Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 3)

Subordinate law SL2023-34

made under the

***Medicines, Poisons and Therapeutic Goods Act 2008*, Section 184 (Regulation-making power)**

EXPLANATORY STATEMENT

PURPOSE AND OUTLINE

The objective of the *Medicines, Poisons and Therapeutic Goods Act 2008* (MPTG Act) is to promote and protect public health and safety by minimising medicinal misadventure with, and diversion of, regulated substances, and the manufacture of regulated substances that are subject to abuse. The MPTG Act outlines the appropriate prescription and supply of medicines and defines the concepts of deal, supply, prescribe and administer in relation to medicines.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. The Poisons Standard (Cwlth) is adopted by reference under Part 3.3 of the MPTG Act. With reference to medicine and poisons categorised by the Poisons Standard, the MPTG Regulation sets out which health professionals can deal with a medicine and the conditions for such dealings. Some provisions of the MPTG Regulation prescribe additional information required for the safe storage of controlled medicines.

Controlled medicines are substances to which the Poisons Standard, Schedule 8 applies. These medicines have additional restrictions to reduce misuse or dependence. These additional restrictions include storage requirements to minimise the risk of misuse or diversion of controlled medicines.

The ACT Health Directorate consulted with affected stakeholders in the development of the proposed amendments.

<u>Overview of amendments</u>

The Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 3) (Amendment Regulation) seeks to make three changes to the MPTG Regulation. These changes concern storage of controlled medicines by research and education (CMR&E)

program licence holders, refrigerated storage of controlled medicines and storage of daily use opioid maintenance treatment medication in community pharmacies. These changes seek to provide storage options that expand the scope of controlled medicines available for use in the ACT to those requiring refrigeration, and to improve operational efficiencies for community pharmacies and CMR&E program licence holders.

Storage of controlled medicines by research and education program licence holders

The MPTG Regulation, section 440 (Authorisations under controlled medicines research and education program licences—Act, s 20 (1) (a)) authorises a CMR&E program licence holder to possess a controlled medicine. All licensed CMR&E programs must be conducted at or under a recognised research institution, defined by the MTPG Act.

Generally, CMR&E licence holders store small quantities of controlled medicines. The risk of diversion or misuse is considered low in these facilities due to the small quantities stored and because research areas are typically secure areas with no public access. Currently, CMR&E program licence holders must store controlled medicine to the same stringent storage requirements as organisations that store high quantities of these medicines.

The MPTG Regulation, section 532 (Storage of controlled medicines for certain health-related occupations—Act, s 61 (b) and (c)) allows less stringent storage requirements for certain health-related occupations. If required, the Chief Health Officer may impose licence conditions on controlled medicine storage requirements for CMR&E licence holders under section 90 of the MPTG Act. This ensures safe storage of medicines with consideration to type and quantity of the medicine. The Amendment Regulation declares CMR&E program licence holders as a designated person under section 532, affording additional options and increased flexibility for the storage of controlled medicines.

Flexible storage options for defined persons storing small quantities of a controlled medicine already exist within ACT and is generally enabled in most other states and territories. Stakeholders supported this amendment.

Refrigerated storage of controlled medicines

The Amendment Regulation enables prescribed persons to store controlled medicines that require refrigeration in a refrigerator. The MPTG Regulation currently allows controlled medicine to be stored in various ambient temperature storage receptables but does not provide an option for refrigerated storage. Some controlled medicines requiring refrigerated storage are already approved for use in the ACT. The Amendment Regulation enables controlled medicines requiring refrigeration to be safely stored by prescribed persons.

The refrigerated storage requirements are intended to minimise the risk of misuse and diversion. These requirements are generally consistent with other jurisdictions where refrigerated storage has been enabled. Enabling refrigerated storage of controlled medicines by prescribed persons is not considered to increase risk to patients or the community and was supported by stakeholders during consultation.

Storage of daily use opioid maintenance treatment medication in community pharmacies

Opioid maintenance treatment (OMT) medications are a type of controlled medicine used to treat opioid dependence. Medicines used for OMT include methadone and buprenorphine.

Community pharmacists authorised under an opioid dependency treatment licence are key service providers in the treatment of opioid dependence and are often required to dispense and supervise multiple doses of OMT each day. The MPTG Regulation currently requires pharmacists to store all controlled medicines in a locked medicines cabinet, safe, strong room or vault when not in immediate use. This can lead to delays in workflow and client services.

The Amendment Regulation enables pharmacists authorised under an opioid dependency treatment licence to store OMT medication in a locked storage cupboard or drawer during the pharmacy's business hours subject to requirements that continue to minimise the risk of potential misuse or diversion.

Regulatory Impact Statement

In accordance with the *Legislation Act 2001,* a regulatory impact statement was not required to be presented with the Amendment Regulation as the amendments do not impose appreciable costs or regulatory burden on the community. These amendments do not operate to the disadvantage of anyone or impose additional liabilities on a person.

Human rights considerations

During the development of the Amendment Regulation, due regard was given to its compatibility with the *Human Rights Act 2004* (HR Act).

The Amendment Regulation engages section 9 (Right to life) under the HR Act.

Ensuring the effective regulation of medicines in the ACT, including appropriate and flexible storage options for controlled medicines through the Amendment Regulation as described above engages and promotes the right to life under the HR Act. The right to life is concerned with preventing the arbitrary deprivation of life and is relevant to the supply of medicines.

The Amendment Regulation expands on existing controlled medicine storage requirements, affording greater flexibility in storage options for controlled medicines proportionate to risk. Enabling refrigerated storage for controlled medicines allows for better options for controlled medicines requiring refrigeration to be prescribed and supplied in the ACT and by extension, improving patient access to medicinal treatment options.

As such, the Amendment Regulation is considered to indirectly engage and promote the right to life.

CLAUSE NOTES

Clause 1 Name of Regulation

This clause declares the name of the Amendment Regulation to be the Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No3).

Clause 2 Commencement

Under this provision, the Regulation commences the day after its notification.

Clause 3 Legislation amended

This clause advises that this Amendment Regulation amends the MPTG Regulation. Upon commencement, this Amendment Regulation will amend the MPTG Regulation in accordance with the provisions that this Amendment Regulation contains. Consequentially, from the date that this Amendment Regulation commences, a republication of the MPTG Regulation will be available. The new republication will feature the amendments made by this Amendment Regulation.

Clause 4 Section 532 (1), definition of *designated person*, new paragraph (d)

This clause inserts new paragraph (d) expanding the definition of designated person to include a controlled medicines research and education program licence-holder. This enables controlled medicine research and education program licence-holders to store controlled medicines with more flexible storage options.

This amendment is considered appropriate as in most cases, controlled medicines research and education program licence-holders will store small amounts of controlled drugs. Where a licence holder proposes to deal with larger quantities, the MPTG Act allows the Chief Health Officer to impose conditions which may include conditions about storage.

Clause 5 New Section 532 (2) (a) (iii)

This clause inserts the new section 532 (2) (a) (iii) to the MPTG Regulation that enables controlled medicines to be stored in a locked refrigerator.

Clause 6 Section 532 (2) (b) and (c)

This clause omits 'medicine is kept in a container' and substitutes 'controlled medicine is kept in a container or refrigerator'. This clause clarifies that these conditions are specifically referring to controlled medicines and that a refrigerator can be used for storage.

Clause 7 Section 532 (2) (d)

This clause inserts the word 'controlled' before the word medicine. This is to clarify that this section only applies to controlled medicines.

Clause 8 New Section 532 (2) (e)

This clause outlines the provisions for the storage of controlled medicines that require refrigeration. The refrigerator used to store controlled medicines requiring refrigeration can only be used to store only medicines.

Clause 9 New Section 533 (3A) and (3B)

This clause inserts new paragraphs (3A) and (3B).

Paragraph (3A) outlines the controls that must be in place for the safe storage of controlled medicines that require refrigeration including if refrigerators have or do not have locks.

Paragraph (3B) outlines the requirements for leaving controlled medicines in an unlocked refrigerator, room or enclosure.

Clause 10 New Section 533A

This clause enables pharmacists authorised under an opioid dependency treatment licence, to store OMT medication in a locked storage cupboard or drawer during the pharmacy's business hours.

Clause 11 Dictionary, note 3

This clause inserts 'medicine (see s 11)' into note 3 of the Dictionary in the MPTG Regulation.