Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2025 (No 2)

Subordinate law SL2025-29

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 the risk of medicinal misadventure, the diversion of regulated substances, and the manufacture of regulated substances that are subject to abuse. The MPTG Act outlines the appropriate prescribing 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 details for the regulatory framework established by the MPTG Act. The Commonwealth's Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) also referred to as the Poisons Standard, 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 and others may deal with a medicine and the conditions for such dealings. The Regulation also includes provisions allowing for the administration of emergency medicines, provisions introducing requirements for the disposal and storage of medicines and restrictions on the prescribing of medicines listed under Schedule 8 (Controlled drugs) (S8) of the SUSMP.

Under the MPTG Regulation, an authorised prescriber must have approval to prescribe an S8 medicine under Chapter 13 of the MPTG Regulation such as a Standing Controlled Medicines Approval or Chief Health Officer (CHO) Controlled Medicines Approval. CHO approvals are issued for each patient for a maximum of three years.

OVERVIEW OF AMENDMENTS

The Medicines, Poisons and Therapeutic Goods Amendment Regulation 2025 (No 2) (Amendment Regulation) seeks to make changes to the MPTG Regulation. These changes concern the:

- controlled medicines CHO standing approvals;
- duration of a CHO approval;
- revision of the definition of adrenaline as an emergency medicine;
- revision of the definition of an ambulance officer or paramedic and related provisions; and
- updates to endorsed prescribers.

Controlled medicines approvals and CHO standing approvals arrangements

Under section 20 (1) (c) of the MPTG Act, a person is authorised to deal with a regulated substance if the CHO approves the dealing under a regulation.

Currently, controlled medicines can only be prescribed with an approval under Chapter 13 of the MPTG Regulation (Controlled medicines and appendix D medicines approvals for human use). The MPTG Regulation, Division 13.1.2 (Standing controlled medicines approvals) permits the prescribing of controlled medicines to hospital in-patients or patient discharge, or for the short-term treatment of patients who are not-drug dependent.

All other controlled medicine prescriptions require approval in accordance with of the MPTG Regulation, Division 13.1.3 (Chief health officer medicines approvals). The Controlled Medicines Prescribing Standards (the Standards), as notified under the MPTG Regulation, set out how the CHO must consider any application for approval to prescribe a controlled medicine submitted under Division 13.1.3. These approvals are referred to as CHO approvals.

The Amendment Regulation inserts new section 554 (Standing CHO approvals to prescribe controlled medicines in certain circumstances—Act, s 20 (1) (c)) into the MPTG Regulation which provides a mechanism to allow the CHO, if satisfied that it is appropriate, to authorise a health practitioner or class of health practitioner to prescribe controlled medicines under a new CHO standing approval. Implementing standing approvals to prescribe controlled medicines, or equivalent authorities, are in-place across Australia and have proven to be a safe and effective regulatory measure in the ACT since introduction of the MPTG Act.

Introduction of a new CHO standing approval to prescribe controlled medicines aims to reduce unnecessary regulatory barriers to patients receiving appropriate treatment and to minimise associated administrative burdens on prescribers when considered safe and appropriate. Any CHO standing approval must be made as a notifiable instrument (NI) and provide the following:

- The class of designated prescribers to whom the approval relates,
- The controlled medicine or category of controlled medicines,
- If applicable, the particular form of the controlled medicine,
- If applicable, the strength of the controlled medicine,
- If applicable, the maximum daily dose of the controlled medicine,
- The conditions to which the approval is subject,
- The unique identifying number for the approval,
- The date the approval starts,
- If the approval is for a defined period, the date the period ends.

Three Year Limit on CHO approvals

Division 13.1.3 contains various restrictions on CHO approvals including that approvals may be valid for up to three years. While this restriction necessitates clinical review and public health assessment of a patient's long-term use of controlled medicines, it has also caused restrictions in a patient's timely access to continued therapy and access to medical specialists. The Amendment Regulation seeks to remove the maximum period under which an approval may be valid to enable the CHO greater flexibility in granting CHO approvals proportionate to public health risk and individual patient circumstances. This change may also help to reduce pressures on the ACT health care system by facilitating improved access to treatment and specialist care.

Minor and technical amendments - Adrenaline

Section 410 of the MPTG Regulation currently provides an authorisation to administer authorised naloxone, salbutamol and adrenaline to someone else who is in immediate need.

The associated definition of *'authorised adrenaline'*, being a *single use automatic injector delivering not more than 0.3mg adrenaline,* currently excludes some adrenaline products such those administering greater than 0.3mg of adrenaline and intranasal adrenaline products. The Amendment Regulation changes the definition of *'authorised adrenaline'* to allow for a broader range of adrenaline products to be administered in an emergency.

The changes are being made to provide for products that do not meet the current requirements as they are listed on the Australian Register of Therapeutic Goods under the Therapeutic Goods Act 1989 (Cwlth) and not because of any negative health outcomes attributable to the current construction of the MPTG Regulation.

Minor and technical amendments - Ambulance Services

The Amendment Regulation updates section 533 of the MPTG Regulation to include a person in charge of an ambulance service as an *'excluded person'* for the purposes of medicine storage requirements.

Currently, section 533 mandates that prescribed persons store controlled medicines in secure facilities as specified under the MPTG Regulation, Schedule 5 (Requirements for storage receptacles). These requirements are highly prescriptive and designed to prevent theft. However, the ACT Ambulance Service (ACTAS) has identified that automated dispensing cabinets used in ambulance stations do not align with these specifications. All persons, including excluded persons, are still subject to an obligation to keep medicines stored in a safe and secure manner so as to prevent unauthorised access.

Listing a '*person in charge of an ambulance service'* within section 533 (Storage of controlled medicines by certain other prescribed people—Act, s 61 (b) and (c)) recognises that ambulance services maintain appropriate security measures and better facilitates all ambulance services, whether operated by the Commonwealth or a State or Territory Government, to adopt more efficient and contemporary storage practices. This change aims to support operational flexibility while maintaining appropriate safeguards against medicine theft, diversion and misuse.

Minor and technical amendments - Endorsed prescribers

The MPTG Regulation has automatically recognised a health professional's professional endorsement to deal with scheduled medicines when issued by a National Board under of the

Health Practitioner Regulation National Law (ACT), section 94 (Endorsement for scheduled medicines) since 2015. Routine review of the MPTG Regulation has identified that this definition may not capture all relevant endorsements, such as those granted to nurse practitioners.

This Amendment Regulation clarifies that all endorsements made under the *Health Practitioner Regulation National Law (ACT),* Division 8 (Endorsement of registration) are recognised automatically under the MPTG Regulation. In keeping with the principles of the Health Professional National Registration and Accreditation Scheme, the Amendment Regulation also confirms that a health practitioner's endorsement of their professional registration prevails to the extent of any inconsistency to the MPTG Regulation.

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). Any limitations placed on human rights must be justifiable as reasonable limits set by laws in a free and democratic society, as required by section 28 of the HR Act.

The Amendment Regulation is considered to support and strengthen the protection of several rights afforded under the HR Act. Rights engaged by this Amendment Regulation are considered reasonable, necessary, proportionate and the least restrictive approach to achieve the overall policy objective.

Rights engaged
This Amendment Regulation engages and promotes the following rights under the HR Act:

- Section 9 – Right to life.

Section 9 - Right to life
Section 9 (1) of the HR Act recognises that everyone has the right to life and that no-one may be arbitrarily deprived of life. The Amendment Regulation is considered to promote the right to life through authorising a broader use of adrenaline products in an emergency and indirectly through establishing regulatory pathways to enable greater access to medicines and specialist healthcare.

Authorised use of adrenaline products in an emergency
Where a government is aware of a real and immediate risk to life, they must take reasonable action to protect individuals, including an obligation to take reasonable measures to safeguard against identifiable risks to life. This is considered to include the protection of health consumers against the harm caused by the misuse or abuse of regulated substances.

This Amendment Regulation authorises the supply and use of broader forms of adrenaline in emergency situations. Adrenaline is widely used as an emergency measure to counter the physiological effects of anaphylaxis, severe asthma and cardiac events. The use of adrenaline in

intranasal forms or automatic injectors is broadly considered safe, well-tolerated and critical to promote health and life in emergency situations. The Amendment Regulation provides that all formulations may be supplied and administered to people in emergency situations. In relation to naloxone, an 'emergency situation' may include a reasonable belief that a person considers that the supply or administration of naloxone is necessary to counter the effects of opioid overdose.

The use of adrenaline is directly related to improved health outcomes following anaphylaxis or severe respiratory or cardiac events. Authorising a person to administer a broader range of adrenaline products in an emergency is considered to directly align with the main object of the MPTG Act 'to promote and protect public health and safety' as well as promote the right to life under section 9 of the HR Act.

CHO controlled medicines standing approval

The Amendment Regulation establishes a new regulatory mechanism to approve the prescribing controlled medicines under new section 554 (Standing CHO approvals to prescribe controlled medicines in certain circumstances—Act, s 20 (1) (c)). It is acknowledged that any future authorisation granted by the CHO would likely engage the HRA. Consistent with Part 5A of the HR Act, the CHO must consider and act consistently with human rights when exercising any statutory functions, including authorising health professions to deal with medicines under new section 554 of the MPTG Regulation.

While section 9 of the HRA expressly protects life in creating an obligation not to arbitrarily take life and to safeguard life. It is widely accepted that this right also imposes a positive obligation on public authorities to take reasonable steps to promote the physical and mental well-being of individuals. Conversely, any arbitrary denial or unreasonable delay in access to necessary treatment may impair a person's physical or mental well-being and therefore engages the right to life.

This new provision will promote the right to life under section 9 of the HRA by enabling improved patient access to prescribed treatment and therapy, improve continuity of care and alleviate pressure on emergency services and hospital systems, and enhance the availability of health practitioners to patients through reduced administrative burdens.

The support for a person's right to life occurs when the CHO considers the need to safeguard and promote the health and wellbeing of patients when issuing a Standing Approval for Controlled Medicines under new section 554. While facilitate patient access to healthcare is a consideration, the obligation to promote access is considered alongside the obligation to protect public health (under the MPTG Act, section 6 (Objects). Accordingly, any Standing Approval instrument made by the CHO under new section 554 may include necessary limits or conditions to protect public health and mitigate against risks of harm from medicines misuse or overdose.

The Health and Community Services Directorate maintains ongoing review of legislative arrangements including instruments made by the CHO which affect consumer access to medicines to ensure regulatory controls continue to protect against medicine-related harms while enabling timely access to healthcare.

Additional reforms aimed at minimising administrative barriers in the delivery of health care — including measures that grant ambulance services greater flexibility in the storage of medicines, removing time restrictions on a CHO controlled medicines approvals, and clarifying who may

act as a witness in the administration or destruction of controlled substances — are expected to indirectly support healthcare operations. These changes may also promote the right to life under section 9 of the HRA by facilitating more efficient access to treatment and strengthening the responsiveness of ACT health care services.

CLAUSE NOTES

Clause 1 Name of Regulation

This clause declares the name of the Amendment Regulation to be Medicines, Poisons and Therapeutic Goods Amendment Regulation 2025 (No 2).

Clause 2 Commencement

This Regulation commences the day after its notification day.

Clause 3 Legislation Amended

This clause advises that this Amendment Regulation amends the Medicines, Poisons and Therapeutic Goods Regulation 2008 (MTPG Regulation). Following notification on the Legislation Register, a republication of the MPTG Regulation will be available. The new republication will feature the amendments made by this Amendment Regulation.

Clauses 4 and 21 Section 11 and Section 100, note

Thess clauses update the list in section 11 that sets out the overview of medicines authorisations under the MPTG Regulation.

Clauses 5-6 Section 12

These clauses update the examples and note in section 12 that provide an overview of the authorisation conditions for medicines.

Clauses 7-10 Sections 30-32

These clauses update the conditions and limits that are placed on a prescriber's authority to prescribe medicines mentioned in Schedule 1 of the MPTG Regulation. These amendments are as a consequence of other changes made by this Amendment Regulation. These amendments maintain existing restrictions that prohibit prescribers from self-prescribing restricted medicines and prevent endorsed health practitioners and prescribers in training from self-prescribing any medicine.

The amendments to section 31 revise the list of authorisation conditions for prescribing medicines. A prescriber's authority is now defined to include authorisation under Section 30 or Section 490.

These clauses update the list in section 32 that sets out the additional requirements for prescribing controlled medicines for human use. This update clarifies that if an approval is for a maximum daily dose of the medicine, the prescription must not exceed the maximum daily dose approved.

Clause 11 Section 41

This clause updates particulars for prescriptions to authorise any endorsed health professional to deal with medicines in accordance with a relevant endorsement by a National Board under the Health Practitioner Regulation National Law.

Clauses 12-16 and 18-20 Section 49 ,51, 56 and 61

Thess clauses omit a person's authorisation under section 50 and substitutes with an authorisation under section 50 or section 490.

Clauses 17, 22 Section 61 and 120

Thess clauses omit a person's authorisation under section 60 and substitutes with an authorisation under section 60 or section 490.

Clauses 23-27, 29-33, 36-37, 40-41 and 49 Section 123, 130, 134, 140, 142, 150,160, 161, 180, 351, 390, 490, Chapter 6 and Table 540

These clauses omit a person's authorisation under section 110 and substitutes with authorisation under section 110 or section 490. An endorsed health practitioner may be authorised to obtain and possess a medicine in accordance with an endorsement of the health practitioner's registration as amended by Clause 43 of this Amendment Regulation.

Clauses 34–35 Section 163

These clauses substitutes (d) if the approval is for a maximum daily dose of the medicine— the supply is for not more than the maximum daily dose approved. This change is required to clarify existing regulatory arrangements regarding the supply of controlled medicines during consultation.

Clauses 38-39 Section 360

These clauses substitute (i) a trainee dentist, intern doctor or endorsed health practitioner; omits section 30 and substitutes with section 30 (3) which revises the signposting for the definition of 'restricted medicine'.

Clause 42 Section 410(2) Definition of *authorised adrenaline*

This clause substitutes a new definition of 'authorised adrenaline' to be *'an automatic injector or intranasal delivery device that delivers a predetermined dose of adrenaline'* this will allow for a broader range of both injectable and non-injectable adrenaline products to be used in an emergency.

The effect of this amendment is described in further detail in the overview section of this Explanatory Statement.

Clause 43 Section 490

This clause substitutes section 490 of the MPTG Regulation to automatically adopt all health practitioner endorsements granted by a National Board under Division 8 of the *Health Practitioner Regulation National Law (ACT).* New section 490 (3) clarifies that an endorsement prevails to the extent of any inconsistency with the MPTG Regulation.

Previously, only those endorsements issued under section 94 of the *Health Practitioner Regulation National Law (ACT)* were subject to adoption by reference.

The effect of this amendment is described in further detail in the overview section of this Explanatory Statement.

Clauses 44-46, 50-51, 53-54 Section 510, 532, 541 and 545

These clauses revise the definition of a designated person to also include ambulance officer or paramedic, noting this does not include a student. This change updates several parts of the MPTG Regulation to include the term 'paramedic' alongside 'ambulance officer' following the establishment of the Paramedicine Board of Australia as a National Board in 2018 and its registration of 'paramedics' as health professionals.

Clause 47-48 Section 533

These clauses revise the definition of an excluded person and inserts *'the person in charge of an ambulance service'* as a person excluded from the storage requirements in section 533.

Clause 52 Section 544

This clause substitutes section 544 to add a new requirement providing a list of practitioners who can witness administration by an intern doctor. The list includes the addition of a paramedic or ambulance officer employed by the Commonwealth, the Territory or a State.

Clauses 55-56 Section 545 and 551

These clauses revise the list of persons who may act as a prescribed witness for the discarding of a controlled medicine. This includes adding a paramedic or ambulance officer employed by the Commonwealth, the Territory or a State to the list of prescribed witnesses.

Clause 57 New section 554

This clause inserts a new section 554 to allow prescribers to prescribe controlled medicines if they are a member of a class of designated prescribers specified by a notifiable instrument made by the CHO. New section 554 includes specific matters that must be listed as part of making any instrument under this section and that the CHO must consider the prescribing activity to be appropriate in the circumstances.

The effect of this amendment is described in further detail in the overview section of this Explanatory Statement under the subheading 'Controlled medicines approvals and CHO standing approvals arrangements'.

Clause 58 New section 559

This clause inserts a new section 559. Clause section 559 exempts approvals made under section 554 from restrictions in Division 13.1.3 of the MPTG Regulation.

Clauses 59 and 61-62 Section 561, 571 and 575

These clauses revise the parameters of a controlled medicine approval as a consequential amendment to other changes made by this Amendment Regulation.

Clause 60 Section 564

This clause omits part of s564 removing the maximum limit for approvals under Division 13.1.3. This will allow for prescribers to prescribe medicines under Division 13.1.3 for as long as clinically appropriate as opposed to the previous three-year limit.

Clause 63-74 Schedule 1

These clauses update the dictionary and associated technical amendments associated in Schedule 1. Amendments are minor, technical and consequential to amendments described above.