

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 3)

Subordinate law SL2020–24

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 medicines 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.

This Medicines, Poisons and Therapeutic Goods Amendment Regulation 2020 (No 3) (amendment regulation) amends the MPTG Regulation to allow the Minister to exempt certain people dealing with buprenorphine or methadone from the MPTG Act. It also exempts certain people from the MPTG Act during the COVID-19 emergency. These exemptions are proposed to ensure that persons who are prescribed buprenorphine or methadone for opioid dependency treatment (ODT, as known as Opioid Maintenance Treatment or OMT) are able to access their ODT during emergency situations by allowing an agent to deal with the prescribed ODT on their behalf.

ODT involves substituting an opiate with either methadone or buprenorphine under the supervision of a prescriber. Methadone and buprenorphine are controlled medicines. Dealing with controlled medicines are highly regulated under the MPTG Regulation.

During a public health emergency (including the COVID-19 pandemic) or other event ODT patients may be unable to attend their usual ODT centre for supervised doses or to collect take away doses. This may put ODT patients at risk of overdose and, in turn, drug-related death if they are unable to access their ODT and attempt to source other drugs as an alternative. Conversely, without adequate contingency arrangements, ODT patients may seek to attend an ODT centre and thereby create other risks (e.g. if the ODT patient should be in isolation due to

a COVID-19 diagnosis, regular attendance at an ODT centre may put the community at increased risk of COVID-19 exposure or transmission). As such, contingency arrangements may provide for an agent to be able to obtain, possess and supply ODT, subject to any conditions.

Section 371 of the MPTG Regulation contemplates a person obtaining and possessing a medicine on someone else's behalf, however may not provide sufficient protection and legal certainty as to all actions to be undertaken by an agent where they are acting in accordance with contingency arrangements.

This amendment regulation is therefore made for the abundance of caution to put the legality of an agent's actions beyond doubt, where they are acting in accordance with approved ODT contingency guidelines.

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. This regulation is not considered to limit civil protections afforded by the *Human Rights Act 2004*.

Details

A detailed explanation of each clause of the amendment regulation follows.

Clauses

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 2020 (No 3).

Clause 2 Commencement

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

Clause 3 Legislation amended

This provision alerts the reader 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. This amendment regulation will then be immediately repealed. Consequently, from the date that this amendment regulation commences, a new republication of the MPTG Regulation will be available. That new republication will feature the alterations made by this amendment regulation.

Clause 4 Part 15.1 heading

This clause substitutes a new heading for Part 15.1.

Clause 5 New sections 631 and 632

This clause inserts a new section 631 and 632 of the MPTG Regulation.

Section 631 provides that the Minister may exempt from the MPTG Act a person who is an agent of an ODT person and who is dealing with buprenorphine or methadone for the ODT person. The purpose of section 631 is to allow the Minister to create such exemptions in response to a public health emergency or other event that may limit an ODT person's access to ODT treatment. Section 190 (2) of the MPTG Act provides that the exemption may be conditional (e.g. subject to guidelines).

The definition of an agent provided by section 631 (3) is set out by the ODT contingency guidelines. The ODT contingency guidelines are made by the Chief Health Officer under section 192 of the MPTG Act.

Section 632 provides that an agent of an ODT person is exempt from the MPTG Act if the agent is dealing with the ODT on behalf of an ODT person who is unable to attend an ODT centre because of a COVID-19 emergency. As an example, an ODT person may be unable to attend an ODT centre for variety of reasons, including:

- the ODT person is, or is a close contact of, a laboratory confirmed case of COVID-19 and is advised to self-isolate or quarantine;
- the ODT person has symptoms of COVID-19 and is advised to self-isolate or quarantine; or
- the circumstances of the COVID-19 pandemic have interrupted the normal operation of an ODT centre(s).

The exemption provided under section 632 only applies if the agent complies with the notified ODT contingency guidelines when dealing with the ODT.

Section 632 will expire when there is no COVID-19 emergency in force.

Clause 6 Dictionary, note 3, new dot point

This clause inserts a new dot point for 'opioid dependency treatment centre' into a list of terms that, for clarity, are noted as having the same meaning in the MPTG Regulation as they do in the MPTG Act.