

**THE LEGISLATIVE ASSEMBLY FOR
THE AUSTRALIAN CAPITAL TERRITORY**

**MEDICINES, POISONS AND THERAPEUTIC GOODS (CONTINUED
DISPENSING) AMENDMENT REGULATION 2020 (NO 1)**

SL2020-3

EXPLANATORY STATEMENT

**Circulated by the authority of
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MEDICINES, POISONS AND THERAPEUTIC GOODS (CONTINUED DISPENSING) AMENDMENT REGULATION 2020 (NO 1)

Overview

The Therapeutic Goods Administration (TGA) administers the Poisons Standard, which classes medicines and poisons into schedules. The ACT adopts the Poisons Standard under the Medicines, Poisons and Therapeutic Goods Act 2008 (the MPTG Act) to regulate the supply of scheduled medicines in the ACT. The Poisons Standard also contains appendices which subject some substances listed in the schedules to additional exceptions or restrictions.

The objective of the 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 SUSMP.

The Medicines, Poisons and Therapeutic Goods Regulation (the MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. The MPTG Regulation sets out which health professionals can prescribe, administer and dispense medicines, 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 Regulation that specify requirements for activities such as labelling or packaging.

In 2013 the MPTG Regulation was amended by SL2013-28 to insert Part 4.3A (Authorisation to supply certain medicines without prescription – continued dispensing). Part 4.3A operates by automatically adopting a Continued Dispensing Determination made under section 89A(3) of the Commonwealth *National Health Act 1953*. A Continued Dispensing Determination made by the Commonwealth would specify pharmaceutical benefits that may be supplied by a pharmacist without a prescription and the conditions of supplying that pharmaceutical benefit.

The original intention behind the continued dispensing provisions of Part 4.3A of the MPTG Regulation was to allow pharmacists in the ACT to supply a prescription-only medicine to a person as a pharmaceutical benefit without a prescription in defined circumstances. This intention was expressed in the Explanatory Statement to SL2013-28:

The ACT Government has chosen to support the Continued Dispensing Initiative as it is envisaged it will improve patient access to prescription only medicines in defined circumstances where a patient has run out of their usual prescription. It is considered the Commonwealth initiative has appropriate conditions and implementation arrangements in place to ensure the safety of the public is maintained in circumstances where a prescription may be supplied by a pharmacist without a prescription.

It has recently been identified that despite the intention to limit continued dispensing to prescription only medicines Part 4.3A could inadvertently extend to other medicines, including those which are at risk of misuse or abuse such as Controlled (Schedule 8) medicines. This is because Part 4.3A automatically adopts a continued dispensing determination and is currently constructed to apply simply to 'a medicine', rather than specifically to prescription only medicines as per the original intention outlined the Explanatory Statement to SL2013-28. Accordingly, if a continued dispensing determination made under section 89A(3) of the Commonwealth *National Health Act 1953* were to include medicines other than prescription only medicines their continued dispensing would be permitted under Part 4.3A contrary to its intended application. This Regulation has been prepared to rectify that deficiency.

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 (CONTINUED DISPENSING) AMENDMENT REGULATION 2020 (NO 1)*.

Clause 2 – Commencement

Pursuant to this provision, the Regulation is to commence on the day after it is notified on the ACT Legislation Register.

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 255

Section 255 is amended by this provision by inserting the words “designated prescription only” before every reference to a ‘medicine’ in section 250. The effect of this simple change will be to significantly narrow the types of medicines for which continued dispensing can occur, and crucially removing the application of Part 4.3A to forms of medicines which commonly risk misuse or abuse. This change will mean the application of Part 4.3A is truer to its original intention, as outlined in the Explanatory Statement for SL2013-28.

Clause 5 – Section 255(2)

The clause inserts a new second subsection into section 255.

Section 255(2) instructs that the meaning of ‘designated prescription only medicine’ is that contained in section 250 of the MPTG Regulation. The meaning of a ‘designated prescription only medicine’ found in section 250 is:

- a prescription only medicine other than –
 - a) an anabolic steroid, and
 - b) an appendix D medicine, and
 - c) a benzodiazepine.

It is important to note that section 255(2) adopts the meaning of ‘designated prescription only medicine’ found in section 250, and not section 250 as a whole.