

REPLACEMENT EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Authorised Supply of Medicines) Rules 2019

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.

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 safe use 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. Therapeutic goods include medicines, biologicals and medical devices.

The *Therapeutic Goods (Authorised Supply of Medicines) Rules 2019* (“the Rules”) is made under subsection 19(7A) of the Act. The Rules specify health practitioners, medicines, circumstances and conditions for the purposes of the subsection. The Rules also repeal the former *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018*.

The Rules reproduce every medicine specified in the former *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018*, and include four new medicines, namely those containing F-18 myocardial perfusion tracer (18F flurpiridaz), F-18 NaF (sodium fluoride), Gallium-68 (Ga-68) Galligas and Gallium-68 (Ga-68) – macroaggregated albumin (MAA). These medicines do not contain substances of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

Principally, the four new medicines specified in the Rules are needed to facilitate immediate access to critical diagnostic medicines for the purpose of myocardial perfusion studies, bone studies, lung ventilation studies and lung perfusion studies. Immediate access is needed to maintain essential diagnostic services to the public, as a result of an unanticipated shortage of a particular radiopharmaceutical in Australia.

Consultation

The Office of Best Practice Regulation (“OBPR”) advised that a regulation impact statement was not required in the circumstances (OBPR reference: 25611).

Consultation on the making of the Rules was appropriately limited to independent specialist nuclear medicine advice and collaboration with the Medical Benefits Division within the Australian Government Department of Health.

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 immediately before the commencement of the Rules. This document is available for free from the TGA website and can be accessed at www.tga.gov.au.

The SAS Guidance is incorporated by reference 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.

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 (Authorised Supply of Medicines) Rules 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Authorised Supply of Medicines) Rules 2019* (“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”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

This instrument is made in accordance with that provision.

Section 4 – Definitions

This section provides the definitions of terms used in the Rules. Some terms are defined in the Act and therefore, as explained in the note, have the same meaning as given in the Act.

Section 5 – Authorisation

This section is the substantive provision that authorises the supply of specified medicines by, or 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, in circumstances specified in paragraphs 5(1)(a) to 5(1)(e). Those circumstances include that specific conditions provided in subsection 5(2) are met.

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 patients of a medical practitioner (*the treating practitioner*) provided the supply is requested by the treating practitioner, and all other circumstances and conditions are met as specified in that provision and subsection 5(4).

Section 6 – Schedules

This section provides that each instrument that is specified in a Schedule to the Rules is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1

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

Schedule 2

This Schedule repeals the *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018*. Each of the medicines specified in that instrument are reproduced in the Rules. 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 (Authorised Supply of Medicines) Rules 2019

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 (Authorised Supply of Medicines) Rules 2019* (“the instrument”) is made under subsection 19(7A) of the *Therapeutic Goods Act 1989* (“the Act”). The instrument specifies classes of health practitioners, medicines, circumstances and conditions for the purposes of the subsection. The instrument also repeals the former *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018*.

The instrument reproduces every medicine specified in the former *Therapeutic Goods (Authorised Supply of Specified Medicines) Rules March 2018*, and include four new medicines, namely those containing F-18 myocardial perfusion tracer (18F flurpiridaz), F-18 NaF (sodium fluoride), Gallium-68 (Ga-68) Galligas and Gallium-68 (Ga-68) – macroaggregated albumin (MAA). These medicines do not contain substances of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

Principally, the four new medicines specified in the instrument are needed to facilitate immediate access to critical diagnostic medicines for the purpose of myocardial perfusion studies, bone studies, lung ventilation studies and lung perfusion studies. Immediate access is needed to maintain essential diagnostic services to the public, as a result of an unanticipated shortage of a particular radiopharmaceutical in Australia.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“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 ensuring 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.

Adrian Bootes, delegate of the Minister for Health