Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2014 (No 2)

Subordinate law SL2014–26

made under the

Medicines, Poisons and Therapeutic Goods Act 2008, s184 (Regulation-making power)
Medicines, Poisons and Therapeutic Goods Act 2008, s188 (Regulations-medicines advisory committee)

EXPLANATORY STATEMENT

Overview

The Therapeutic Goods Administration administers the Standard for the Uniform Scheduling of Medicines and Poisons (the SUSMP), which classes medicines and poisons into schedules. The ACT adopts the SUSMP under the *Medicines, Poisons and Therapeutic Goods Act 2008* (the MPTG Act) to regulate the supply of scheduled medicines in the ACT. The SUSMP 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 2008 (the 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 Regulation specifying requirements for activities such as labelling or packaging.

Section 194 of the MPTG Act establishes the Medicines Advisory Committee (MAC). The MAC serves to provide advice or direction to the Chief Health Officer (CHO) regarding decisions on applications for approval to prescribe a controlled medicine and applications for endorsement to treat drug-dependency. The MAC may also consider applications for a review of any of the above decisions made by the CHO.

Section 188 of the MPTG Act specifies that a regulation may make provision in relation to the appointment of members to, and the procedures of, the MAC. In accordance with Part 15.2 of the MPTG Regulation, the MAC membership is limited to three medical doctors including a person with experience in the teaching or practice of psychiatry and a representative of the ACT branch of the Australian Medical Association.

This amendment regulation seeks to increase the membership of the MAC to address a perceived lack of expertise and community representation within the public health sector. The change allows for seven persons to be appointed to the MAC including a consumer representative, pharmacist, general practitioner, and doctor with experience in pain or addiction medicine.

This amendment regulation also seeks to affirm the MAC as an advisory committee by stipulating that the committee may only provide advice and not direction to the CHO on regulatory matters.

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 2014 (No 2).

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence the day after 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 557 (3)(d)

This amendment affirms the MAC's position as an advisory committee by expressing that the MAC may only give recommendations, not direction, to the CHO regarding decisions on applications for approval to prescribe a controlled medicine.

Clause 5 Section 563 (a)

This clause substitutes a reference to section 574 as amended by this Regulation.

Clause 6 Section 566 (3) and 566 (4)

This clause provides that the MAC may only give recommendations to the CHO after reviewing a decision made about an application for approval to prescribe a controlled medicine. The CHO must consider the MAC's recommendation. A recommendation must be in writing.

Clause 7 Section 567 (2) and 567 (3)

This provision amends subsections 567 (2) and 567 (3) of the MPTG Regulation to provide that the MAC may only give a recommendation to the CHO to amend or revoke a controlled medicines approval, whether or not the approval was given on the recommendation of the committee.

Clause 8 Section 568 (4)

This provision amends section 568 of the MPTG Regulation to state that the MAC may only provide recommendations to the CHO on regulatory matters.

Clause 9 Section 569 (3) and 569 (4)

This provision amends subsections 569 (3) and 569 (4) of the MPTG Regulation to provide that the MAC may only give a recommendation to the CHO following review of an application made under section 568 of the MPTG Regulation.

Clause 10 Section 570 (2) and note

This provision provides that the MAC may only recommend that the CHO include conditions for the safe and proper use of a controlled medicine in a controlled medicines approval. A note is included to clarify that the CHO must consider the MAC's recommendation.

Clause 11 Section 573 heading

This clause amends the heading of section 573 of the MPTG Regulation to complement other changes made by this Regulation.

Clause 12 Section 573 (1)

This provision amends section 573 of the MPTG Regulation to state that the MAC may only provide recommendations to the CHO on regulatory matters.

Clause 13 Section 573 (2) (a)

This clause amends section 574 of the MPTG Regulation to provide that the CHO may make a decision after considering a MAC recommendation.

Clause 14 Section 574

This clause amends section 574 of the MPTG Regulation to specify that the MAC may give draft guidelines to the CHO in relation to decisions on applications for approval to prescribe a controlled medicine. The CHO may approve the guideline as a notifiable instrument.

Clause 15 Section 584 (5) and (6)

This provision amends section 584 of the MPTG Regulation to provide that the MAC may issue a recommendation to the CHO after considering an application to prescribe a controlled medicine. A recommendation issued to the CHO must be in writing.

Clause 16 Section 635 (1) (b)

This provision amends the number of members that may be appointed to the MAC (excluding chairperson). This provision establishes six member positions.

Clause 17 Section 635 (2)

Subsection 635 (2) of the MPTG Regulation currently states that a person is not eligible for appointment to the MAC unless the person is a doctor. This clause amends sub-section 632 (2) to specify that persons appointed to the MAC under subsections 635 (3)(ac) and 635 (3)(ad) need not be doctors.

A pharmacist and consumer representative may be appointed to the MAC under subsections 635 (3)(ac) and 635 (3)(ad) as provided by Clause 18 of this Regulation. This amendment ensures that other members are not eligible for appointment to the MAC unless they are doctors.

Clause 18 New section 635 (3) (aa) to (ad)

This clause amends the MAC membership structure to allow for the appointment of a pharmacist, general practitioner, consumer representative and doctor with experience in pain or addiction medicine. These positions provide the MAC with greater expertise and consumer representation in-line with community expectation.

Clause 19 New section 635 (3A)

This clause inserts a new section to allow the MAC to continue functioning, despite the operation of section 635 (3), following an appointed member's dismissal or resignation before his/her appointed term until the earlier of 4 months or a new member is appointed.

Clause 20 Section 640

This clause adjusts the quorum of the MAC from two members to four members following the introduction of four new member positions under section 635 of the Regulation.

Clause 21 Section 643 (4)

This clause adjusts the quorum for the MAC when deciding if a member may participate in a discussion or decision about an issue for which the member has declared a material conflict of interest.

Clause 22 Section 643 (4), example

This clause adjusts an example to inform the operation of section 643 (4) in-line with the Regulation.

Clause 23 Section 644 (2)(a)

This clause inserts a provision stating that the Minister must end the appointment of a member appointed under section 635 (3)(ac) if the appointed member ceases to be a pharmacist.