

Australian Capital Territory

Medicines, Poisons and Therapeutic Goods (Monitored Medicine) Declaration 2021 (No 1)

Disallowable instrument DI2021–224

made under the

Medicines, Poisons and Therapeutic Goods Act 2008, section 97A (Meaning of monitored medicine)

EXPLANATORY STATEMENT

The *Medicines, Poisons and Therapeutic Goods Act 2008* (the MPTG Act), section 97A (Meaning of *monitored medicine*) defines a monitored medicine to be either a controlled medicine or a medicine declared by the Minister to be a monitored medicine.

Section 97A also provides that the Minister may declare a medicine to be a monitored medicine if satisfied that the declaration is consistent with the purposes of the monitored medicines database.

On 4 June 2019 Chief Coroner Walker delivered her findings in response to the *Inquest into the death of Lauren Maree Johnstone* in the ACT Coroners Court. Chief Coroner Walker highlighted deficiencies with the ACT monitored medicine system including the lack of monitoring of prescription drugs that have the potential to result in dependence or harm, that are not listed in schedule 8.

On 11 February 2020 the *ACT Government response to the Coronial Inquest into the Death of Lauren Maree Johnstone* was tabled in the ACT Legislative Assembly. The ACT Government committed to declaring diazepam, and tramadol as monitored medicines subject to the ACTs adoption of the national real time prescription monitoring system and undertaking consultation to identify other schedule 4 medicines associated with harms.

ACT Health Directorate conducted an evidence-based review of harms associated with a range of schedule 4 medicines identifying several medicines or classes of medicines for potential monitoring due to evidence of their abuse and misuse leading to harms and deaths in the Australian community. ACT Health Directorate undertook stakeholder consultation between 24 November 2020 to 5 February 2021 on this review. All stakeholders who responded to the consultation supported the proposed

list of medicines for monitoring; specifically codeine, tramadol, all benzodiazepines, quetiapine, zolpidem, zopiclone, gabapentin and pregabalin.

This instrument is a declaration by the Minister issued under section 97A of the MPTG Act. This instrument declares codeine, tramadol, all benzodiazepines, quetiapine, zolpidem, zopiclone, gabapentin and pregabalin, in all forms and strengths to be monitored medicines.

These medicines have been declared monitored medicines due to evidence of harms including death associated with the abuse and misuse of these medicines following ACT Government commitments in response to the Chief Coronial Inquest into Ms Johnstone's death. This declaration is consistent with the purposes of the monitored medicines database as it will ensure information for the declared medicines is available in the ACT's database to promote and protect public health and safety.

Prescribing certain Schedule 4 medicines as monitored medicines engages the *Human Rights Act 2004* (HRA). This instrument engages and supports the right to life (HRA, section 9) by providing a framework for the safe and effective administration of the medicines in accordance with the purposes of the monitored medicines framework under section 97C of the MPTG Act.

This instrument also engages and limits the right to privacy and reputation under the HRA, section 12 in that it extends approval and other requirements for the prescribing and dispensing of certain schedule 4 medicines. It is considered the limitations on the right to privacy are reasonable and proportionate given the public health benefits of monitoring these medicines. Safeguards are also available under the MPTG Act and the *Health Records (Privacy and Access) Act 1997* to ensure that approval and reporting processes protect a person's privacy and to ensure personal health information is only disclosed for a lawful purpose.

A more detailed assessment of the impacts of the monitored medicines framework on the right to privacy is included in the Explanatory Statement for the Medicines, Poisons and Therapeutic Goods Amendment Bill 2018 which was passed by the ACT Legislative Assembly on 7 June 2018.

This instrument will commence on 1 October 2021 to ensure the commencement of a data feed for the declared medicines coincides with the technical release of the ACT's new monitored medicines database, to be known as Canberra Script, which forms part of the national real time prescription monitoring system from October 2021.

This declaration will bring into effect obligations upon certain persons to report information to the Chief Health Officer about the supply of declared schedule 4 medicines during consultations and on prescriptions in accordance with sections 81 and 164 of the Medicines, Poisons and Therapeutic Goods Regulation 2008.

As a result of this declaration, information will be collected and stored on the ACT's monitored medicines database in relation to the supply and prescription of monitored medicines in the ACT and other jurisdictions via the National Data Exchange, which forms part of the national real time prescription monitoring system.

Information on the database will be disclosed to health practitioners and other persons who may access the database, consistent with the purpose of the database to promote and protect public health and safety.