Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2025 (No 1)

Subordinate law SL2025–7

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 medications.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. The MPTG Regulation sets out which health professionals are able to deal with a medicine and the conditions for such dealings.

The MPTG Act enables the Chief Health Officer (CHO) to approve dealings under a regulation. The MPTG Regulation provides details for authorisations to deal with medicines.

OVERVIEW OF AMENDMENTS

Section 20 of the MPTG Act outlines authorisations to deal with regulated substances. Regulated substances include medicines, low harm poisons and moderate harm poisons. 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 health professionals are authorised to deal with medicines under Schedule 1 of the MPTG Regulation and section 490 of the MPTG Regulation. Schedule 1 of the MPTG Regulation lists health related occupations and their specific authorisations.

Section 490 of the MPTG Regulation authorises endorsed health practitioners to deal with medicine. Section 490 applies to a health practitioner whose registration is endorsed under the *Health Practitioner Regulation National Law (ACT)*. Endorsed health practitioners are only authorised to deal with a medicine in accordance with their endorsement. Currently nurse

practitioners, endorsed midwives, endorsed podiatrists and endorsed optometrists are authorised under section 490.

Health professional expanded scope of practice (ESOP) is increasing across Australia. While some health professional groups such as registered nurses are working with their national board to seek formal endorsement under the *Health Practitioner Regulation National Law,* other health professional groups are undertaking ESOP work at a state and territory level. For health professionals whose profession has not sought endorsement, such as pharmacists and Aboriginal and Torres Strait Islander Health Workers, states and territories may consider local legislative mechanisms to enable these health professions to deal with medicines.

The Amendment Regulation creates a mechanism to allow the CHO, if satisfied that it is appropriate, to authorise a health practitioner or class of health practitioner to deal with medicine or class of medicines to which the authorisation relates to, subject to conditions, through a notifiable instrument (NI). The NI must provide the following:

- The approved health practitioner or class of health practitioners,
- The dealings that the approval authorises,
- The medicines that the approval relates to,
- 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 period, the date the period ends.

The intent is for the NI to provide conditions that outline what services can be provided as part of the ESOP, where acting outside of these conditions is outside of the authorisation. This limitation is to ensure that all services provided as part of the ESOP are provided safely and correctly, for the benefit of the wider community.

"Health practitioner" is used, per its definition in the *Legislation Act 2001* to apply to any person registered under the *Health Practitioner Regulation National Law (ACT)* to practice a health profession, except for students. This mechanism is designed to be available to any regulated health profession that the CHO considers appropriate.

This mechanism affords a degree of flexibility with respect to the circumstances and conditions that may be provided including where the use section 490 is not considered appropriate, where health system needs are identified or updates to analogous authorisations are made in other jurisdictions.

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). As the Amendment Regulation creates a regulatory mechanism but does not explicitly authorise a group of health professionals to deal with a medicine, the Amendment Regulation is considered to not engage any human rights.

It is acknowledged that authorisations made under the MPTG Regulation by the CHO are likely to promote the right to life as these authorisations will improve patient access to certain medicines. 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 as part of their scope of practice and employment.

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 2025 (No 1).

Clause 2 Commencement

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

Clause 3 Legislation amended

This clause advises that this Amendment Regulation amends the MPTG Regulation. Upon commencement, this Amendment Regulation will alter 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 New section 11 (2) (w)

Section 11 of the MPTG Regulation provides an overview of medicine authorisations made under the regulation. This clause adds the authorisation under the new section 490A to the section 11 list of authorisations available under the MPTG Regulation.

Clause 5 Part 9.6 heading

This clause renames Part 9.6 “Authorisations for endorsed health practitioners” to “Other medicines authorisations for health practitioners” to reflect the addition of section 490A.

Clause 6 New section 490A

This clause inserts new section 490A- ‘Authorisations for health practitioners to deal with medicines with CHO approval- Act, s 20 (1) (c).

Section 490A enables the CHO to authorise a health practitioner or a class of health practitioners to deal with a medicine if the CHO is satisfied the approval is appropriate in the

circumstances. The approval must be in writing by NI and include the health practitioner or class of health practitioners approved, the dealings and medicines to which the approval relates, any conditions to which the approval is subject to, a unique identifying number for the approval, the date approval starts and if the period is for a period, then the date of the period.