

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2024 (No 1)

Subordinate law SL2024-36

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 prescribing and supply of medicines and defines the concepts of deal, supply, prescribe and administer in relation to medicines.

The Medicines, Poisons and Therapeutic Goods Regulation 2008 (MPTG Regulation) provides the details for the regulatory framework established by the MPTG Act. The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)(Cwlth) also referred to as the Poisons Standard 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 and others may deal with a medicine and the conditions for such dealings. Some provisions of the MPTG Regulation prescribe information about Schedule 4 (S4) and Schedule 8 (S8) medicine supply, administration and prescribing, and Medicines Advisory Committee (MAC) membership.

Additional provisions aim to reduce misuse or dependence and enhance the safety of S4 and S8 medicines and enhance safety for the possession and use of dangerous poisons.

The ACT Health Directorate consulted with relevant stakeholders in the development of the proposed amendments.

Overview of amendments

The *Medicines, Poisons and Therapeutic Goods Amendment Regulation 2024 (No 1)* (Amendment Regulation) seeks to make changes to the MPTG Regulation. These changes concern the:

- self-prescribing of monitored medicines
- inclusion of date of birth (DOB) on prescriptions
- emergency supply and administration of naloxone
- removal of limits on MAC membership and
- possession for industrial use of Schedule 7 (S7) poisons.

ACT Health undertook targeted stakeholder engagement during development of the proposed amendments.

Strong support was received for prohibiting the self-prescribing of monitored medicines, with respondents agreeing that the self-prescribing of monitored medicines poses a risk of harm and that this amendment would improve public safety and confidence.

Consultation with prescribers, pharmacists and the medical software industry regarding the scope of mandating DOB on prescriptions supported mandating DOB on all prescriptions as this aligns with NSW. This component of the proposed amendments will commence six months after notification due to feedback from the medical software industry regarding implementation timeframes.

Targeted consultation supported the inclusion of naloxone as an emergency medicine and agreed that including naloxone as an emergency medicine would improve access.

Discussion with the current MAC found strong support for expansion to include additional members.

Prohibiting self-prescribing of monitored medicines

Section 97A of the MPTG Act defines a monitored medicine to be a controlled medicine or a medicine declared by the Minister to be a monitored medicine.

On 30 August 2021, the Minister for Health, by disallowable instrument (DI), declared codeine, tramadol, all benzodiazepines, quetiapine, zolpidem, zopiclone, gabapentin and pregabalin to be monitored medicines.

The MPTG Regulation currently prohibits the self-prescribing of restricted medicines. Section 30 (2) of the MPTG Regulation defines restricted medicines to be anabolic steroids, appendix D medicines, benzodiazepines and/or controlled medicines. Benzodiazepines are now declared by the Minister to be monitored medicines.

The Amendment Regulation expands the definition of restricted medicines to all monitored medicines. Stakeholder consultation indicated strong support for prohibiting the self-prescribing of monitored medicines.

DOB on prescriptions

Under section 81 of the MPTG Regulation, pharmacists are required to provide the Chief Health Officer (CHO) with the patient's DOB prior to the supply of all monitored medicines. Under section 164 of the MPTG Regulation, a prescriber is required to provide the CHO with the patient's DOB for the supply of all monitored medicines. The Amendment Regulation requires the inclusion of a patient's DOB on all prescriptions. The amendments allow a pharmacist to dispense a prescription if a prescriber does not include this information.

Including DOB on all prescriptions seeks to improve the data quality within Canberra Script and potentially identify misuse of monitored medicines. At present, the ACT is the only Australian jurisdiction that has not mandated patient DOB for S8 prescriptions. NSW has successfully mandated DOB on all prescriptions. The Amendment Regulation provides better jurisdictional consistency with NSW and reduces cross-border inconsistencies. The amendment proposal was supported by stakeholders during consultation.

Supply and administration of naloxone in emergency situations

Currently, section 410 of the MPTG Regulation authorises the emergency supply and administration of adrenaline and salbutamol.

Section 410 of the Amendment Regulation authorises the supply and administration of naloxone in emergency situations. This enables timely and suitable assistance to individuals who are at risk of an opioid overdose or adverse reaction.

All registered naloxone available in Australia is permitted for use under section 410 of the Amendment Regulation. Subsequently, a definition of authorised naloxone is not included in the Amendment Regulation.

MAC Membership

Currently, section 635 of the MPTG Regulation limits the total number of MAC members to seven (one chair and six other members) and outlines membership requirements. The MAC limits its members to doctors, one pharmacist and one consumer representative.

The Amendment Regulation removes the cap on the number of MAC members, including the limit on pharmacists and members nominated by the Australian Capital Territory Branch (ACT Branch) of the Australian Medical Association (AMA). Additionally, the Amendment Regulation requires members to be health practitioners except for the consumer representative position. The Amendment Regulation allows additional members to assist in areas that are deemed beneficial, as long as they are health practitioners. Authorising health practitioners to join the MAC is intended to diversify the skillset and experience of the MAC by enabling other professions to join the MAC such as nurse practitioners. The Amendment Regulation also requires a chair to be appointed from the membership of the MAC. This allows a member to hold a position on the MAC and to be appointed as chair.

Section 644 of the MPTG Regulation requires that the Director-General end a member's appointment if they cease to be a doctor or a pharmacist, except for the consumer representative. The Amendment Regulation now requires that a member's appointment end if they cease to be a health practitioner, except for the consumer representative. This is to reflect the amendment to section 635 requiring members to be health practitioners, except for the consumer representative.

Consultation with current MAC members found strong support for the amendment proposal.

Licensing scheme for possession for industrial use of S7 poisons

The Poisons Standard listed in Appendix J, S7 poisons as requiring additional controls. This includes an appropriate authorisation for analytical or research purposes only. Additional restrictions on their possession and use must be applied for through an authorisation or licensing process.

The Amendment Regulation enables the CHO to determine that a person is authorised to deal with S7 poisons by DI. As a result, the CHO may authorise a person to use a S7 poison for the possession for industrial use of dangerous poisons.

DOB Regulatory Impact Analysis

The Chief Minister, Treasury and Economic Development Directorate confirmed that a Regulatory Impact Analysis was not required for mandating DOB on prescriptions as this amendment will not give rise to an appreciable impact.

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). Any limitations on human rights are justifiable as reasonable limits set by laws in a free and democratic society, as required by section 28 of the HR Act.

The Amendment Regulation is considered to support and strengthen the protection of several rights afforded under the HR Act as well as other statutory protections under the *Health Records (Privacy and Access) Act 1997* and MPTG Act. The human rights engaged by this Amendment Regulation are considered reasonable, necessary, proportionate and the least restrictive approach to achieve the overall policy objective.

Rights engaged

This Amendment Regulation engages and limits the following rights under the HR Act:

- Section 12 – Right to privacy and reputation.

Rights Promoted

This Amendment Regulation promotes the following rights under the HR Act:

- Section 9 – Right to life
- Section 12 – Right to privacy and reputation.

Section 9 - Right to life

Section 9 (1) of the HR Act recognises that everyone has the right to life and that no-one may be arbitrarily deprived of life. The right to life requires the ACT Government to safeguard life where there may be a real and immediate direct or indirect risk to life.

Where a government is aware of a real and immediate risk to life, they must take reasonable action to protect individuals, including an obligation to take reasonable measures to safeguard against identifiable risks to life, including to protect health consumers in the ACT against the harm caused by the misuse or abuse of prescription medicines.

This Amendment Regulation authorises the supply and use of naloxone in emergency situations. Naloxone is widely used as an emergency measure to counter the physiological effects of opioid overdose. The use of naloxone is generally considered safe and well-tolerated and is broadly regarded as critical in combating rates of injury and death due to opioid overdose. Naloxone may be administered in a range of methods including intravenously, intramuscular, subcutaneously, or intranasally. The Amendment Regulation provides that all formulations may be supplied and administered to people in emergency situations. In relation to naloxone, an 'emergency situation' may include a reasonable belief that a person considers that the supply or administration of naloxone is necessary to counter the effects of opioid overdose.

The use of naloxone is directly related to improved health outcomes following opioid overdose. Enabling consumers to lawfully supply and administer naloxone in emergency situations is considered to directly align with the main object of the MPTG Act 'to promote and protect public health and safety' as well as promote the right to life under section 9 of the HR Act.

In regard to DOB, this Amendment Regulation promotes the right to life under the HR Act by mandating to include patients' DOB in all prescriptions. This seeks to prevent individual harm from potential misuse of prescription medications by improving the ability to correctly identify a person.

Section 12 - Right to privacy and reputation

Section 12 (a) of the HR Act recognises that everyone has the right not to have their privacy interfered with unlawfully or arbitrarily.

This Amendment Regulation engages the right to privacy under the HR Act by requiring that a patient's DOB be a required field for prescriptions under the MPTG Act. A patient's DOB is considered personal information that may be used to identify the person. This requirement is therefore considered to engage the right to privacy under section 12 of the HR Act.

Legitimate purpose (HR Act, s 28 (2) (b))

The main objective of the MPTG Act is to promote and protect the public health and safety through minimising harm arising from the misuse, abuse or diversion of regulated substances and therapeutic goods.

Measures to include a patient's DOB on prescriptions for medicines are in pursuit of a legitimate purpose and further the objects of the MPTG Act. Including a patient's DOB on prescriptions improves patient identification and accuracy in health records. Enhanced accuracy in patient health records seeks to ensure appropriate access and safe use of prescription medicines, particularly monitored medicines. Including additional fields on prescriptions to correctly identify a patient is also considered to enhance the security of health records and reduce fraudulent activity. However, ACT Health does not have information available to demonstrate that this measure may reduce instances of fraud concerning prescription medicines.

Proportionality (HR Act, s 28 (2) (e))

A person's DOB is already collected by a range of government services to verify their identity and protect personal information. With exception to the ACT, all states and territories require a patient's DOB be recorded on a prescription for S8 medicines. This information is also collected by the Australian Government in providing Medicare services and is therefore routinely collected or validated by medical services such as GP clinics and hospitals when

providing health services. Given these arrangements, very few people could access prescription medicines without providing their DOB to one or more medical providers.

Inclusion of a person's DOB in health contexts is also subject to existing strict statutory controls under the *Health Records (Privacy and Access) Act 1997*. Identifying patient information is also protected from inappropriate access and use by health professionals under the MPTG Act (as it relates to the monitored medicines database), the *Health Practitioner Regulation National Law (ACT)* and the *My Health Records Act 2012 (Cwlth)*.

To ensure the operation of this Amendment Regulation operates in the least restrictive manner and ensure consumer access to a prescribed medicine is not inadvertently limited, new section 121 (2A) of the Amendment Regulation provides that a prescription is not invalid for failing to include a patient's DOB or address.

Furthermore, new subsection 41 (1) (da) allows a period for prescribers and dispensers to put in place arrangements with practice software providers to include patient DOB as a required field. This new requirement commences six months from the Amendment Regulation's notification day. This delayed commencement enables software providers to update medical prescribing and dispensing software to recognise patient DOB.

In recognising the existing statutory controls that govern the access and use of patient health information, the collective community benefits of including a patient's DOB be listed on prescriptions is considered reasonable, proportionate and in pursuit of a legitimate purpose.

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 2024 (No 1)*.

Clause 2 Commencement

Under this provision, the Regulation commences the day after its notification, except for clauses 6-8 which commence 6 months after its notification day.

Clause 3 Legislation amended

This clause advises that this Amendment Regulation amends the MPTG Regulation. Following its notification on the Legislation Register, a republication of the MPTG Regulation will be available. The new republication will feature the amendments made by this Amendment Regulation.

Clause 4 Section 11 (2) (m)

Section 11 (Overview of medicines authorisations under this regulation) provides an overview or summary of authorisations that are specific to health-related occupations and other authorisations under the MPTG Regulation. This clause inserts the word 'naloxone' after the word 'adrenaline' under subsection 11 (2) (m). This subsection signposts the

operative provision section 410 (Authorisations to supply and administer adrenaline, naloxone and salbutamol—Act, s 26 (1) (b) and s 37 (1) (b)) as amended.

Clause 5 Section 30 (2), definition of *restricted medicine*, paragraphs (c) and (d)

Section 30 (1) (c) (ii) prohibits self-prescription of restricted medicines. This clause substitutes paragraphs '(c) a benzodiazepine; or' and '(d) a controlled medicine' with a new paragraph "(c) a monitored medicine."

The Amendment Regulation expands the definition of restricted medicines to all monitored medicines. Monitored medicines are controlled medicines (S8) and other medicines declared by the Minister to be a monitored medicine, including benzodiazepines. This extends the prohibition of self-prescribing to all monitored medicines.

Clause 6 Section 41 (1) (d)

Section 41 (Particulars for prescriptions) sets out the mandatory information requirements for prescriptions. Existing subsection 41 (1) (d) requires that all prescriptions include the name and address of the person for whom the medicine is prescribed. Subsection (1) (d) has been amended to include date of birth. This amendment will require that a patient's DOB is included on all prescriptions.

Clause 7 New section 121 (2A)

This clause inserts subsection (2A). This allows pharmacists to dispense a medicine if the prescription does not comply with the requirement of including person's address or DOB. This ensures patient access to prescribed medications and promotes access to healthcare.

The inclusion of the patient's address in 121(2A) in the Amendment Regulation is intended to allow pharmacists to dispense a prescription in the event the prescription omits DOB or address. This will significantly reduce delays in patients accessing their medication as it reduces the risk of the pharmacist voiding a prescription due to lack of these particulars. This also ensures the regulation does not operate in a manner that discriminates against vulnerable groups, such as individuals experiencing housing insecurity and promotes access to primary healthcare.

Clause 8 Section 125 (g)

Section 125 (Recording dispensing of medicines) sets out the particulars that must be recorded by the dispensing pharmacist. Section 125 (g) requires the dispensing pharmacist to ensure the name and address of the person for whom the medicine is dispensed is made on all prescriptions. This clause inserts 'date of birth' after the word 'name'. This ensures the dispensing pharmacist makes a written record of DOB on all prescriptions.

Clause 9 Part 9.2 heading

This clause substitutes the heading for Part 9.2 to insert the word 'naloxone' after the word 'adrenaline'. This includes naloxone in the requirements for an emergency supply and administration.

Clause 10 Section 410 heading

This clause substitutes the heading for section 410 to insert the word ‘naloxone’ after the word ‘adrenaline’. This includes naloxone in the requirements for an emergency supply and administration.

Clause 11 Section 410 (1)

This clause inserts the word ‘naloxone’ after the word ‘adrenaline’ to authorise the supply and administration of naloxone in emergency situations.

Clause 12 Section 635 (1) and (2) and note

Section 635 (Medicines advisory committee—membership) sets out the membership requirements for the MAC as appointed by the Director-General. Section 635 limits the total number of MAC members to seven (one chair and six other members) and outlines membership requirements.

This clause substitutes new subsections (1), (2) and the note removing the restriction on the number of members that may be appointed by the Director-General.

Subsection (1) removes the cap on the number of MAC members.

Subsection (2) outlines that the chair must be selected from the members appointed by the Director-General.

Subsection (2A) outlines that only a health practitioner is eligible for appointment to the MAC, except for the consumer representative.

The amendment does not change requirements for members to be drawn from health professional groups and one member who represents consumers. As such the removing of the cap on the number of members does not erode the number and representative character of the MAC.

Clause 13 Section 635 (3) (d) and (f)

This clause inserts ‘at least’ before ‘1 member’ in subsections (3) (d) and (f). This permits more than one member to be appointed as pharmacist or nominated by the ACT Branch of the AMA.

Clause 14 Section 644 (2) (a) and (b)

This clause omits paragraphs “(a) if the member (other than a member mentioned in section 635 (3) (d) or (e)) ceases to be a doctor; or” and “(b) for a member mentioned in section 635 (3) (d)—if the member ceases to be a pharmacist; or” and substitutes a new paragraph “(a) if the member (other than a member mentioned in section 635 (3) (e)) ceases to be a health practitioner; or”. This requires that a member of the MAC to continue to be a health practitioner to remain on the committee.

Clause 15 Section 690 (1), definition of relevant dealing, paragraph (d)

This clause is minor and technical in the it removes a duplication. The clause omits paragraphs “(d) issuing a purchase order for the poison” which duplicate the dealing listed at paragraph (a).

Clause 16 New Section 690 (3) and (4)

Section 690 (Manufacturing etc authorisations for dangerous poisons—Act, s 20 (2) (a)) provides for the dealings by certain categories of people of certain dangerous poisons with reference to schedule 4 (Dangerous poisons— manufacturing etc authorisations) of the Regulation.

This clause inserts subsection (3) and (4) after the note at the end of subsection (2).

Clause 690 (3) enables the CHO to determine a person to deal with a dangerous poison (S7) for an industrial use.

Clause 690 (4) required the determination to be made by DI.

Clause 17 Dictionary, note 3

This clause inserts ‘monitored medicine (see s 97A)’ into note 3 of the Dictionary in the MPTG Regulation.