Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024

Explanatory notes for SL 2024 No. 230

made under the

Medicines and Poisons Act 2019

General Outline

Short title

Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024

Authorising law

Sections 54 and 240 of the *Medicines and Poisons Act 2019*.

Policy objectives and the reasons for them

The main purposes of the *Medicines and Poisons Act 2019* (Act) include ensuring particular substances are made, sold, used and disposed of in an appropriate, effective and safe way and ensuring that health risks arising from the use of these substances are appropriately managed.

The *Medicines and Poisons (Medicines) Regulation 2021* (Medicines Regulation) regulates medicines and complements the Act by:

- setting out the 'authorised way' for a person to perform regulated activities with certain regulated substances (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.

The Medicines Regulation requires updating periodically to keep up with changes to Queensland Health policies and practices, reflect changes to Commonwealth legislation affecting the regulation of therapeutic goods, and improve access to high-quality health services throughout Queensland.

The *Medicines and Poisons (Medicines) Amendment Regulation (No. 3) 2024* (Amendment Regulation) amends the Medicines Regulation to implement recent Commonwealth vaping reforms that ban recreational and disposable vaping goods and introduce strict requirements for therapeutic vaping goods, including restrictions on their importation, manufacture, possession and supply. States and territories will be primarily responsible for enforcing these requirements at the wholesale and retail levels.

Under the Commonwealth reforms, only pharmacists will be lawfully permitted to sell vaping goods to members of the public in Queensland, and only for the purpose of helping people to quit smoking or manage nicotine dependence.

Consistent with the purposes of the Act, the Amendment Regulation focuses on imposing controls on vaping goods to the extent they contain nicotine, which is the 'regulated substance' under the Act. While the additional controls imposed by the Amendment Regulation will not apply to therapeutic vaping devices or vaping accessories that do not contain nicotine, the Commonwealth legislation will still apply to those items, meaning that they cannot be sold by a person who is not a pharmacist and cannot be advertised.

To reflect the new pharmacy-based supply arrangements and ensure that regulated substances in vaping goods are subject to appropriate regulatory controls, the Amendment Regulation amends the Medicines Regulation to:

- classify therapeutic nicotine[1] as a diversion-risk medicine[2];
- restrict the sale of therapeutic nicotine to a community pharmacy;
- restrict the sale of schedule 2 (S2), schedule 3 (S3) and schedule 4 (S4) medicines, other than therapeutic nicotine, to a pharmacy[3];
- ensure when therapeutic nicotine is stored at a community pharmacy it 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 nicotine has been lost or stolen.

These amendments also address practical and operational issues that have been identified following passage of the Commonwealth vaping reforms, including the down-scheduling of nicotine from an S4 to an S3 medicine from 1 October 2024.

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) commenced. The Commonwealth Amendment Act amends the *Therapeutic Goods Act 1989* (Cth) (TG Act) to ban the importation, manufacture, supply and possession of recreational vaping goods (vaping devices, accessories and substances). Under the TG Act as amended, pharmacists and other prescribed health professionals may supply therapeutic vaping goods for smoking cessation and nicotine dependence.

The Commonwealth Amendment Act also amends the Standard for the Uniform Scheduling of Medicines and Poisons (Poisons Standard) to 'down-schedule' nicotine in some therapeutic vaping goods (for example, liquid nicotine in certain concentrations) from an S4 to an S3 medicine. 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.

[1] Therapeutic nicotine means nicotine in a therapeutic vaping good, which includes vaping accessories, vaping devices and vaping substances. Therapeutic nicotine does not include nicotine replacement therapy, for example, nicotine patches and gum.
[2] Diversion-risk medicines are medicines that may have value as an illicit substance, such as anabolic steroids and pseudoephedrine products.
[3] A pharmacy is defined as a community pharmacy or a place in a relevant institution, such as a hospital, aged care facility or prison, where medicines are supplied by a pharmacist to the public.

From 1 October 2024, only pharmacists will be authorised to sell vaping goods to the public (whether or not the vaping goods contain nicotine), and only 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 goods.

To supply therapeutic vaping goods, pharmacists will be required to provide professional advice on alternative smoking cessation supports and therapies, appropriate dose and frequency depending on age and weight, 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 vaping goods, 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*, 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.

The Tobacco and Other Smoking Products (Vaping) and Other Legislation Amendment Act 2024 (Vaping Act) received royal assent on 19 September 2024.

The Vaping Act 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 Vaping Act also gives effect to recommendations of the former Health and Environment Committee including to streamline approaches between tobacco and medicines and poisons legislation and to prevent supply of vapes to children.

The Vaping Act 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 Act.

Achievement of policy objectives

The Amendment Regulation commences on 1 October 2024.

Diversion-risk medicine

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 therapeutic nicotine as a diversion-risk medicine to ensure the diversion-risk controls apply.

The Amendment Regulation amends schedule 2, part 3 of the Medicines Regulation to classify therapeutic nicotine as a diversion-risk medicine. 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.

Sale of therapeutic nicotine and S2, S3 and S4 medicines

The Amendment Regulation amends schedule 9, section 2 of the Medicines Regulation to provide that:

- therapeutic nicotine can only be sold at a community pharmacy; and
- S2, S3 and S4 medicines, other than therapeutic nicotine, can only be sold at a pharmacy.

Queensland Health considers the intent of the Medicines Regulation is that a pharmacist may only sell S2, S3 and S4 medicines at a pharmacy 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 therapeutic nicotine or other S2, S3 or S4 medicines from another retail environment such as a vape store.

The proposed amendments will not prevent a general practitioner who prescribes an S3 or S4 medicine, including therapeutic nicotine, from also dispensing the medicine. The amendment only limits the sale of S2, S3 and S4 medicines without a prescription from a pharmacy.

It should be noted that the table in schedule 9, section 2 of the Medicines Regulation relates to the authorisation of pharmacists selling S2s who are ‘practising in the pharmacy profession’. This amendment does not affect S2 retail licence holders, such as charter vessels or roadhouses that are greater than 25km from a pharmacy, buying or selling S2 medicines under the conditions of their licences.

Display of therapeutic nicotine

The Amendment Regulation amends section 199(2) of the Medicines Regulation to provide that if therapeutic nicotine 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 therapeutic nicotine out of sight from members of the public is an offence which carries a maximum penalty of 40 penalty units. This provision replicates the requirements already in place for pseudoephedrine, which is also a diversion-risk medicine.

The amendment aims to reduce the risk of theft, and to ensure vaping goods are not being displayed or promoted to children or those who are nicotine dependent.

Reporting loss or theft of therapeutic nicotine

The Amendment Regulation amends section 226(1)(c) of the Medicines Regulation to ensure the Queensland Government is made aware of illegal diversion of vaping goods by providing that if a pharmacist reasonably suspects therapeutic nicotine 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 substance. Failure to notify the chief executive and the police service is an offence which carries a maximum penalty of 40 penalty units. This provision replicates the requirements already in place for pseudoephedrine, which is also a diversion-risk medicine.

Definition of community pharmacy

On 28 March 2024, the *Pharmacy Business Ownership Act 2024* received assent. On 1 September 2024, a proclamation was made commencing certain provisions of the *Pharmacy Business Ownership Act 2024*, including the definition of *pharmacy business*.

As a result of the commencement of the definition of pharmacy business, an amendment is required to the definition of community pharmacy in the Medicines Regulation to capture both the *Pharmacy Business Ownership Act 2001*, which has yet to be repealed and replaced, and the *Pharmacy Business Ownership Act 2024*.

Consistency with policy objectives of authorising law

The Amendment Regulation is consistent with the policy objectives of the authorising Act.

Inconsistency with policy objectives of other legislation

No inconsistencies with the policy objectives of other legislation have been identified.

Alternative ways of achieving policy objectives

An alternative way of achieving the policy objective would be to rely on the strict interpretation of the Commonwealth Amendment Act, which down-schedules nicotine in therapeutic vaping goods (within the meaning of the Commonwealth *Therapeutic Goods Regulations 1990*) from an S4 to an S3 medicine, which a pharmacist can supply without a prescription.

The following controls would apply in Queensland, regardless of any amendments made to the Medicines Regulation:

- supply is to a person 18 years of age or older;
- the pharmacist must sight evidence of the patient's identity and age;
- quantity of therapeutic nicotine sold does not exceed 1 month's supply;
- concentration of nicotine does not exceed 20 mg/mL;
- the pharmacist must provide professional advice to the patient on alternative smoking cessation supports and therapies;
- pharmacists cannot display vaping goods; and

- pharmacists must report sales through the Special Access Scheme Category C (SAS C) process as therapeutic nicotine products are unapproved by the Therapeutic Goods Administration.

Adopting the Commonwealth's changes without amending the Medicines Regulation would mean additional controls would not be implemented that place safeguards on the sale of therapeutic nicotine. The Amendment Regulation provides for the following additional controls:

- make therapeutic nicotine a diversion-risk medicine. This will ensure vapes sold at a community pharmacy, which have a high illicit value similar to anabolic steroids and pseudoephedrine products, have additional controls imposed on them, including requirements to report attempts to obtain excessive supply, and requirements relating to disposal and destruction of waste;
- clarify the intention of the Medicines Regulation that S2, S3 and S4 medicines can only be sold at a pharmacy. This will ensure that a pharmacist cannot be employed by a vape store or other business to sell vaping goods;
- replicating requirements already in place for pseudoephedrine which will ensure therapeutic nicotine stored at a community pharmacy must be kept in an area that is out of sight from members of the public, and that a pharmacist must notify the chief executive and the police service if they reasonably suspect therapeutic vaping substances have been lost or stolen. This will ensure that pseudoephedrine and therapeutic nicotine, which can both be an S3 or S4 diversion-risk medicine, have the same display and reporting requirements placed on them.

Benefits and costs of implementation

The cost of implementing the amendments will be met within existing budget allocations, and the resources to manage and administer the existing regulation framework will continue to be used. The amendments do not impose any new or increased fees.

The amendments to the Medicines Regulation will give effect to the Commonwealth's vaping reforms, which address the health risks posed by vaping, while ensuring therapeutic vaping goods remain available, where clinically appropriate, to patients in pharmacy settings. The amendments also address practical and operational issues that have been identified following passage of the Commonwealth reforms.

Adding further safeguards on the sale of therapeutic nicotine at community pharmacies will ensure that individuals, including children, are not routinely exposed to display of these products when they visit pharmacies for other health requirements. It will also ensure that diversion risk of these products is mitigated. These additional controls are important to reduce the normalcy of vaping product use and contribute to achieving the aim of the national vaping reforms to prevent uptake and use of vaping products, especially by children and young adults.

Consistency with fundamental legislative principles

The Amendment Regulation is generally consistent with fundamental legislative principles in section 4 of the *Legislative Standards Act 1992*.

Whether the proposed legislation has sufficient regard to the rights and liberties of individuals

Under section 4(2)(a) of the Legislative Standards Act, legislation must have sufficient regard to the rights and liberties of individuals. In considering whether the proposed amendments have sufficient regard to the rights and liberties of individuals, the following issues are relevant.

Offences

Although not specifically enumerated in the Legislative Standards Act, for legislation to have sufficient regard to the rights and liberties of individuals, the consequences imposed by legislation should be proportionate and relevant to the actions to which they are applied. The offences and penalty amounts contained in the Amendment Regulation are consistent with similar offences and penalty amounts contained in the Medicines Regulation.

Display of therapeutic nicotine

The high illicit value of vaping goods means that the risk of diversion is significant, requiring sound and comprehensive security arrangements for their storage, including controls on the physical site. These controls seek to deter, delay, and allow timely detection of unauthorised removal of, or interference with, stored vaping goods.

The amendment to section 199(2) (Preventing unauthorised access to medicines) provides it is an offence if therapeutic nicotine is possessed at the place, and the medicine store is kept in an area that can be seen by members of the public. The amendments set consistent standards for storing therapeutic nicotine that are commensurate with the risks associated with the particular substance and effectively restricts access to vaping goods to people who are authorised to possess them on an as-needed basis.

The amendment mirrors the existing offence in section 199(2), which applies to the storage of pseudoephedrine, which is also a diversion-risk medicine with a high illicit value. The penalty is the same as for the pseudoephedrine offence of failing to keep the medicine store in an area that is out of sight from members of the public. The penalty is justified to ensure that only authorised persons can access vaping goods, which are associated with abuse, illicit use and diversion.

The offence applies to the person responsible for establishing the medicine store and managing its day-to-day operation, rather than placing obligations on the medicine store user for matters outside their control.

Reporting loss or theft of therapeutic nicotine

The requirements for reporting are central to the control of access to medicines and the safe treatment of patients with medicines. The reporting of lost or stolen medicines also allows action to be taken, for example, to investigate diversion of medicines such as pharmaceutical opioids or pseudoephedrine to the illicit drug market, or to identify situations which might result in self-harm using stolen medicines.

The amendment to section 226(2)(c) (Reporting lost or stolen medicine) provides it is an offence if a pharmacist fails to give notice about the suspected loss or theft of therapeutic nicotine to the chief executive in the approved form and notify the police service about the

incident, as soon as practicable, but no later than the end of the next business day after the incident.

The amendment mirrors the existing offence in section 226(2)(c), which requires a pharmacist to report lost or stolen pseudoephedrine, which is also a diversion-risk medicine with a high illicit value, to the chief executive in the approved form and notify the police service about the incident.

The penalty for failing to report lost or stolen therapeutic nicotine is justified due to the seriousness of the consequences related to unauthorised access to medicines and potential harm from access to medicines associated with abuse, diversion, and illicit use. The requirements are necessary to achieve the purposes of the Act to ensure health risks are managed and that people possessing and supplying medicines have the competencies to perform these activities safely and are authorised to deal with the medicines.

Consultation

Pharmacy and medical stakeholder groups were consulted during preparation of the Commonwealth Amendment Act and the Vaping Act.

In July 2024, a consultation paper on the proposed therapeutic nicotine amendments was published on the Queensland Health website and disseminated to relevant stakeholders. There was strong support from most stakeholders on the proposed amendments to the Medicines Regulation.

A number of stakeholders commented on the policy rationale or practical implications of allowing therapeutic vaping products to be supplied in pharmacy settings without a prescription. These issues are beyond the scope of the Amendment Regulation as they are the direct result of amendments at the Commonwealth level in relation to the regulation of vaping products and the down-scheduling of nicotine.

Queensland Health has assessed the amendments in accordance with the *Queensland Government Better Regulation Policy* as being unlikely to result in significant adverse impacts. The Office of Best Practice Regulation was notified of this assessment when developing the Impact Analysis Statement for the Amendment Regulation. The Minister for Health, Mental Health and Ambulance Services and Minister for Women, and the Director-General of Queensland Health are satisfied that the regulatory review requirements have been met and have approved the Impact Analysis Statement for publication.