Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2014 (No 1)

Subordinate law SL2014–23

made under the

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

EXPLANATORY STATEMENT

Overview

The Therapeutic Goods Administration (TGA) 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 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.

The TGA announced that sodium oxybate will be scheduled as a schedule 8 and Appendix D medicine under the SUSMP from 1 October 2014. Sodium oxybate is a salt derivative of gamma hydroxybutyrate and is indicated for the treatment of severe narcolepsy, sleep fragmentation and cataplexy. The change will allow specialists practicing in the areas of paediatrics, neurology and sleep medicine to prescribe sodium oxybate.

While changes to the SUSMP are adopted under the MPTG Act, local prescriber restrictions for Appendix D medicines under the MPTG Regulation require amendment to give specialist prescribers authority to prescribe sodium oxybate.

An additional change to the MPTG Regulation is also required to substitute reference to the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* with the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.* This update will help ensure that ACT medicine wholesalers act in accordance with best practice guidelines.

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 1).

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence the day after notification with exception to section 11. Section 11 is to commence on 1 October 2014.

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 270 (a)(i)

Section 270 of the MPTG Regulation specifies conditions for wholesalers supplying medicines under corresponding laws.

This clause substitutes reference to the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* with the updated *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.* This update is required in order to reference the most recent medicine wholesaler's code and promote best practice guidelines for ACT medicines wholesale.

Clause 5 Section 270 (a), note

This clause substitutes the note under section 270 of the MPTG Regulation in-line with earlier amendments.

Clause 6 Section 461 (b) (i)

Section 461 of the MPTG Regulation specifies authorisation conditions for medicines wholesalers licences as issued under section 44 of the *Medicines, Poisons and Therapeutic Goods Act 2008*.

This clause substitutes reference to the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* with the updated *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8.* This update applies the most recent medicines wholesaler code as an authorisation condition for wholesaler licences in line with best practice guidelines.

Clause 7 Section 461 (b), note

This clause substitutes the note under section 461 (b) of the MPTG Regulation in-line with amendments made by Clause 6 of this Regulation.

Clause 8 Section 650, note

This clause updates the note under section 650 of the MPTG Regulation to provide the reader with clearer information about where the referenced document can be accessed.

Clause 9 New section 863 (aa) and (ab)

Section 863 of the MPTG Regulation displaces the operation of section 47(6) of the *Legislation Act 2001* in regard to a range of publications made by a government or agency other than the ACT Government. Displacing the operation of section 47(6) of the *Legislation Act 2001* removes the requirement that the applied documents be a notifiable instrument under the MPTG Regulation.

This clause inserts subsections 863 (aa) and 863 (ab) in order to list the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8 and Medicines Australia Code of Conduct* as documents for which section 47(6) of the *Legislation Act 2001* does not apply.

Clause 10 Section 863, new notes

This clause inserts new notes 3A and 3B under section 863 of the MPTG Regulation to inform the reader that the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8* is accessible at www.tga.gov.au and the *Medicines Australia Code of Conduct* is accessible at www.medicinesaustralia.com.au.

Clause 11 Schedule 3, part 3.2, new item 6

The focus of Schedule 3 is standing approvals for designated Appendix D medicines. The Schedule consists of two Parts. Part 3.1 of the Schedule defines the four different approval conditions that are then placed upon certain specialist doctors by Part 3.2. Appendix D medicines are listed in the SUSMP.

This provision inserts a new item 6 into Part 2.3 of Schedule 3. The effect of item 6 is to authorise specialists practising in the specialist area of neurology, paediatrics or sleep medicine, to prescribe sodium oxybate; the medicine listed in column 3. Column 4 is left empty, reflecting that no special conditions are imposed on the prescribing of sodium oxybate. Sodium oxybate is a salt derivative of gamma hydroxybutyrate and is used to treat patients with severe narcolepsy, cataplexy and sleep fragmentation.

Clause 12 Dictionary, new definition of *Australian code of good wholesaling practice for medicines in schedules 2, 3, 4 and 8*

This clause substitutes the current dictionary definition for the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* with the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8* in-line with earlier amendments. The dictionary update informs the reader that that the new code has been prepared by the National Coordinating Committee on Therapeutic Goods, as in force from time to time.

The amendment also inserts a note to inform the reader that the *Australian Code of Good Wholesaling Practice for Medicines in Schedules 2, 3, 4 & 8* is accessible at www.tga.gov.au.

Clause 13 Dictionary, definition of *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use*

This clause omits the current dictionary definition of the *Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use* as substituted by Clause 12 of this Regulation.

Clause 14 Dictionary, definition of *medicines Australia code of conduct* , note

This clause updates the note under the MPTG Regulation's dictionary definition of *medicines Australia code of conduct* to provide the reader with clearer information about where the *Medicines Australia Code of Conduct* can be accessed.