Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2021 (No 2)

Subordinate law SL2021-28

made under the

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

EXPLANATORY STATEMENT

PURPOSE AND OUTLINE

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 health professionals are able to prescribe, administer and dispense a medicine, and conditions relating to such dealings. Some provisions of the MPTG Regulation also prescribe additional information required for licences or authorisations.

Overview

The Amendment Regulation includes amendments to support the adoption of Canberra Script in the ACT. Canberra Script is a new online, real time prescription monitoring system being implemented in the ACT to assist prescribers (including medical practitioners and nurse practitioners) and pharmacists when they prescribe or dispense monitored medicines for consumers. Canberra Script is designed to reduce harm and preventable deaths in the community by supporting the safe and effective use of monitored medicines.

Canberra Script will replace the existing DAPIS Online Remote Access (DORA) real time prescription monitoring system which was implemented in 2019. Canberra

Script forms part of the new national Real Time Prescription Monitoring (RTPM) system being implemented across Australia. Each Australian jurisdiction will implement their own local version of the national RTPM system with core features and functionality to enable national consistency.

The Amendment Regulation changes to support the adoption of Canberra Script include:

- clarification of the standing approval to prescribe controlled medicines for hospital in-patient to include medicines provided on discharge,
- clarifying the standing short-term approval for prescribing controlled medicines to allow up to 2 months of treatment,
- removing the requirement for the quantity of controlled medicines to be annotated for a controlled medicine approval, and
- removing the requirement for pharmacists to check that a controlled medicines approval is in place prior to dispensing, with the exception of opioid maintenance treatment (OMT).

Other technical amendments that have been made in this Amendment Regulation include:

- updating the definition of an authorised activity for research institutions,
- updating the definition of the national residential medication chart (NRMC),
- removing the need to annotate the word cancelled after dispensing certain electronic prescriptions,
- the disapplying section 47(6) of the Legislation Act to allow for the ambulatory application of certain Australian Government and other instruments,
- allowing specialist dentists to prescribe hydroxychloroquine, and
- minor amendments to support electronic prescribing.

The Amendment Regulation includes amendments to increase the amount of morphine sulfate and allow a small amount of hydromorphone that may be kept at a residential aged care facility for administration to residents. This amendment follows consultation with stakeholders between 2019 and 2020 and is intended to assist with emergency palliative care in the aged care setting.

The Amendment Regulation substitutes the Minister with the Director-General for the MPTG Act as the appointer for the Medicines Advisory Committee (MAC). This change aligns the appointment process for the MAC with other comparable boards and committees across the ACT Government.

The ACT adopts the Appendix D in the Commonwealth Poisons Standards by reference, under the MPTG Act. The Therapeutic Goods Administration (TGA) has recently added ivermectin and nicotine for human consumption to Appendix D. Ivermectin was added to Appendix D due to concerns that ivermectin was been used as a non-approved treatment for COVID-19. The addition of ivermectin to Appendix D, restricts its use by general practitioners to certain medical conditions. Nicotine

was added to Appendix D by the TGA as part of the Commonwealth Governments amendments. These amendments enable nicotine to be legally supplied in Australia under a prescription from an Australian medical practitioner.

A detailed explanation of each clause of the Amendment Regulation follows.

Regulatory Impact Statement

In accordance with the *Legislation Act 2001,* a regulatory impact statement was not required to be presented with the Amendment Regulation as the amendments will not impose appreciable costs on the community.

The amendments made in the Amendment Regulation are predominantly technical in nature and are designed to reduce regulatory burden and red tape.

Human rights considerations

During the development of the Amendment Regulation, due regard was given to its compatibility with the *Human Rights Act 2004* (HR Act).

Rights Engaged

The Amendment Regulation will support the purposes of the MPTG Act, in particular to promote and protect public health and safety by minimising:

- the diversion of regulated substances for abuse and
- harm from regulated therapeutic goods.

Ensuring the effective administration of the regulation of medicines and poisons in the ACT through the Amendment Regulation as described in the outline above engages and promotes human rights under the HR Act including the right to privacy and the right to life.

The Amendment Regulation does not limit any rights under the HR Act.

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CLAUSE NOTES

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 2021 (No 2).

Clause 2 Commencement

Under this provision, the Regulation commences 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 clause advises 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 amendments made by this Regulation.

Clause 4 Section 31 (2) and note

The MPTG Regulation, section 31 (Authorisation conditions for prescribing medicines—Act, s 44 (1) (b) and (2) (b)) sets out the authorisation conditions for prescribing medicines via a NRMC prescription.

This clause amends the definition of an NRMC to refer to current Australian Government legislation. This amendment was required as the prior legislation referred to in the MPTG Regulation was repealed.

Clause 5 Section 41 (4), definition of relevant approval particulars

The MPTG Regulation, section 41 (Particulars for prescriptions) outlines the particulars for prescriptions and outlines the information that must be included on a prescription.

Clause 5 of the Amendment Regulation omits section 41 (4) of the regulation which established the definition for ‘relevant approval particulars”. This change brings section 42 into line with 2016 changes to the MPTG Regulation which removed the requirement in section 41(4) to annotate the Chief Health Officer (CHO) approval

number on a prescription when prescribing a controlled medicine. Omitting section 41 (4) removes any doubt as the information to be included with approval particulars.

Clause 6 Section 121 (3), definition of *authorised prescriber* and examples

The MPTG Regulation, section 121 (How medicines are dispensed) outlines how medicines are dispensed. This section has been amended to define an authorised prescriber for this section for prescription only and controlled medicines to be a person who is authorised to issue the prescription under the Act or another territory law with the exception of methadone and buprenorphine for the treatment of OMT. An authorised prescriber prescribing methadone and buprenorphine for OMT will still be a person who is authorised to issue the prescription under part 13.1.

Clause 7 Section 124 (1)

Clause 7 amends Section 124 to exempt electronic prescriptions from the requirement of 124 (3). The MPTG Regulation, section 124 (Marking dispensed prescriptions) establishes the requirements regarding how medicines are dispensed. Section 124 (3) required a pharmacist to mark an electronic prescription as "cancelled" in certain circumstances. Pharmacists are not able to meet this requirement as they are unable to mark an electronic prescription with the work cancelled as required under Section 124 (3) because the Australian Governments electronic prescription system or an electronic NRMC prevent a prescription from being reused.

Clause 8 Section 124 (3)

Clause 8 is consequential to the amendment in clause 7 described above.

Clause 9 Section 124 (4), new definition of national residential medication chart

Clause 9 is consequential to the amendment in clause 4 described above.

Clause 10 Section 430 (4), definition of authorised activity, new paragraph (d)

Clause 10 inserts new paragraph (d) within the definition of an ***authorised activity*** in section 430 (Authorisations for non-controlled medicines research and education—Act, s 26 (1) and (2) (b)) to include reasonable use of a non-controlled medicine to carry out the research if the relevant non-controlled medicine is integral to genuine medical or scientific research at the institution. This amendment was made following concerns by a research institution that the definition of an authorised activity was unclear on the auxiliary use of non-controlled medicines for research. This definition has been amended to ensure all research related purposes are captured within the definition of an authorised activity. Prior to this amendment section 430 did not

allow research institutions to use non-controlled medicines for auxiliary use in research.

Clause 11 Sections 555 and 556

Clause 11 amends the MPTG Regulation section 555 (Standing approval to prescribe controlled medicines for hospital in-patients) to include the prescription of controlled medicines for hospital in-patients on discharge. This amendment clarifies the intent of section 555 of the MPTG Regulation as this section did not previously specify if controlled medicines required for discharge were included in the standing approval under this section.

Clause 11 also amends the MPTG Regulation, section 556 (Standing approval to prescribe controlled medicines for short-term treatment) to clarify the intent of section 556 (b) to allow a prescriber to prescribe a controlled medicine under a standing short-term approval for up to 2 months in line with established medicine practice involving multiple single prescriptions designed to support patient safety and effectiveness.

Clause 12 Section 561 (1) (c) (i), except note

Clause 12 amends the MPTG Regulation, section 561 (Requirements for CHO controlled medicines approval applications), subsection 561 (1) (c) (i) to allow a quantum of controlled medicine for the approval period to be expressed as a daily dose from a start to end date. This amendment will facilitate prescribers to apply for CHO approvals for a defined duration without specifying the quantity of controlled medicines.

Clause 13 Section 635 (1)

Clauses 13 to 15 amend relevant sections in the MPTG Regulation, Part 15.2 (Medicines advisory committee) to change responsibility for the appointment of MAC members from the Minister to the Director-General for the MPTG Act. This change aligns appointment processes for the MAC with comparable advisory boards and committees across the ACT Government. Prescribing the Director-General as the appointer of the MAC is appropriate given the body's role is responsible for provides advice and recommendations to the Chief Health Officer and is made up of individuals with professional expertise and qualifications specified by the MPTG Regulation.

The MAC is established by section 194 of the MPTG Act. The MAC is established to provide expert advice to the Chief Health Officer on matters involving the prescription and supply of medicines in the ACT. This includes advice regarding controlled medicine approvals and applications for endorsement to treat drug dependency.

The MPTG Act, section 188 (Regulations—medicines advisory committee) provides that a regulation may make provision in relation to the appointment and procedures of the MAC.

Clause 14 Section 635 (1), note 2

This clause is explained under clause 13 above.

Clause 15 Sections 637 and 644

This clause is explained under clause 13 above.

Clause 16 Section 695 (3), definition of authorised activity, new paragraph (d)

Clause 16 amends the MPTG Regulation, section 695 (Authorisations for dangerous poisons research and education—Act, s 26 (1) and (2) (b)) to include within the definition of an ***authorised activity*** the 'reasonable use of the poison to carry out the research if the poison is integral to genuine medical or scientific research at the institution'. This definition has been amended to ensure all research related purposes are captures within the definition of an authorised activity. Prior to this amendment section 695 did not allow research institutions to use dangerous poisons for auxiliary use in research. This amendment relates to the amendment to section 430 in Clause 10 described above.

Clause 17 Section 863 (d)

Clause 17 amends the MPTG Regulation, section 863 (Disapplication of Legislation Act, s 47 (6)) to update the reference to the remade National Health (Pharmaceutical Benefits Regulations 2017 (Cwlth).

Clause 18 New section 863 (g) to (k)

This clause amends the MPTG Regulation, section 863 (Disapplication of Legislation Act, s 47 (6)) to displace the operation of section 47(6) of the *Legislation Act 2001* in regard to a range of publications made by the Australian Government or one of its agencies. 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 as they are remade or updated thereby allowing for an ambulatory application of the instruments.

Section 189(1) of the MPTG Act provides that a regulation may adopt or incorporate an instrument as in force from time to time as outlined in section 47 of the Legislation Act 2001. Section 863 of the MPTG Regulation allows for disapplication of section 47 (6) of the *Legislation Act 2001*, so that the adopted law as in force from time to time (ambulatory application) without requiring that a new version of instrument is notified on the Legislation Register.

Clause 18 amends section 863 to allow for disapplication of the following:

- National Immunisation Education Framework for Health Professionals

- Australian Immunisation Handbook
- National Vaccine storage guidelines: Strive for 5
- Australian Technical Advisory Group on Immunisation (ATAGI) Clinical guidance on use of COVID-19 vaccine in Australia
- National Guidelines for Medication-Assisted Treatment of Opioid Dependence

Disapplying the Legislation Act 2001, section 47(6) for each instrument is appropriate as the Australian Government or the relevant agency publishes the instrument on a website. This ensures the document is readily available to anyone affected by the instrument.

Clause 19 Section 863, new note
This clause inserts a new note signposting www.health.gov.au.

Clause 20 Schedule 1, part 1.11, item 1, column 3, paragraph (a) (ii)
Part 3.3 of the MPTG Regulation authorises a person to issue purchase orders, obtain, possess and supply medicines that are outlined in Schedule 1 of the MPTG Regulation. Schedule 1, Part 1.11 authorises the director of nursing or medical superintendent of a residential care facility to issue a purchase order, obtain, possess and supply not more than 5 ampoules, each of 1mL or less of morphine sulfate, at a concentration of 30mg or less of morphine sulfate per mL.

Clause 20 increases the amount of morphine sulfate ampoules and adds a small quantity of the lowest available strength of hydromorphone ampoules, that the director of nursing or medical superintendent of a residential care facility, which allows them to issue a purchase order, obtain, possess and supply for emergency administration to residents.

The amendment changes Schedule 1 Part 1.11 to:
- not more than 30 ampoules, each of 1mL or less, of morphine sulfate, at a concentration of 30mg/mL of less; and
- not more than five ampoules, each of 1mL or less, of hydromorphone, at a concentration of 2mg/mL or less.

The intent of this amendment is to facilitate improved access to controlled medicines for emergency administration to residents and to support end of life care. The quantity, type and strength of medicines included in the amendment has been limited to mitigate risks of harm from the administration of a controlled medicine at a facility due to potential dosing or selection error arising from the storage of both morphine and hydromorphone at aged care facilities. The amendments follow consultation with key stakeholders and reflect the current palliative care treatment practice.

Clause 21 Schedule 3, section 3.1, new definition of approved indication
Schedule 3 of the MPTG Regulation lists the Appendix D medications with standing approvals in the ACT.

Clause 21 inserts a new term in the definitions part for Schedule 3 being ***approved indication***.

Clause 22 Schedule 3, part 3.2, item 5, column 2

Clauses 22 to 25 are relevant to Schedule 3 of the MPTG Regulation. Medicines listed in Appendix D of the Poisons Standard are schedule 4 and 8 medicines that require additional controls on the possession and supply. Examples of these additional controls include limitations on who can prescribe these medicines and/or restricting the indications for use. The MPTG Act adopts the Commonwealth Poisons Standard by reference.

Under part 13.2 of the MPTG Act, a prescriber must have approval to prescribe an Appendix D medicine. Schedule 3 of the MPTG Regulation provides a standing approval to authorised prescribers to prescribe Appendix D listed medicines.

Minor amendments were made to hydroxychloroquine in Schedule 3, part 3.2, items 5 and 6. On 2 April 2020 the Commonwealth Government amended the Poison Standard to allow a specialist dental practitioner in the recognised speciality of oral health medicine to prescribe hydroxychloroquine. Schedule 3, part 3.2, item 5, column 2. has been amendment to allow dental health practitioners to prescribe hydroxychloroquine.

Clause 23 Schedule 3, part 3.2, item 6, column 2

Schedule 3, part 3.2, item 6, column 2 stated that a designated prescriber could prescribe hydroxychloroquine. The definition of a designated prescriber in the MPTG Regulation applies for part 13.1 Controlled Medicine Approvals. As there is no definition for a designated prescriber for schedule 3, it was unclear who was able to prescribe hydroxychloroquine. Clause 23 amends Schedule 3, part 3.2, item 6, column 2 to omit the word 'designated' and enable a prescriber to prescribe hydroxychloroquine.

Clause 24 Schedule 3, part 3.2, new items 7 to 9

Clause 24 inserts both ivermectin and nicotine for human use into the table in Part 3.2. The listing of ivermectin in Appendix D was introduced by the Therapeutic Goods Administration because of concerns with the prescribing of oral ivermectin for the claimed prevention or treatment of COVID-19. Ivermectin is not approved for use in COVID-19 in Australia or in other developed countries, and its use by the general public for COVID-19 is currently strongly discouraged by the National COVID Clinical Evidence Taskforce, the World Health Organisation and the US Food and Drug Administration.

Clause 24 inserts ivermectin at new items 7 and 8 in the table in Part 3,2 (Standing approvals for ACT listed Appendix D medicines). This amendment provides a standing approval for specialists from dermatology, gastroenterology and hepatology, infectious diseases, paediatric gastroenterology and hepatology, paediatric infectious diseases to prescribe ivermectin for any indication, and for use

in clinical trials. The amendment also provides an Appendix D standing approval for ivermectin to be prescribed, by a health practitioner authorised under their scope of practice to prescribe, for an approved indication.

The listing of nicotine in Appendix D was introduced by the Therapeutic Goods Administration as part of the Australian Governments amendments to the Poisons Standard to make nicotine, in liquid preparations, a Schedule 4 medication. As of 1 October 2021, liquid nicotine may be legally supplied in Australia under a prescription from an Australian medical practitioner.

Clause 24 inserts nicotine at new item 9 in the table in Part 3,2 (Standing approvals for ACT listed Appendix D medicines).

Clause 25 Schedule 3, part 3.2, new note

Clause 25 inserts a note with the *Poisons Standard Amendment (Hydroxychloroquine and Salbutamol) instrument 2020* (Cwlth) to signpost the relevant instrument.

Clause 26 Dictionary, definition of *national residential medication chart prescription*

Clause 26 updates the MPTG Regulation dictionary definition of the national residential medication chart.