

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines—Authorised Supply) Rules 2022

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in or exported from Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Commonwealth Department of Health and Aged Care.

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising classes of health practitioners to supply specified therapeutic goods (or classes of such goods) for use in the treatment of specified recipients, provided the goods are supplied in specified circumstances and the specified conditions (if any) are satisfied.

Subsection 19(7B) of the Act provides that, in making rules under subsection 19(7A), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. Subregulation 12B(5) of the *Therapeutic Goods Regulations 1990* provides that rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

Health practitioners who supply therapeutic goods pursuant to rules made under subsection 19(7A) are required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act. These provisions are mainly intended to facilitate access to therapeutic goods with an established history of use in Australia and overseas, in circumstances where those goods are not included in the Australian Register of Therapeutic Goods (“the Register”), or not otherwise the subject of an exemption, approval or authority under the Act.

The *Therapeutic Goods (Medicines—Authorised Supply) Rules 2022* (“the Rules”) are made under subsection 19(7A) of the Act. The Rules specify health practitioners, medicines, circumstances and conditions for the purposes of that subsection. The Rules repeal and replace the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* (“the former Rules”).

The Rules make a number of changes as compared to the former Rules, to:

- omit two medicines;
- add three new medicines;
- amend an item in relation to one medicine; and
- otherwise reproduce the medicines authorised for supply under the former Rules.

The new medicines that are introduced by the Rules are those containing the active ingredients metolazone, amiloride and ganciclovir. These medicines do not contain substances of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

The medicines that have been omitted are medicines containing amifampridine (3,4 diaminopyridine), and medicines containing lorazepam. These items have been omitted because medicines containing these active ingredients have been included in the Register and are available for commercial supply in Australia.

The medicine that is amended by the Rules is the medicine containing gallium 68 prostate specific membrane antigen), and the amendment is designed principally to include an additional indication for this medicine that is based on an established history of use.

Incorporation by reference

The Rules incorporate by reference the document titled *Special Access Scheme Guidance for health practitioners and sponsors* (Version 1.1, September 2017) (“the SAS Guidance”), which is published by the TGA. This document provides guidance for health practitioners and sponsors involved in providing patients with access to therapeutic goods that are not included in the Register (and are not otherwise the subject of an exemption, approval or authority under the Act) through the Special Access Scheme. It outlines the various access pathways and the regulatory obligations when accessing and supplying such therapeutic goods.

The Rules incorporate the SAS Guidance as in force or existing at the commencement of the Rules, in accordance with paragraph 14(1)(b) of the *Legislation Act 2003*, which permits a legislative instrument to incorporate a document (that is not an Act or legislative instrument) as it exists at, or before, the time the instrument commences.

The SAS Guidance is available for free from the TGA website and can be accessed at www.tga.gov.au.

Consultation

The Office of Impact Analysis has advised that a regulation impact statement was not required in relation to the making of the Rules (OBPR ID 43030).

The TGA engaged with sponsors of a small number of medicines which are already on the list of medicines that a medical practitioner may supply to their patients without ethics committee approval, but that have since been included in the Register. Through these discussions it has been identified that although the affected medicines are now included in the Register, it is unlikely that they would be made available for general supply in Australia if removed from the list.

Consultation in relation to the making of the Rules was appropriately undertaken with clinical advisors within the Department of Health and Aged Care. Consultation with internal clinical advisors was to confirm products added to the Rules met the safety and established history of use criteria. Only products and indications that met the established history of use criteria were found to be appropriate for inclusion in the Rules.

Details of the Rules are set out in **Attachment A**.

The Rules are compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Rules are disallowable for the purposes of the *Legislation Act 2003* and commence on the day following registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2022* (“the Rules”).

Section 2 – Commencement

This section provides that the Rules commence on the day following registration on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Rules is subsection 19(7A) of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 – Definitions

This section provides the definitions of terms used in the Rules. In particular, this section defines ‘SAS Guidance’. The section also notes that a number of terms have the meaning given in subsection 3(1) of the Act, including ‘health practitioner’, ‘sponsor’ and ‘supply’.

Section 5 – Authorisation

This section is the substantive provision that authorises the supply of specified medicines by a health practitioner who is a medical practitioner or by a health practitioner to a patient of a medical practitioner, with reference to certain matters specified in Schedule 1.

Subsection 5(1) provides that a medical practitioner is authorised to supply a medicine containing an active ingredient specified in column 2 of an item in the table in Schedule 1, to a patient of that practitioner, where the other circumstances specified in that subsection are met. Those circumstances include that the conditions specified in subsection 5(2) are satisfied.

Similarly, subsection 5(3) provides that a health practitioner is authorised to supply a medicine containing an active ingredient specified in column 2 of an item in the table in Schedule 1, to a patient of a medical practitioner (“the treating practitioner”), provided the supply is requested by the treating practitioner and the other circumstances specified in that subsection are met. These include that the conditions specified in subsection 5(4) are satisfied.

Section 6 – Repeals

This section provides that each instrument that is specified in Schedule 2 to the Rules is repealed as set out in the applicable items in that Schedule.

Schedule 1 – Medicines authorised for supply

This Schedule specifies the medicines and circumstances for the purposes of section 5 with reference to the active ingredient, dosage form, route of administration and indication in relation to the medicine.

Schedule 2 – Repeals

This Schedule repeals the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020*. The Rules therefore comprise a consolidated version of all medicines specified pursuant to subsection 19(7A) of the Act.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods (Medicines—Authorised Supply) Rules 2020

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of legislative instrument

The *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* (“the instrument”) is made under subsection 19(7A) of the Act. The instrument specifies health practitioners, medicines, circumstances and conditions for the purposes of that subsection. The instrument repeals and replaces the *Therapeutic Goods (Authorised Supply of Medicines) Rules 2019* (“the former instrument”).

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising classes of health practitioners to supply specified therapeutic goods (or classes of such goods) for use in the treatment of specified recipients, provided the goods are supplied in specified circumstances and the specified conditions (if any) are satisfied.

Subsection 19(7B) of the Act provides that, in making rules under subsection 19(7A), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. Subregulation 12B(5) of the *Therapeutic Goods Regulations 1990* provides that rules made under subsection 19(7A) of the Act must not specify a medicine or a class of medicines if the medicine, or a medicine included in the class, contains a substance of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

Health practitioners who supply therapeutic goods pursuant to rules made under subsection 19(7A) are required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act. These provisions are mainly intended to facilitate access to therapeutic goods with an established history of use in Australia and overseas, in circumstances where those goods are not included in the Australian Register of Therapeutic Goods (“the Register”), or not otherwise the subject of an exemption, approval or authority under the Act.

The instrument makes a number of changes as compared to the former instrument. In short, the instrument omits two medicines, adds three new medicines, amends an item in relation to one medicine, and otherwise reproduces the medicines authorised for supply under the former instrument.

The new medicines are those containing metolazone, amiloride and ganciclovir. These medicines do not contain substances of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

The medicines that have been omitted are medicines containing amifampridine (3,4-diaminopyridine), and medicines containing lorazepam. These items have been omitted because medicines containing these active ingredients have been included in the Register and are available for commercial supply in Australia.

The instrument amends an item under the former instrument, being the item for medicine containing gallium 68 prostate specific membrane antigen to include an additional indication with an established history of use.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health* (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by facilitating the supply of certain medicines by health practitioners in specified circumstances, and subject to certain conditions. As a consequence of the instrument, a practitioner is able to supply a specified medicine by way of notification rather than approval; thus enabling the timely availability of such medicines to Australian patients in need.

Conclusion

This instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.