EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medicines—Authorised Supply) Rules 2020

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 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 2020* ("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 (Authorised Supply of Medicines) Rules 2019* ("the former Rules").

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

- omit eight medicines;
- add ten new medicines;
- amend the items in relation to six medicines; 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 acyclovir, carbidopa, dexamethasone, doxycycline, F-18 DCFPyl (PSMA), Gallium-68 prostate specific membrane antigen (PSMA), neomycin, riboflavin 0.1% in 1.1% hydroxylpropyl methylcellulose (HPMC), riboflavin 0.22% in sodium chloride, and tinidazole. 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 are omitted are those containing *Bifidobacterium bifidum* & *Lactobacillus acidophilus*, insulin neutral-concentrated (Humulin R U-500), melatonin modified release, midodrine, rufinamide, and stiripentol capsule, stiripentol tablet, and stiripentol sachet. These items have been omitted as the medicines are either included in the Register or are no longer being supplied in Australia.

The medicines that are amended by the Rules are medicines containing clofazimine, cyclosporin 0.05%, flunarizine tablet, flunarizine capsule, levofloxacin and triamcinolone acetonide and the amendments are designed principally to include additional indications for these medicines that are

based on an established history of use, or to clarify or correct the indications that are already specified for these medicines.

Consultation

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

Consultation in relation to the making of the Rules was appropriately undertaken with clinical advisors within the Department of Health and the National Tuberculosis Advisory Committee (the NTAC). Consultation with internal clinical advisors was to confirm products added to the Rules met the safety and established history of use criteria. The NTAC, as an expert advisory committee to the Department of Health on tuberculosis, put forward a list of recommendations for anti-tuberculosis medicines to be included in the Rules. Only products and indications that met the established history of use criteria were found to be appropriate for inclusion in the Rules.

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.

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.

Attachment A

Details of the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* ("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. 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 (Authorised Supply of Medicines) Rules 2019*. The Rules therefore comprise a consolidated version of all medicines specified pursuant to subsection 19(7A) of the Act.

Attachment B

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") are 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").

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 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 eight medicines, adds ten new medicines, amends the items in relation to six medicines, and otherwise reproduces the medicines authorised for supply under the former instrument.

The new medicines are those containing acyclovir, carbidopa, dexamethasone, doxycycline, F-18 DCFPyl (PSMA), Gallium-68 prostate specific membrane antigen (PSMA), neomycin, riboflavin 0.1% in 1.1% hydroxylpropyl methylcellulose (HPMC), riboflavin 0.22% in sodium chloride, and tinidazole. 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 are omitted are those containing *Bifidobacterium bifidum* & *Lactobacillus acidophilus*, insulin neutral-concentrated (Humulin R U-500), melatonin modified release, midodrine, rufinamide, and stiripentol capsule, stiripentol tablet, and stiripentol sachet. These items have been omitted as the medicines are either included in the Register or are no longer being supplied in Australia.

The instrument amends a number of items under the former instrument, being items for medicines containing clofazimine, cyclosporin 0.05%, flunarizine, levofloxacin, and triamcinolone acetonide to include an additional indication with an established history of use or to clarify or correct the indication specified.

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 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.