Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 2)

Subordinate law SL2023-17

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 outlines the appropriate prescription and supply of medicines and defines the concepts of deal, supply, prescribe and administer in relation to medications.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the detail for the regulatory framework established by the MPTG Act. The Poisons Standard (Cwth) is adopted by reference under Part 3.3 of the MPTG Act. With reference to medicine and poisons categorised by the Poisons Standard, the MPTG Regulation sets out which health professionals can deal with a medicine and the conditions for such dealings. Some provisions of the MPTG Regulation also prescribe additional information required for licences or authorisations.

Overview of amendments

Under Division 13.1.3 of the MPTG Regulation, a person may apply to the Chief Health Officer (CHO) for approval to prescribe a controlled medicine. Applications are processed by ACT Health Directorate (ACTHD) staff as CHO delegates. In processing applications, CHO delegates are required to consider the objectives of the MPTG Act and follow any relevant guidelines or standards published under sections 574 – 575 of the MPTG Regulation. Applications approved by CHO delegates under Division 13.1.3 MPTG Regulation are entered into the Monitored Medicines Database.

A person may not be required to seek approval to prescribe a controlled medicine if the prescription relates to an in-patient at a hospital or for short-term treatment not exceeding two months in length (standing approvals). Prescribers and pharmacists are not currently obliged to consult the monitored medicines database before prescribing or dispensing controlled medicines.

On 3 February 2023, the Therapeutic Goods Administration (TGA) announced their final decision regarding the rescheduling of psilocybin and 3,4-methylenedioxy-methamphetamine (MDMA) in the Poisons Standard as a Schedule 8 substance (controlled medicine) in defined circumstances.

The TGA decisions will permit prescribing of MDMA for the treatment of post-traumatic stress disorder (PTSD) and psilocybin for treatment-resistant depression (TRD) by psychiatrists who are specifically authorised under the TGA's Authorised Prescriber scheme, effective from 1 July 2023.

Should MDMA or psilocybin be prescribed under an existing standing approval (Division 13.1.2), bypassing the CHO application pathway (Division 13.1.3), there is the potential for these medicines to be used in conjunction with other prescribed therapies. However, it is important to recognise that combining these substances with certain prescribed medicines can pose significant risks and potential harm to patients. It is this concern that has prompted the regulatory amendment.

The Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 2) (Amendment Regulation) seeks to amend the MPTG Regulation to enable the CHO to declare (via notifiable instrument) a controlled medicine to not be within the scope of Division 13.1.2. This mechanism grants the CHO the ability to declare in the future, any substance that necessitates exclusion from standing approvals. If further clinical evidence or guidance arises for these products, the notifiable instrument that declares their exclusion can be repealed.

The Amendment Regulation will allow the CHO to declare MDMA and psilocybin to be exempt from Division 13.1.2, and therefore require CHO approval in all circumstances. Requiring CHO approval will ensure all prescriptions for MDMA and psilocybin are entered into the Monitored Medicines Database. This information will improve drug safety by enabling treating health practitioners to view a psilocybin or MDMA therapy approval in the Monitored Medicines Database and inform prescribing or dispensing decisions.

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 do not impose appreciable costs or regulatory burden on the community. These amendments do not operate to the disadvantage of anyone or impose additional liabilities on a person.

It is however acknowledged that future declarations by the CHO under Division 13.1.2, section 556A of the MPTG Regulation through notifiable instrument, may potentially place a minor burden on medical specialists. In making any notifiable decision, the CHO will diligently evaluate all possible burdens and consider relevant human rights considerations.

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).

The Amendment Regulation engages the following HR Act rights:

- Section 8 – Right to recognition and equality before the law

The Amendment Regulation engages the right to recognition and equality before the law under the HR Act. This is because the initial medications subject to the CHO declaration under the new section 556A will be used to treat mental health conditions. As these medications provide new treatment options that are not currently available for people with PTSD and TRD, it is considered that the Amendment Regulation promotes equality.

Should other medications be declared by the CHO under section 556A, this may impact individuals with other health conditions. While acknowledging that Amendment Regulation encroaches on the right to equality, it is intended to promote patient safety.

- Section 9 – Right to life

Ensuring the effective regulation of medicines and poisons in the ACT, the Amendment Regulation as described above engages and promotes the right to life under the HR Act. The right to life is concerned with preventing the arbitrary deprivation of life and is relevant to the delivery of medical treatment.

The amendment has been prepared to improve patient safety for those prescribed MDMA or psilocybin as their treating health practitioners will be aware that the patient has taken these medications. This engagement is likely to also arise for any other future medicines that may be subject to a CHO declaration under new section 556A.

- Section 12 – Right to privacy and reputation

The Amendment Regulation outlined above engages the right to privacy and reputation under the HR Act. The right to privacy and reputation protects physical, psychological and bodily privacy, including the mandatory reporting of injuries or illnesses, as well as communication and informational privacy, such as the collection, use, retention and disclosure of personal or confidential information.

The right to privacy and reputation is engaged as the Amendment Regulation will result in the mandatory reporting of all prescriptions for MDMA and psilocybin in the ACT. This engagement is considered to be reasonably restricted and necessary in order to pursue a legitimate aim of improved safety and quality use of medicines. These changes are considered to closely align with core objects of the MPTG Act including to protect public health and safety through minimising accidental and deliberate poisons, and medicinal misadventures relating to regulated substances.

Information collected by ACT Government relating to the prescription of controlled medicines, including information stored on the Monitored Medicines Database, is considered personal health information and subject to strict privacy protections under the *Health Records (Privacy and Access) Act 1997* and MPTG Act. The Monitored Medicine Database records information on those using the site including username, device and records accessed. This information is available for ACTHD to safeguard against unauthorised access of information.

CLAUSE NOTES

Clause 1 Name of Regulation

This clause declares the name of the Amendment Regulation to be the Medicines, Poisons and Therapeutic Goods Amendment Regulation 2023 (No 2).

Clause 2 Commencement

Under this provision, the Regulation commences the day after notification.

Clause 3 Legislation amended

This clause advises that this Amendment Regulation amends the MPTG Regulation. Upon commencement, this Amendment Regulation will alter the MPTG Regulation in accordance with the provisions that this Amendment Regulation contains. Consequentially, from the date that this Amendment Regulation commences, a republication of the MPTG Regulation will be available. The new republication will feature the amendments made by this Amendment Regulation.

Clause 4 New section 556A

This clause inserts new section 556A to the MPTG Regulation that enables controlled medicines to which standing approvals do not apply. Under new section 556A(1) the CHO may declare a controlled medicine to which approvals under sections 555 and 556 do not apply. Under new section 556A(2) the declaration is a notifiable instrument.