicine. Failure to notify the chief executive and the police service is an offence which carries a maximum penalty of 40 penalty units.

To ensure the state government is made aware of illegal diversion of vaping goods, it is proposed to amend section 226(1)(c) to provide that a pharmacist must notify the chief executive and the police service if a therapeutic vaping substance is identified as lost or stolen. Notification must occur as soon as possible, and no later than the end of the next business day. Failure to comply with this requirement will also carry a maximum penalty of 40 penalty units.

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<sup>3</sup> A *therapeutic vaping substance* means “a therapeutic good that is a liquid or other substance designed or intended for use in or with a vaping device.” *Therapeutic Goods Regulations 1990* (Cth) s 2.