Legislative Assembly for the

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2013 (No 1)

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Explanatory Statement

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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 (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 has announced a change to the Appendix D entry for nabiximols under the SUSMP that is to commence on 1 September 2013. Nabiximols is a cannabinoid medicine that delivers a similar therapeutic effect to cannabis. It is used to treat patients with moderate to severe spasticity secondary to multiple sclerosis. Nabiximols is commonly referred to by its trading name 'Sativex'.

At present nabiximols fall with paragraph 3 in Appendix D of the SUSMP, which requires that prescribers seek approval from the Secretary of the Commonwealth Department of Health and Ageing to be able to prescribe nabiximols. The change to the SUSMP announced by the TGA will move the nabiximols entry under Appendix D of the SUSMP from paragraph 3 to paragraph 1. This will remove the requirement to seek approval from the Secretary of the Commonwealth Department of Health and Ageing, and would instead restrict the prescribing of nabiximols to authorised medical practitioners.

Sativex has not been previously available in Australia. It is intended to become available from October 2013 following the TGA's approval of the product onto the Australian Register of Therapeutic Goods. The TGA's approval of the product is conditional upon it being prescribed by specialist physicians practising in neurology or rehabilitation.

While changes to the SUSMP are automatically adopted under the Act, local prescriber restrictions for Appendix D medicines are noted in Schedule 3 of the Regulation and require amendment to give Appendix D standing approval to allow for specialist prescribing of nabiximols.

An additional update to Schedule 3 of the Regulation is also required to give standing Appendix D prescribing approval for the medicine corifollitropin alfa to specialists practising in endocrinology, gynaecology or obstetrics. This amendment is consistent with Appendix D updates to the SUSMP in August 2010 that were previously overlooked. Corifollitropin alfa is used for ovarian stimulation in women undergoing in-vitro fertilisation.

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 2013 (No 1).

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence on 1 September 2013.

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 Schedule 3, part 3.2, item 2, column 3

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.

Item 2 in Part 2.3 of Schedule 3 relates to specialists practising in the specialist areas of endocrinology, gynaecology or obstetrics. Item 2 lists in the third column already lists eight Appendix D medicines that specialists in this area may prescribe. This provision adds corifollitropin alfa for human use to the medicines listed in column 3, consistent with the changes to the SUSMP being made by the TGA. Corifollitropin alfa is used for ovarian stimulation in women undergoing in-vitro fertilisation.

Clause 5 Schedule 3, part 3.2, new item 5

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 SUSDP.

This provision inserts a new item 5 into Part 2.3 of Schedule 3. The effect of item 5 is to authorise specialists practising in the specialist area of neurology or rehabilitation, listed in column 2, to prescribe nabiximols; the medicines listed in column 3. Column 4 is left empty, reflecting that no special conditions are imposed on the prescribing. Nabiximols is a cannabinoid medicine that delivers a similar therapeutic effect to cannabis. It is used to treat patients with moderate to severe spasticity secondary to multiple sclerosis