THE LEGISLATIVE ASSEMBLY FOR

THE AUSTRALIAN CAPITAL TERRITORY

MEDICINES, POISONS AND THERAPEUTIC GOODS AMENDMENT REGULATION 2010 (NO 5)

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EXPLANATORY STATEMENT

Circulated by the authority of
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Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 5)

Overview

The *Medicines, Poisons and Therapeutic Goods Act 2008* (the Act) consolidated four Acts and their regulations regarding ACT law on medicines, poisons and prohibited substances; by repealing and replacing the *Poisons and Drugs Act 1978*, the *Poisons Act 1933,* the *Public Health (Prohibited Drugs) Act 1957*, and significantly amending the *Drugs of Dependence Act 1989.*

The Act gave effect to reforms required by the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (Galbally Review), and served to provide a more unified and workable scheme. In doing so, the Act adopts the Standard for the Uniform Scheduling of Drugs and Poisons (the SUSDP), developed by the National Drugs and Poisons Schedule Committee established under the *Therapeutic Goods Act 1989* (Cwlth).

The objective of the Act, as recommended by the Galbally Review, is to promote and protect public health and safety by minimising medicinal misadventure with and diversion of regulated substances, accidental or deliberate poisonings and the manufacture of regulated substances that are subject to abuse. The 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 Act establishes an authorisation and licensing framework for medicines and poisons, as well as grounds and powers for disciplinary action to be taken against authorised and licensed persons. The Act also controls the way in which medicines and poisons are dealt with through a range of offences, imposing a range of potential penalties, including the imposition of terms of imprisonment where appropriate. Enforcement of the offences is achieved through a comprehensive range of inspection and seizure powers, including the capacity to take and analyse samples.

The Medicines, Poisons and Therapeutic Goods Regulation

The Medicines, Poisons and Therapeutic Goods Regulation (the MPTG Regulation) provides the detail for the regulatory framework established by the Act. The MPTG Regulation contains the more substantive detail, specific requirements, or conditions for a range of activities and obligations contained within the Act. 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 MPTG Regulation specifying requirements for activities such as labelling or packaging.

This Regulation

The Act and the MPTG Regulation were developed to maintain, as much as possible, the status quo for health professionals in the ACT in the performance of their duties. On that basis, what a health professional, including midwives, could and could not do prior to the commencement of the Act was intended to be the same following the commencement of the Act.

In the 2009 Federal Budget the Commonwealth Government announced reforms that would give patients access to the Pharmaceutical Benefits Scheme (PBS) subsidies for services provided by midwives. To give full effect to these reforms amendments to State and Territory legislation to give midwives prescribing rights is necessary. In order for midwives to have the authorisation to prescribe medicines in the ACT amendments to the MPTG Regulation is necessary, which is the purpose of this Regulation.

Clauses

Clause 1 – Name of regulation

This section sets out the name of the Regulation as the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2010 (No 5).*

Clause 2 – Commencement

Pursuant to this provision, the Regulation is to commence on the day after notification on the ACT Legislation Register.

Clause 3 - Legislation amended

This section expressly states that the legislation amended is the *Medicines, Poisons and Therapeutic Goods Regulation 2008*.

Clause 4 – Section 30 (1)(c)(i)

Under section 30 of the MPTG Regulation, persons mentioned in column 2 of Schedule 1 of the MPTG Regulation may be authorised to prescribe a medicine. Prescribing a medicine is authorised if prescribing of the medicine is amongst the authorised dealings for the person listed in column 3 of Schedule 1 in relation to that person, and the prescribing is consistent with any listed restriction in column 3 of Schedule 1.

Additionally, where the prescription is a self-prescription, section 30(1)(c) currently states that the person must not be a trainee dentist or intern doctor. This clause amends that provision, adding trainee nurse practitioners and persons training to be an eligible midwife. This is consistent with the intention of the subsection, which is to expressly prevent those in training, be it dentists, doctors or midwives, from prescribing medications for themselves.

Clause 5 – New section 41 (1)(ia)

The MPTG Regulation requires that all prescriptions include the particulars listed in section 41(1). This provision inserts into section 41(1) and new paragraph ia. This additional paragraph applies if the prescriber is an eligible midwife. Consequently, if the prescriber is an eligible midwife the prescription must include the words ‘for midwifery use only’.

Clause 6 – New section 123 (ba)

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, as well as the authorisation conditions that apply to the dispensing of medicines. Section 123 imposes requirements that must be met in regard to the labelling of dispensed medicines. This provision inserts an additional paragraph into section 123; paragraph (ba). This additional paragraph applies if the prescriber is an eligible midwife. Consequently, if the prescriber is an eligible midwife the label on the dispensed medicine must state ‘for midwifery use only’.

Clause 7 – New section 161 (ia)

The supply of medicines, such as 'sample packs', during consultations is regulated by Division 4.2.6 of the MPTG Regulation. Like medicines dispensed under section 123, a medicine supplied pursuant to section 161 must have a label, and that label must include certain prescribed information. This provision inserts an additional paragraph into section 161; paragraph (ia). This additional paragraph applies if the prescriber is an eligible midwife. Consequently, if the prescriber is an eligible midwife the label on the supplied medicine must state 'for midwifery use only'.

Clause 8 - Section 360 (2)(a)(i)

Section 360 of the MPTG Regulation enables a person that is authorised to prescribed medicines to self-administer medicines in certain circumstances.

The provision permits a prescriber to self administer a restricted medicine, provided that the restricted medicine has been prescribed or supplied by another person who is authorised to prescribe. There are two exceptions. Under subsection (2)(a)(ii) the person that prescribed the restricted medicine cannot be related to or employed by the person that is self-administering.

The other exception, in subsection (2)(a)(i), is where the prescriber is a trainee dentist or intern doctor. This subsection is amended by clause 8 to also include trainee nurse practitioners and persons training to be an eligible midwife. As with clause 4, this is consistent with the intention of the subsection.

Clause 9 – Section 510(a), except notes

Section 510 of the MPTG Regulation sets out who is, for the purposes of Chapter 11, a prescribed person. Included at paragraph (a) are certain health professionals such as doctors, dentists and podiatrists. The effect of clause 9 is to add nurse practitioners and eligible midwives to that list of health professionals in paragraph (a) of section 510.

It is important to observe that the notes attached to section 510(a) are not affected, and therefore remain unaltered.

Clause 10 – New section 861 (4)

Section 861 of the MPTG Regulation operates to enable the Chief Health Officer to issue a permit to a public employee enabling that person to lawfully deal with a regulated substance or regulated therapeutic good, provided the dealing is in accordance with the permit. Such permits may identify the public employee by name, or by position held. The section also sets out the required contents of such a permit for it to be valid.

The *Legislation Act 2001* defines who is a public employee. In the majority of cases a public employee is a public servant. However, a public employee also includes a person employed by a territory instrumentality, a statutory office-holder, or a person employed by a statutory office-holder. Accordingly, it is through this provision that certain public servants are lawfully able to handle a regulated substance through the course of their employment.

This clause adds a fourth subsection to section 861. This new addition provides that in section 861 a reference to a public employee includes a policy officer. This amendment removes any doubt that the Chief Health Officer can give an authorisation to a police officer to deal with a regulated substance or regulated therapeutic good, just as the Chief Health Officer can for a public health officer or any other public employee.

Clause 11 - Schedule 1, part 1.5, new item 2

Schedule 1 of the MPTG Regulation sets out the authorisations for medicines held by each type of health-related occupation. This includes midwives, who are listed in Part 1.5 of the Schedule. Part 1.5 consists of a table with three columns; item, person authorised, and authorisation. At present there is only a single item, item 1, giving authorisations to a midwife.

The effect of this amendment is to add a second item, which gives authorisations to an eligible midwife. What constitutes an *eligible midwife* is defined by the *National Health Act 1953* (Cwlth).

Clause 12 - Schedule 3, part 3.2, item 4

The focus of Schedule 3 of the MPTG Regulation 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 Standard for the Uniform Scheduling of Drugs and Poisons (the SUSDP).

This clause amends item 4 of Part 3.2. The amendment adds to the medicines in column 3 ambrisentan for human use and sitaxentan for human use, with conditions 1 and 3 assigned. Lenalidomide for human use is also added, but is subject to conditions 1 and 2.

Clause 13 – Dictionary, new definitions

This provision inserts into the dictionary of the MPTG Regulation definitions of *authorised midwife* and *eligible midwife*, which are to have the meanings assigned to them by the *National Health Act 1953* (Cwlth).

A definition of *pharmaceuticals benefits scheme* is also inserted. This definition states that the *pharmaceuticals benefits scheme* is the scheme established under Part 7 of the *National Health Act 1953* (Cwlth) for the supply of pharmaceutical benefits.