Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2019 (No 1)

Subordinate law SL2019–23

made under the

***Medicines, Poisons and Therapeutic Goods Act 2008*, Section 184 (Regulation-making power)**

EXPLANATORY STATEMENT

The objective of the *Medicines, Poisons and Therapeutic Goods Act 2008* (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 provides for adoption of the Commonwealth Poisons Standard, which is used to categorise medicines and poisons for regulatory purposes as adopted by each State and Territory.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. With reference to medicine and poisons categorised by the Poisons Standard, the MPTG Regulation sets out which medicines health professionals are able to prescribe, administer and dispense, and the conditions relating to such dealings. Some provisions of the MPTG Regulation also prescribe additional information required for licences or authorisations.

Appendix D of the Poisons Standard, as adopted by the MPTG Act, sets out additional controls on the availability and use of Schedule 4 and Schedule 8 medicines. Certain health professionals are also afforded standing approval to deal with certain Appendix D listed medicines in accordance with the MPTG Regulation, Schedule 3. Currently a doctor may also apply to the Chief Health Officer for authority to deal with an Appendix D listed medicine, if the medicine is listed within Schedule 3 of the MPTG Regulation. This amendment regulation clarifies the ACT's adoption of the Poisons Standard Appendix D controls and under what circumstances and by whom these medicines may be dealt with through introduction of the new term of 'ACT listed Appendix D medicine'.

As part of their professional scope of practice and employment, some nurse practitioners may need to prescribe Appendix D medicines. This amendment regulation therefore specifies that a 'prescriber' may apply for approval to prescribe an Appendix D medicine, or deal with Appendix D medicines in accordance with the MPTG Regulation, Schedule 3. This wording is consistent with analogous provisions of the MPTG Act that concern a health professional's authority to prescribe medicines.

This regulation also makes amendments to provide that the Controlled Medicine Prescribing Standards, as notified by the Chief Health Officer, should be considered for all applications for approval to prescribe a controlled medicine. Currently the Controlled Medicine Prescribing Standards are limited to determining the circumstances where a health professional may deal with a defined category of controlled medicine as opposed to a stated form, strength and quantity of medicine.

The changes introduced by this amendment regulation update the MPTG Regulation clarify the ACT's controls concerning the prescription of Appendix D medicines and consolidate regulatory controls regarding applications to prescribe a controlled medicine within the Controlled Medicines Prescribing Standards. These amendments are technical in nature and are consistent with existing regulatory practices.

In accordance with the *Legislation Act 2001*, a regulatory impact statement was not required to be presented with this amendment regulation as the proposed subordinate law is not likely to impose appreciable costs on the community, or a part of the community.

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 the *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2019 (No.1)*.

Clause 2 Commencement

Pursuant to this provision, the Regulation is to commence on the day after its notification day.

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 30 (2), definition of restricted medicine, paragraph (b)

This clause substitutes the term 'designated Appendix D medicine' with 'Appendix D medicine' within section 30 of the MPTG Regulation to align with new terms as inserted by this amendment regulation.

Clause 5 Section 31 (1) (e)

This clause substitutes the term 'designated Appendix D medicine' with 'Appendix D medicine' within section 31(1)(e) of the MPTG Regulation to align with new terms as inserted by this amendment regulation and omit reference to section 33 of the MPTG Regulation.

Clauses 6-7 Section 33 and Section 41 (1) (h)

Clause 6 and Clause 7 of the amendment regulation omit section 33 and sub-section 41(1) (h) of the MPTG Regulation. These provisions are being omitted as they are made superfluous by this

amendment regulation. Regulatory controls imposed by these sections are incorporated elsewhere within the MPTG Regulation.

Clause 8 Section 41 (2)

This Clause restructures subsection 41(2) of the MPTG Regulation to reflect current drafting practices. This Clause also omits reference to not requiring details of relevant approval particulars for prescribing designated Appendix D medicines to reflect existing regulatory practice.

Clauses 9–12

Clauses 9 – 12 of this amendment regulation makes minor amendments to sections 41, 160 and 250 of the MPTG Regulation to provide greater clarification on the ACT's adoption of substances listed under Appendix D of the Poisons Standard (Cth), and those substances which may be subject to a standing approval authorisation in the MPTG Regulation.

Clause 13 – 14

Clauses 13 – 14 of this amendment regulation make minor consequential amendments to sections 562 and 563 of the MPTG Regulation to reflect change to s575 (Controlled Medicines Prescribing Standards) as introduced by Clause 17 this amendment regulation.

Clause 15 New section 563 (3) and (4)

This clause provides that the Chief Health Officer may make a decision on an application to prescribe a controlled medicine that does not align with any Controlled Medicines Prescribing Standards as notified under new section 575 of the MPTG Regulation in defined circumstances. These circumstances, as described by new section 563(3) of the MPTG Regulation include: if the application is in accordance with an entry listed in the Australian Register of Therapeutic Goods; if the Medicines Advisory Committee has provided a relevant recommendation; or if it is considered necessary for the continuation of the patient's treatment in the particular circumstances.

Clause 16 Section 571 (1) (b) (ii)

This clause makes a minor update to the wording of section 571 of the MPTG Regulation to reflect other changes as inserted by this amendment regulation.

Clause 17 Section 575

This clause substitutes section 575 'Category approval determination' of the MPTG Regulation to provide that decisions on applications for approval to prescribe a controlled medicine are considered against the Controlled Medicines Prescribing Standards. This change reflects current operational practices and aligns with the Controlled Medicines Prescribing Standards as currently notified under MPTG Regulation, s 575 - Category approval determination.
The Controlled Medicines Prescribing Standards are a notifiable instrument under this section.

Clause 18 Part 13.2 heading, note

Clause 17 substitutes a note to Part 13.2 of the MPTG Regulation to include reference to the term 'ACT listed Appendix D medicine' as inserted by this amendment regulation.

Clause 19 New sections 588 and 589

This clause inserts new sections 588 and 589 to the MPTG Regulation to clarify the ACT's adoption of the Poisons Standard Appendix D controls and under what circumstances these medicines may dealt with. New section 588 provides that the MPTG Regulation considers an Appendix D medicine to be a medicine listed in Appendix D of the Commonwealth Poisons Standard, but does not include a controlled medicine.

Any regulatory controls placed on Appendix D listed controlled medicines will be incorporated and applied within the ACT through the Controlled Medicines Prescribing Standards. Previous regulatory controls on the prescription of nabiximols and sodium oxybate (as existing Appendix D listed controlled medicines) have been repealed and incorporated within the Controlled Medicines Prescribing Standards, consistent with controls for all other controlled medicines.

New Section 589, as inserted by this amendment regulation introduces the term 'ACT listed Appendix D medicine'. An ACT listed Appendix D medicine means an Appendix D medicine that may appear in Schedule 3 of the MPTG Regulation 'Standing approvals for ACT listed Appendix D medicines'.

Clauses 20-24

Clauses 20 – 24 of this amendment regulation make minor consequential amendments to sections 591, 592, 593 and 594 as a result of introducing the terms 'ACT listed Appendix D medicine' and 'Appendix D' medicine. These clauses also updates the term 'doctor' with 'prescriber' under subsections 592(2) and 592(3) to reflect the potential for other health professionals to deal with Appendix D medicines as part of their professional scope of practice and employment.

Clauses 25-28

Clauses 25 – 28 of this amendment regulation make consequential updates to sections 593, 594 and Schedule 3 of the MPTG Regulation to reflect use of the new term ACT listed Appendix D medicine and other changes made by this amendment regulation. These clauses also retitle Schedule 3 of the MPTG Regulation as 'ACT listed Appendix D medicine – standing approvals'.

Clause 29 Schedule 3, Part 3.1

This clause amends the prescribing conditions within Schedule 3, Part 3.1 of the MPTG Regulation to reflect use of the new term ACT listed appendix D medicine. This clause also incorporates the *Poisons Standards (Cth)* Appendix D substances follitropin delta, pomalidomide, riociguat, enzalutamide, and macitentan as substances that may be dealt with under a standing approval authority and attaches conditions related to those dealings.

Clause 30 Schedule 3, Part 3.2

This clause amends the title of Schedule 3, Part 3.2 of the MPTG Regulation to reflect use of the new term ACT listed Appendix D medicine. This clause also updates the list of substances under Schedule 3, Column 3 to omit controlled medicines subsequent to the definition of Appendix D medicines as inserted by Clause 19 of this regulation.

Clauses 31 - 35

Clauses 31 – 35 of this amendment regulation makes minor consequential amendments to the MPTG Regulation's dictionary to reflect use of the terms 'Appendix D medicine' and 'ACT listed Appendix D medicine' as updated by this amendment regulation.