EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—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 41HC(6) of the Act provides that the Minister may, by legislative instrument, make rules authorising classes of health practitioners to supply a specified kind of medical device 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 41HC(6A) of the Act provides that, in making rules under subsection 41HC(6), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. No regulations have been made for the purposes of subsection 41HC(6A).

Health practitioners who supply kinds of medical devices pursuant to rules made under subsection 41HC(6) of the Act are required to notify the Secretary in accordance with subsections 41HC(6B) and 41HC(6C) 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 (Medical Devices—Authorised Supply) Rules 2022* ("the Rules") are made under subsection 41HC(6) of the Act. The Rules specify health practitioners, medical devices, circumstances and conditions for the purposes of that subsection. The Rules repeal and replace the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020* ("the former Rules").

The Rules make some changes as compared to the former Rules. The Rules reproduce the kinds of medical devices specified in the former Rules, and omit two items. The kinds of medical device that have been omitted are the Geistlich Fibro-Gide and the Journey II Bi-Cruciate Stabilized (BCS) Total Knee System - Articular Insert, to reflect that those kinds of devices are now included in the Register.

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).

Consultation in relation to the making of the Rules was appropriately undertaken with internal client advisors within the Department of Health and Aged Care. Consultation with internal clinical advisors was to confirm that products added to the Rules met the safety and established history of use criteria.

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 (Medical Devices—Authorised Supply) Rules 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—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 41HC(6) 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 by 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 kinds of medical devices by, or to a patient of, a specified health practitioner, with reference to certain matters specified in Schedule 1.

Subsection 5(1) provides that a health practitioner specified in column 4 of an item in the table in Schedule 1 is authorised to supply a kind of medical device specified in column 2 of that item, to a patient of that practitioner, where the other circumstances specified in that provision 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 kind of medical device specified in column 2 of an item in the table in Schedule 1 to patients of a health practitioner specified in column 4 of that item ("the treating practitioner"), provided the supply is requested by the treating practitioner, and the other circumstances specified in that provision, including 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 – Medical devices authorised for supply

This Schedule specifies the kinds of medical devices and circumstances mentioned in section 5 with reference to the kind of medical device, purpose and authorised health practitioner.

Schedule 2 – Repeals

This Schedule repeals the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020*. The Rules therefore comprise a consolidated version of all medical devices specified pursuant to subsection 41HC(6) 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 (Medical Devices—Authorised Supply) Rules 2022

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 (Medical Devices—Authorised Supply) Rules 2022* ("the instrument") is made under subsection 41HC(6) of the *Therapeutic Goods Act 1989* ("the Act"). The instrument specifies classes of health practitioners, kinds of medical devices, circumstances and conditions for the purposes of that subsection. The instrument repeals and replaces the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020* ("the former instrument").

Subsection 41HC(6) of the Act provides that the Minister may, by legislative instrument, make rules authorising classes of health practitioners to supply a specified kind of medical device 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 41HC(6A) of the Act provides that, in making rules under subsection 41HC(6), the Minister must comply with such requirements, restrictions or limitations (if any) prescribed in the regulations. No regulations have been made for the purposes of subsection 41HC(6A).

Health practitioners who supply kinds of medical devices pursuant to rules made under subsection 41HC(6) are required to notify the Secretary in accordance with subsections 41HC(6B) and 41HC(6C) 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 some changes as compared to the former instrument. The instrument reproduces the kinds of medical devices specified in the former instrument, and omits two items. The kinds of medical device that have been omitted are the Geistlich Fibro-Gide and the Journey II Bi-Cruciate Stabilized (BCS) Total Knee System - Articular Insert, to reflect that those kinds of devices are now included in the Register.

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 medical devices 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 kind of medical device by way of notification rather than approval; thus enabling the timely availability of such medical devices 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.