Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Controlled Medicines) Amendment Regulation 2016 (No 1)

Subordinate law SL2016–16

made under the

***Medicines, Poisons and Therapeutic Goods Act 2008*, Section 184 (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 Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act.

This MPTG Regulation amendment will support increased clinical flexibility for prescribers when prescribing certain controlled medicines for their patients within predetermined therapeutic limits for up to three years. The Chief Health Officer (CHO) will determine therapeutic limits and specific categories of approval which will be notified by notifiable instrument.

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 (Controlled Medicines) Amendment Regulation 2016 (No 1).*

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence one month after its notification day.

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 This Regulation will then be immediately repealed.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 41 (1) (g) (i)

Clause 5 Section 41 (2) (b)

These provisions remove the requirement for prescriptions to include 'relevant approval particulars' for controlled medicines.

Clause 6 Section 41 (4), definition of *relevant approval particulars*

This provision substitutes the meaning 'relevant approval particulars' to remove reference to an approval under section 556 of the MPTG Regulation requiring the words 'standing short-term approval', an approval under section 557 of the MPTG Regulation requiring the words 'standing opioid dependency treatment approval', and an approval under Division 13.1.13 of the MPTG Regulation requiring the words 'CHO approval number' followed by the approval's identifying number.

The requirement for prescriptions for designated Appendix D medicines to include the words 'standing approval' with further details when prescribed under section 591 of the MPTG Regulation remains in place.

The requirement for prescriptions for designated Appendix D medicines to include the words 'CHO approval number' followed by the approval's identifying number under section 593 of the MPTG Regulation also remains in place.

Clause 7 Section 561 (1) (c) and (d)

Clause 11 Section 571 (1) (b) and (c)

These provisions establish increased flexibility when prescribers apply for CHO controlled medicines approvals. In addition to applying for the form, strength and quantity of the medicine, these clauses also provide for an application to be made for an approved category. This category approval determination is made under the new section 575 of the MPTG Regulation.

Clause 12 Section 571 (1) (e)

This provision removes the requirements for a CHO controlled medicines approval to include an identifying number for the approval.

Clause 8 Section 561 (2)

Clause 9 Section 563 (b)

Clause 13 Section 571 (2)

These provisions remove reference to provisions relating to a person with a terminal illness. Under the previous legislation, a person with a terminal illness was only permitted to apply for morphine or oxycodone all forms, strengths and quantities for pain management.

Clause 10 Section 564

This provision establishes increased flexibility when prescribers apply for CHO controlled medicines approvals by increasing the validity of approvals from 1 year to 3 years.

Clause 14 New section 575

This new provision enables the CHO to determine the circumstances relating to a category approval determination. This category approval determination must be made by notifiable instrument and supports the establishment of increased flexibility when prescribers apply for CHO controlled medicines approvals. This provision provides examples of approval categories, although these examples are not exhaustive. One example is that there may be an approval category to allow prescribing of all forms, strengths and quantities of certain controlled medicines (anticipated to include more than morphine and oxycodone) for people with terminal illness.