Legislative Assembly for the

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2013 (No 2)

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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 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.

The Fifth Community Pharmacy Agreement (Fifth Agreement) between the Australian Government and the Pharmacy Guild of Australia (the Guild) commenced on 1 July 2010 and is in place for five years. It recognises the key role played by community pharmacies in primary health care through the delivery of Pharmaceutical Benefits Scheme (PBS) medicines and related services. The initiatives announced under the Fifth Agreement aim to improve the quality use of medicine in the community and enhance access to quality pharmacy services in rural and remote areas.

Two of the initiatives announced under the Fifth Agreement are:

- The *Supply and PBS Claiming from a Medication Chart in Residential Aged Care Facilities Initiative* (the Medication Chart Initiative); and
- The *Continued Dispensing of Medicines in Defined Circumstances Initiative* (the Continued Dispensing Initiative)

Both initiatives were enabled under the *National Health Act 1953* on 1 July 2012.

The Continued Dispensing Initiative facilitates PBS funding for pharmacists to supply certain prescription-only medicines in defined circumstances. Continued dispensing can only occur in accordance with the conditions outlined by the Commonwealth's National Health (Continued Dispensing) Determination 2012 (the Continued Dispensing Determination).

The Continued Dispensing Determination, made under section 89A(3) of the *National Health Act 1953*, limits continued dispensing to circumstances where:

- the dispensing pharmacist considers it not practicable for a person to obtain a prescription for the medicine;
- the person held a valid prescription for the medicine immediately preceding continued dispensing;
- the medicine has not been supplied under continued dispensing within the last 12 months;
- the person has been assessed by a doctor to receive the medicine for a prolonged period and the person has been assessed by a doctor since commencing the medicine;
- the dispensed medicine is listed under the Determination; and
- the person or agent of the person, signs a declaration acknowledging receipt of the medicine without a prescription.

Adopting the 'Continued Dispensing Initiative' under the MPTG Regulation allows pharmacists in the ACT to supply a prescription-only medicine to a person as a pharmaceutical benefit without a prescription in defined circumstances.

The Continued Dispensing Determination is made under section 89A(3) of the *National Health Act 1953*. The Determination outlines the pharmaceutical benefits that may be supplied by a pharmacist without a prescription and the conditions of supplying a pharmaceutical benefit under the Continued Dispensing Initiative. The initiative's scope is currently limited to the dispensing of oral hormonal contraceptives and lipid modifying agents, through the range of pharmaceutical benefits listed in the Determination.

The National Health (Pharmaceutical Benefits) Regulations 1960 lists several conditions around the supply of pharmaceutical benefits under the Continued Dispensing Initiative including document keeping obligations. The Commonwealth Department of Health and Ageing consider these medicines to be well tolerated and pose a minimal health risk. The Pharmaceutical Society of Australia has also developed professional guidelines for pharmacists to reduce any risks associated with dispensing medicines under the initiative.

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.

The Medication Chart Initiative allows pharmacists to claim for the supply of PBS medicines to a residential aged care facility (RACF) from a standardised medication chart. At present, medication charts are used in addition to PBS prescriptions, which can lead to inefficiencies and medication errors. The Medication Chart Initiative aims to reduce the duplication of work by pharmacists and prescribers. The use of medication charts as a prescription is intended to improve processes and supply of medicines to RACFs.

The National Health (Residential Medication Chart) Determination 2012 (the Residential Medication Chart Determination) outlines the pharmaceutical benefits that may be supplied to a RACF using a standardised medication chart. The Determination also sets conditions for dispensing medicines using a standardised medication chart as well as particulars for a standardised medication chart. The Determination is made under section 93A(2) of the *National Health Act 1953*.

The ACT Government has chosen to support the Medication Chart Initiative as it is envisaged it will improve medicine management and supply arrangements to residential aged care facilities.

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 2).

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 New section 11 (2) (ea)

Throughout the MPTG Regulation there are sections that assign medicines authorisations. Section 11 is essentially a list of the MPTG Regulation sections that assign medicines authorisation, with those specific to health-related occupations in subsection 1, and all others in subsection 2.

Clause 13 of this Regulation will add into the MPTG Regulation a new Part 4.3A, containing two new sections; sections 255 and 256. Section 255 gives approved pharmacists authorisation to supply certain medicines without a prescription. As such, section 255 needs to be listed in section 11(2).

Accordingly, this provision adds a reference to section 255 into subsection 2, to be located at paragraph (ea) so that the numerical order of sections listed in the subsection is maintained.

Clause 5 Section 31 (b) (ii)

A prescriber's authorisation to prescribe medicines is subject to conditions set out in section 31 of the MPTG Regulation. Where a prescription is issued in writing, paragraph (b) (ii) of the provision currently requires that the prescription include the particulars mentioned in section 41 "on the front of the prescription".

National residential medication chart prescriptions will have several pages, generally set out in a booklet format. Many of the key particulars such as the details of the patient and of the prescriber will still be on the first page (the cover or front of the prescription), but the nature of national residential medication chart prescriptions is such that not all of the particulars can or should be on what would amount to the 'front' of the prescription. Accordingly, this provision modifies section 31 (b) (ii) by adding "(other than a national residential medication chart prescription)". The effect of these additional words is that the need for the particulars in section 41 to appear on the front of a prescription will still apply for all written prescriptions except for national residential medication chart prescriptions.

Clause 6 New section 31 (b) (iia)

As stated above, a prescriber's authorisation to prescribe medicines is subject to conditions set out in section 31 of the MPTG Regulation. This includes a condition that where a prescription is issued in writing, the prescription must include the particulars mentioned in section 41 "on the front of the prescription".

The nature and format of national residential medication chart prescriptions is such that it is not possible or appropriate for all of the key particulars to appear on the 'front' of the prescription. For this reason the previous clause of this Regulation modifies section 31 (b) (ii) so that the need for the particulars in section 41 to appear on the front of a prescription will still apply for all written prescriptions except for national residential medication chart prescriptions.

Without something further, excluding national residential medication chart prescriptions from the requirement in section 31 (b) (ii) would not only remove the need for all of the particulars to be on the front of the prescription, it would entirely remove the requirement for all necessary particulars to appear on national residential medication chart prescriptions.

Accordingly, this provision of the Regulation inserts into section 31 (b) a new paragraph (iia) which specifically deals with national residential medication chart prescriptions. The provision establishes that a

national residential medication chart prescription must contain all of the particulars mentioned in section 41 of the MPTG Regulation, but unlike paragraph (ii) of section 31 (b) these particulars only need to be present; they do not need to be on the front of the prescription.

Clause 7 New section 31 (2)

This provision inserts into section 31 of the MPTG Regulation a new subsection 2, which provides a definition for *national residential medication chart*. The meaning of a *national residential medication chart* included in subsection 2 is tied to the definition of a residential medication chart contained within section 19AA of the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960, as in force from time to time. The words "as is in force from time to time" operate so that the most current version of the National Health (Pharmaceutical Benefits) Regulations 1960 will always be the version to which reference is to be drawn.

A note is included with the subsection that advises that the National Health (Pharmaceutical Benefits) Regulations 1960 does not need to be notified under the Legislation Act to apply because the operation of section 47(6) of the Legislation Act has been specifically and expressly displaced. The note also gives the reader guidance as to where the National Health (Pharmaceutical Benefits) Regulations 1960 can be accessed.

Clause 8 New section 41 (2A)

Section 41 of the MPTG Regulation sets out the particulars that must appear on prescriptions. Included amongst this list is a requirement that the prescriber's professional qualifications be included, and also that the quantity of the medicine to be dispensed or administered be included. These two requirements are not considered necessary for national residential medication chart prescriptions. As such, this provision inserts into section 41 a new subsection, subsection (2A), which expressly provides that national residential medication chart prescriptions do not need to include the prescriber's professional qualifications or the quantity of the medicine to be dispensed or administered.

Clause 9 New section 100 (ba)

Section 100 of the MPTG Regulation gives an overview of the supply authorisations for medicines contained in the MPTG Regulation; currently listing sections 110, 251 and 260.

Clause 13 of this Regulation will add into the MPTG Regulation a new Part 4.3A, containing two new sections; sections 255 and 256. Section 255 gives approved pharmacists authorisation to supply certain medicines without a prescription. As such, section 255 needs to be listed in section 100. Accordingly, this provision adds a reference to section 255 into the section, to be located at paragraph (ba) so that the numerical order of sections listed in the subsection is maintained.

Clause 10 Section 120 (3), definition of *completed*, new paragraph (c)

Division 4.2.2 of the MPTG Regulation governs the dispensing of medicines. As only a pharmacist may dispense medicines the requirements imposed by this Division only concern pharmacists.

The Division instructs how medicines are to be dispensed, including authorisation conditions as set out in section 120. One such condition requires that completed prescriptions and associated records be kept for at least 2 years, commencing on the day that the prescription became completed. Subsection 3 of this provision gives guidance on when a prescription is regarded as completed.

As currently constructed however, subsection 3 could not apply to national residential medication chart prescriptions adequately or appropriately. This provision resolves that problem by inserting a new paragraph (c) into section 120(3) to provide for when a national residential medication chart prescription is to be considered complete, which is to be as of the date that the prescription is dispensed for the last time.

Accordingly, irrespective of how long a national residential medication chart prescription has been in effect, the requirement to keep it and associated records for two years will not commence until the day when medicines ceased to be dispensed under the national residential medication chart prescription.

Clause 11 Section 124 (2) (a)

Section 124 of the MPTG Regulation requires prescriptions to be marked and outlines how they are to be marked. Subsection 2 of the section requires paper-based prescriptions that have been completed to be marked 'cancelled'.

As currently constructed however, subsection 2 could not apply to national residential medication chart prescriptions adequately or appropriately. This provision resolves that problem by substituting the existing wording in paragraph (a) with wording that includes a reference to a national residential medication chart prescription.

Clause 12 Section 124 (3) (a)

Section 124 of the MPTG Regulation requires prescriptions to be marked, and outlines how they are to be marked. Subsection 3 of the section requires electronic prescriptions that have been completed to be marked 'cancelled'.

As currently constructed however, subsection 3 could not apply to national residential medication chart prescriptions adequately or appropriately. This provision resolves that problem by substituting the existing wording in paragraph (a) with wording that includes a reference to a national residential medication chart prescription.

Clause 13 New part 4.3A

Clause 13 of this Regulation will add into the MPTG Regulation a new Part 4.3A, which deals with the authorisation to supply certain medicines without a prescription; generally referred to as continued dispensing.

The part contains two new sections; sections 255 and 256. Section 255 gives approved pharmacists authorisation to supply certain medicines without a prescription. Section 256 imposes labelling requirements on approved pharmacists' authorisation to supply certain medicines without a prescription.

Section 255 applies only to an approved pharmacist. Clause 18 of this Regulation amends the dictionary of the MPTG Regulation to include a definition of an *approved pharmacist*, which is tied to section 84(1) of the Commonwealth *National Health Act 1953.* The provision directs that approved pharmacists are authorised to supply a medicine without a prescription if the medicine is listed as a pharmaceutical benefit under a continued dispensing determination, and the supply is in accordance with that determination.

Again, clause 18 of this Regulation amends the dictionary of the MPTG Regulation to include a definition of a *continued dispensing determination.* The definition of *continued dispensing determination* directs the reader to a determination made by the relevant federal Minister under section 89A of the Commonwealth *National Health Act 1953.*

The purpose of section 256 is to impose a requirement that any medicine supplied pursuant to section 255 has a label and sets out the required contents of that label. The labelling requirements in section 256 are generally consistent other provisions of the MPTG Regulation about labelling of medicines, requiring such details as the name of the person to whom the medicine is supplied, the date of supply, the details of the pharmacy, the name and brand of the medicine and its form, strength and quantity.

Clause 14 Section 752

Section 752 of the MPTG Regulation permits a paint to be manufactured, supplied or used for application to toys if it complies with specifications for coating materials for toys contained in the standard entitled "Safety of toys – Migration of certain elements". This standard is published jointly by Standards Australia and Standards New Zealand.

The standard on "Safety of toys – Migration of certain elements" used to be referenced as 'AS/NZS ISO 8124.3:2003', but has since been changed to 'AS/NZS ISO 8124.3'. This section is a technical amendment to update section 752 so that the current and correct citation for the standard is used.

Clause 15 Section 752, new note

Following on from clause 14, this provision contains another technical amendment relating to the manufacture, supply and use of paints for toys. This provision inserts a note that follows section 752 of the MPTG Regulation. The note clarifies that AS/NZS ISO 8124.3 does not need to be notified under the Legislation Act to apply because the operation of section 47(6) of the Legislation Act has been specifically and expressly displaced. The note also guides the reader to www.standards.org.au where standard AS/NZS ISO 8124.3 can be purchased.

Clause 16 Section 863

Section 863 of the MPTG Regulation displaces the normal operation of section 47(6) of the Legislation Act in regard to a range of publications made by a government or agency other than the ACT Government.

Prior to this Regulation, section 863 applied to just two documents, the Australian and New Zealand Standard to which section 752 relates, and to the Optometry Endorsement Scheduled Medicines Registration Standard. Section 863 also contained three notes. This provision of the Regulation removes the existing construction of section 863, and replaces it with an expanded version of the section with a slightly different construction, including extra notes.

Accordingly, section 863 as amended by this provision will displace the normal operation of section 47(6) of the Legislation Act for the following:

- AS/NZS ISO 8124.303 (Safety of toys – Migration of certain elements);
- the Optometry Endorsement Scheduled Medicines Registration Standard;
- the Commonwealth *National Health Act 1953;*
- the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960*; and*
- a continued dispensing determination made by the Federal Minister under section 89A of the *National Health Act 1953.*

Notes 3 to 5 in the section guide the reader to where the laws and standards mentioned in the section can be accessed or purchased.

Clause 17 Dictionary, note 2

The dictionary to the MPTG Regulation begins with three notes. The first note explains that the Legislation Act contains provisions relevant to the MPTG Regulation, including definitions, and Note 2 cites some specific examples of terms that are used in the MPTG Regulation for which a definition is found in the Legislation Act.

This provisions adds another term to Note 2, that of "AS/NZS", and refers the reader to section 164(2) of the Legislation Act. Section 164 of the Legislation Act is about references to standards published by or on behalf of Standards Australia, or by or on behalf of Standards New Zealand and Standards Australia jointly.

Clause 18 Dictionary, new definitions

This provision inserts into the dictionary new definitions of *approved pharmacist*, *continued dispensing determination*, *national residential medication chart prescription*, and *pharmaceutical benefit*, together with notes connected to those definitions.

The definitions of *approved pharmacist* and *pharmaceutical benefit* direct the reader to section 84(1) of the Commonwealth *National Health Act 1953*, as in force from time to time. The words "as is in force from time to time" operate so that the most current version of the *National Health Act 1953* will always be the version to which reference is to be drawn.

The definition given to *continued dispensing determination* is a determination, as in force from time to time, made by the relevant federal Minister under section 89A of the Commonwealth *National Health Act 1953*. The words "as is in force from time to time" operate so that the most current version of the *National Health Act 1953* will always be the version to which reference is to be drawn.

The meaning of a *national residential medication chart prescription* is tied to the definition of a medication chart prescription contained within section 19AA of the Commonwealth National Health (Pharmaceutical Benefits) Regulations 1960, as in force from time to time. As with the other definitions, the words "as is in force from time to time" operate so that the most current version of the National Health (Pharmaceutical Benefits) Regulations 1960 will always be the version to which reference is to be drawn.

The Commonwealth's *National Health Act 1953* deals with the provision of pharmaceutical, sickness and hospital benefits, and matters pertaining to medical and dental services. Section 84 of the *National Health Act 1953* is an interpretation provision, containing definitions specific to the Part pertaining to pharmaceutical benefits. When pharmaceutical benefits may be supplied by approved pharmacists without a prescription is addressed in section 89A of the *National Health Act 1953*. Subsection 3 of that provision gives the Minister for the Act the power to determine by legislative instrument what pharmaceutical benefits may be supplied by approved pharmacists without a prescription, and any conditions associated with that supply.

The notes that follow each of the definitions clarify that the subject of the definitions do not need to be notified under the Legislation Act to apply because the operation of section 47(6) of the Legislation Act has been specifically and expressly displaced. The note also gives the reader guidance as to where Commonwealth legislation such as the *National Health Act 1953* can be accessed.