Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2015 (No 1)

Subordinate law SL2015–19

made under the

Medicines, Poisons and Therapeutic Goods Act 2008, s184 (Regulation-making power)

EXPLANATORY STATEMENT

Overview

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 also has the purpose of ensuring that consumers of prescription and non-prescription medicines have adequate information to allow them to use medicines safely and effectively. The MPTG Act outlines a range of offences relating to dealings with regulated substances according to their listing in the Standard for the Uniform Scheduling of Medicines and Poisons.

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 prescribe, administer and dispense a medicine, and conditions relating to such dealings. Some provisions of the MPTG Regulation prescribe additional information required for licences or authorisations, whereas other provisions impose statutory licence conditions. There are also provisions of the MPTG Regulation specifying requirements for activities such as labelling, packaging and reporting information.

Section 31 of the MPTG Act specifies that a person must supply information as prescribed by regulation to the Chief Health Officer when a controlled medicine or declared substance is supplied on a supply authority. Section 81 of the MPTG Regulation details the information that must be supplied to the Chief Health Officer following the supply of a controlled medicine on a supply authority.

This Regulation seeks to adjust the rate at which information must be reported to the Chief Health Officer after a controlled medicine is supplied on a supply authority. This change will allow the Chief Health Officer to better monitor, identify and respond to public health risk events associated with the supply of controlled medicines. New electronic reporting methods have been introduced to help facilitate statutory reporting requirements.

This Regulation also seeks to align a health practitioner's authority to deal with medicines with any endorsement on their registration to deal with scheduled medicines under the *Health Practitioner Regulation National Law (ACT).* The change will enable health professionals to

practice and deal with medicines in the ACT in accordance with their registered scope of practice under the National Registration and Accreditation Scheme.

The change aims to prevent future inconsistencies between the ACT and other jurisdictions regarding a health practitioner endorsement for scheduled medicines.

Details

A detailed explanation of each clause of the Regulation follows.

Clauses

Clause 1 Name of regulation

The first clause of the Regulation declares the name of the Regulation to be the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2015 (No 1).*

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence the day after notification with exception to section 5. Section 5 is to commence two months after the date of notification.

Due to the operation of section 75(1) of the *Legislation Act 2001* (the Legislation Act) the naming and commencement provisions of this Regulation, clauses 1 and 2, commence automatically on the day the Regulation is notified. A note to that effect is included in the provision.

Clause 3 Legislation amended

This provision alerts the reader that this Regulation amends the MPTG Regulation.

Upon commencement this Regulation will alter the MPTG Regulation in accordance with the provisions that this Regulation contains. This Regulation will then be immediately repealed. Consequentially, from the date that this Regulation commences a new republication of the MPTG Regulation will be available. That new republication will feature the alterations made by this Regulation.

Clause 4 Section 11 (2) (v)

This provision inserts subsection 11(2)(v) to the MPTG Regulation to inform the reader that endorsed health practitioners are authorised to deal with scheduled medicines in accordance with section 490 of the MPTG Regulation.

Clause 5 Section 81

This provision amends section 81 of the MPTG Regulation to provide that a person must give the Chief Health Officer details about a controlled medicine supplied on a supply authority not later than seven days after the day the medicine is supplied. This change aims to provide the CHO with sufficient information to timely identify and respond to public health risk events. The reported information will also allow the CHO to make more timely and informed regulatory decisions relating to the supply of controlled medicines.

Clause 6 New part 9.6

This provision inserts new Part 9.6 and section 490 to the MPTG Regulation.
This change seeks to align a health practitioner's registered scope of practice with their authority to deal with medicines in the ACT. Section 490 authorises a registered health practitioner to deal with scheduled medicines in accordance with any practitioner endorsement as issued under section 94 of the *Health Practitioner Regulation National Law (ACT).*

This change better aligns the ACT with other jurisdictions under the health practitioner National Registration and Accreditation Scheme by allowing health practitioners to deal with medicines in accordance with their professional registration.

Clause 7 Section 863 (d) and note 6

Section 863 of the MPTG Regulation lists documents to which the Legislation Act, section 47 (6) does not apply. This clause omits section 863 (d) and note 6 from the MPTG Regulation as their inclusion is made unnecessary by the omission of schedule 1, part 1.8 item 2 as performed by this Regulation.

Clause 8 Schedule 1, part 1.8, item 2 and note

Schedule 1, Part 1.8, item 2 of the MPTG Regulation allows for a registered optometrist to deal with scheduled medicines in accordance with an endorsement issued by the Optometry Board of Australia under section 94 of the *Health Practitioner Regulation National Law (ACT).*

This clause omits Schedule 1, part 1.8, item 2 and note from the MPTG Regulation to remove unnecessary duplication in regulation. The operation of the omitted regulation is captured by new part 9.6 as inserted by this Regulation.

Clause 9 Dictionary, definitions of *national list* and *Optometry endorsement scheduled medicines registration standard*

This clause omits the dictionary definitions of *national list* and *Optometry endorsement scheduled medicines registration standard* as they are no longer required consequent to amendments made by this Regulation.