

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Authorised Supply) Amendment (Medicines and Medical Devices) 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.

Subsection 19(7A) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified 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 also required to notify the Secretary in accordance with subsections 19(7C) and 19(7D) of the Act.

Similarly, subsection 41HC(6) of the Act provides that the Minister may, by legislative instrument, make rules authorising specified classes of health practitioners to supply a specified kind of medical device for use in the treatment of specified recipients, provided the kinds of medical devices 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 also 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 safe use in Australia or 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 (Authorised Supply) Amendment (Medicines and Medical Devices) Rules 2022* (“the Amendment Rules”) amends the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* (“the Medicines Rules”) and the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020* (“the Devices Rules”) to add a number of specified medicines and medical devices to, and remove a number of specified medicines and medical devices from, the Medicines Rules and Devices Rules respectively, and to make some clarifications and corrections.

Specifically, the Amendment Rules make a number of changes to the Medicines Rules, to:

- specify seven new medicines that are considered to have an established history of use;
- remove one medicine which has now been included in the Register; and
- amend the spelling of two active ingredients (in three items) to align with international use.

The Amendment Rules make a number of changes to the Devices Rules, to:

- specify two new kinds of medical devices that are considered to have an established history of use, and two new kinds of medical devices that are subject to a high volume of special access scheme approvals without significant safety alerts;

- remove three medical devices to reflect that two are now included in the Register and one has been the subject of a hazard alert (a hazard alert is issued for implanted therapeutic goods with a deficiency or potential deficiency relating to its safety, quality, performance or efficacy because implanted therapeutic goods cannot be recalled);
- update the specified classes of health practitioner that are authorised to supply nine kinds of medical devices, to better reflect the health practitioners who have requested the device under the Special Access Scheme - Category C pathway in the past; and
- correct the name of one kind of medical device.

Consultation

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

Consultation in relation to the making of the Amendment Rules was appropriately undertaken with clinical advisors within the Department of Health, in particular to confirm that the products added to the Medicines Rules and Devices Rules by the Amendment Rules are considered to have an established history of safe use and are appropriate for supply and use under this pathway.

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

The Amendment 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) Amendment (Medicines and Medical Devices) Rules 2022*

Section 1 – Name

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

Section 2 – Commencement

This section provides that the Rules commence on the day after they are registered on the Federal Register of Legislation.

Section 3 – Authority

This section provides that the legislative authority for making the Rules is subsection 19(7A) and subsection 41HC(6) 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. The Amendment Rules are made in accordance with that provision.

Section 4 – Schedules

This section gives legal effect to the amendments in Schedule 1 to the Amendment Rules.

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* (“the Medicines Rules”) and the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020* (“the Devices Rules”).

Part 1 – Medicines

Items 1 to 11 amend the Medicines Rules.

Item 1 removes aciclovir from the Medicines Rules.

Items 2 to 5 correct the names of colecalciferol and ciclosporin in the Medicines Rules and include these medicines in alphabetical order.

Items 6 to 11 add the following medicines to the Medicines Rules:

- disulfiram;
- iloprost;
- interferon alpha-2b;
- lifitegrast;
- injectable progesterone;
- progesterone in oil; and
- Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)-I&S.

These medicines do not contain a substance of a kind covered by an entry in Schedule 8, 9 or 10 to the Poisons Standard.

Part 2 – Medical devices

Items 12 to 28 amend the Devices Rules.

Items 13, 16, 27 and 28 add the following kinds of medical devices to the Devices Rules:

- AltiVate Reverse Shoulder system – DJO Global;
- Duraloc Acetabular Cup System – Hip Insert/Liner – Johnson & Johnson t/a DePuy Synthes;
- Primetech Piezo Micro Manipulator and microinjection pipettes; and
- Regeneten Bioinductive Implant – Bone Anchors with Anthroscopic Delivery System.

Items 14, 15, and 17 to 23 amend the specified class of health practitioner that may supply 9 kinds of medical devices, to update the class of health practitioner to better reflect the kinds of medical practitioners who have requested the device under the Special Access Scheme - Category C pathway in the past.

Items 12, 24 and 25 remove the following kinds of medical devices from the Devices Rules:

- Aequalis Pyrocarbon Humeral Head – Tornier;
- Matriderm® Acellular Dermal Substitute; and
- METS Modular Proximal Femur - CoCr Femoral Head – Stanmore Implants.

Item 26 makes a minor correction to the name of the Natural Knee II System – Durasul PE Congruent Tibial Insert – Zimmer Biomet (620108809 – 620110916).

Statement of Compatibility with Human Rights

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

Therapeutic Goods (Authorised Supply) Amendment (Medicines and Medical Devices) 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 (Authorised Supply) Amendment (Medicines and Medical Devices) Rules 2022* (“the instrument”) is made under subsection 19(7A) and subsection 41HC(6) of the Act. These provisions are mainly intended to facilitate access for patients to therapeutic goods that are considered to have an established history of safe use in Australia or 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 amends the *Therapeutic Goods (Medicines—Authorised Supply) Rules 2020* (“the medicines rules”) and the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020* (“the devices rules”). The instrument adds and removes a number of specified medicines and kinds of medical devices to and from the medicines rules and devices rules respectively, and makes some clarifications and corrections.

Specifically, the instrument makes a number of changes to the Medicines Rules, to:

- specify seven new medicines that are considered to have an established history of use;
- remove one medicine that has now been included in the Register; and
- amend the spelling of three active ingredients to align with international use.

The instrument makes a number of changes to the Devices Rules, to:

- specify two new kinds of medical devices that are considered to have an established history of use, and two new kinds of medical devices that are subject to a high volume of special access scheme approvals without significant safety alerts;
- remove three medical devices to reflect that two are now included in the Register and one has been the subject of a hazard alert (a hazard alert is issued for implanted therapeutic goods with a deficiency or potential deficiency relating to its safety, quality, performance or efficacy because implanted therapeutic goods cannot be recalled);
- update the specified classes of health practitioner that are authorised to supply nine kinds of medical devices, to better reflect the health practitioners who have requested the device under the Special Access Scheme - Category C pathway in the past; and
- correct the name of one kind of medical device.

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 and kinds of medical devices by health practitioners in specified circumstances, and subject to certain conditions, to patients who may otherwise not be able to access such products in connection with their treatment. As a consequence of the instrument, relevant kinds of health practitioners are able to supply a number of additional medicines and kinds of medical devices to their patients by way of notification rather than approval; thus reducing delay and enabling the timely availability of such medicines and 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.