EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 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 Australian Government Department of Health and Aged Care ("the Department").

Section 41FDB of the Act sets out preliminary assessment requirements in relation to an application to the Secretary for a kind of medical device to be included in the Australian Register of Therapeutic Goods ("the Register"). These include the requirements that an application be accompanied by information that is of a kind determined under subsection 41FDB(7), in a form determined under subsection 41FDB(8), for the relevant classification of medical device (subparagraphs 41FDB(2)(d)(i) and (ii) refer).

Relevantly, subsections 41FDB(7) and (8) of the Act provide that the Secretary may, by legislative instrument, determine a kind and form of information respectively for the purposes of an application mentioned in subparagraphs 41FDB(2)(d)(i) and (ii) of the Act in relation to medical devices of a particular classification.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("the Principal Determination") is made under subsections 41FDB(7) and (8) of the Act. The Principal Determination determines the kind and form of information that must accompany an application for kinds of medical devices of a particular classification to be included in the Register.

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the particular kinds of medical devices. The conformity assessment documents include certificates and other documents that have been issued or recognised by the Secretary or comparable overseas regulators within the meaning of section 41BIB of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022* ("the Amendment Determination") is made under subsection 41FDB(7) of the Act, read together with subsection 33(3) of the *Acts Interpretation Act 1901*.

The Amendment Determination amends the Principal Determination, principally to specify that an extract from, or copy of, the entry in the Singapore Register of Health Products, may accompany an application for the inclusion in the Register of a Class IIa, Class IIb, Class III or Class AIMD medical device, or a Class 2 IVD or Class 3 IVD medical device. This has the effect that such a document will be accepted by the TGA in support of an application for inclusion in the Register for kinds of medical devices with those classifications, as an alternative to the existing conformity assessment documents specified for such kinds of devices in the Principal Determination.

The Amendment Determination reflects related amendments made to the *Therapeutic Goods (Overseas Regulators) Determination 2018* by the *Therapeutic Goods (Overseas Regulators) Amendment (Singapore) Determination 2022*, to determine the Health Sciences Authority of Singapore as a (comparable) overseas regulator for the purposes of section 41BIB of the Act.

The effect of the Amendment Determination, together with the determination of the Health Sciences Authority of Singapore as an overseas regulator, will be to provide greater flexibility for sponsors and manufacturers of Class IIa, Class IIb, Class III and Class AIMD medical devices, and Class 2 IVD and Class 3 IVD medical devices, regarding the kinds of conformity assessment documents that may be provided with an application for inclusion. Additional administrative measures have also been established to ensure such applications may be selected for audit in relation to the documentary evidence provided to substantiate the safety and quality of the device, prior to the device's inclusion in the Register.

Consultation

The recognition of the Health Sciences Authority of Singapore as a comparable overseas regulator reflects the request of, and ongoing consultation and dialog with, the Health Sciences Authority of Singapore in relation to this measure. Industry stakeholders were also alerted to this measure at the Regulatory and Technical Consultative Forum for medical devices ("RegTech") meeting held on 11 March 2021. RegTech is a consultative forum designed to prioritise and discuss issues of a regulatory and technical nature relating to the regulation of medical devices, both current and emerging. Its membership includes, for example, the TGA, the Medical Technology Association of Australia, the Australian Dental Industry Association, AusBiotech and Pathology Technology Australia.

The Office of Best Practice Regulation ("OBPR") advised that the proposal to recognise Singapore as a comparable overseas regulator, as reflected in the Amendment Determination, is unlikely to have more than a minor regulatory impact, and did not require a regulation impact statement (OBPR ID 43719).

Documents incorporated by reference

The primary purpose of the Amendment Determination is to specify an additional kind of information that may accompany an application for inclusion in the Register for certain classes of medical devices, being an extract from, or copy of, the entry in the Singapore Register of Health Products for the specified class of device. This is achieved by inserting a definition of 'Singapore Register of Health Products' into the Principal Determination, which means the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under section 34 of the Singapore Health Products Act. The 'Singapore Health Products Act' is in turn defined to mean the Health Products Act 2007 of Singapore as in force on 1 July 2022.

The Singapore Health Products Act provides the framework for a uniform approach for the registration of health products, and the regulation of the manufacture, import, supply, storage, presentation and advertisement of health products, in Singapore. The Act may be accessed for free at: https://sso.agc.gov.sg/Act/HPA2007.

In accordance with section 14 of the *Legislation Act 2003*, this document is incorporated as in force at 1 July 2022. This means that any subsequent changes to this document will not be automatically applied under the Determination.

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

The Amendment Determination is compatible with the 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 Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences at the same time as the *Therapeutic Goods (Overseas Regulators) Amendment (Singapore) Determination 2022* commences.

Attachment A

Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences at the same time as the *Therapeutic Goods (Overseas Regulators) Amendment (Singapore) Determination 2022* commences. However, the Amendment Determination will not commence at all if that instrument does not commence.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is subsection 41FDB(7) 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 – Schedules

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

Schedule 1 – Amendments

This Schedule amends the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("the Principal Determination").

Item 1 of this Schedule amends section 4 of the Principal Determination to introduce definitions of 'Singapore Health Products Act', which means the Health Products Act 2007 of Singapore as in force on 1 July 2022, and 'Singapore Register of Health Products' which is the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under section 34 of the Singapore Health Products Act.

Item 2 of this Schedule amends Part 2 of Schedule 1 to the Principal Determination, which sets out the kinds of information that must accompany an application for the inclusion of a Class IIa medical device in the Australian Register of Therapeutic Goods ("the Register") for the purposes of subsection 5(3) of the Principal Determination, to include (in new item 9 of the table in Part 2 of Schedule 1) an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B medical device.

Item 3 of this Schedule amends Part 3 of Schedule 1 to the Principal Determination, which sets out the kinds of information that must accompany an application for the inclusion of a Class IIb medical

device in the Register for the purposes of subsection 5(5) of the Principal Determination, to include (in new item 12 of the table in Part 3 of Schedule 1) a reference to an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C medical device.

Item 4 of this Schedule amends Division 1 of Part 4 of Schedule 1 to the Principal Determination, which sets out the kinds of information that must accompany an application for the inclusion of a Class III medical device in the Register (other than a specified medical device as defined in the Principal Determination) for the purposes of subsection 5(7) of the Principal Determination, to include (in new item 13 of the table in Division 1 of Part 4 of Schedule 1) a reference to an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D medical device.

Item 5 of this Schedule amends Division 1 of Part 5 of Schedule 1 to the Principal Determination, which sets out the kinds of information that must accompany an application for the inclusion of an AIMD medical device in the Register (other than a specified medical device as defined in the Principal Determination) for the purposes of subsection 5(9) of the Principal Determination, to include (in new item 13 of the table in Division 1 of Part 5 of Schedule 1) a reference to an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D medical device.

Item 6 of this Schedule amends Part 1 of Schedule 2 to the Principal Determination, which sets out the kinds of information that must accompany an application for the inclusion of a Class 2 IVD medical device in the Register for the purposes of subsection 6(1) of the Principal Determination, to include (in new item 9 of the table in Part 1 of Schedule 2) a reference to an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class B IVD.

Item 7 of this Schedule amends Part 2 of Schedule 2 to the Principal Determination, which sets out the kinds of information that must accompany an application for the inclusion of a Class 3 IVD medical device in the Register for the purposes of subsection 6(3) of the Principal Determination, to include (in new item 13 of the table in Part 2 of Schedule 2) a reference to an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class C IVD.

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—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 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—Information that Must Accompany Application for Inclusion) Determination 2018* ("the principal instrument") is made under subsections 41FDB(7) and (8) of the Act. The principal instrument determines the kind and form of information that must accompany an application for kinds of medical devices of a particular classification to be included in the Australian Register of Therapeutic Goods ("the Register").

The kinds of information specified in the principal instrument relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the particular kind of medical device. The conformity assessment documents include certificates and other documents that have been issued or recognised by the Secretary or comparable overseas regulators within the meaning of section 41BIB of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Singapore) Determination 2022* ("the instrument") is made under subsection 41FDB(7) of the Act, read together with subsection 33(3) of the *Acts Interpretation Act 1901*. It amends the principal instrument, principally to specify that an extract from, or copy of, the entry in the Singapore Register of Health Products, may accompany an application for the inclusion in the Register of a Class IIa, Class IIb, Class III or Class AIMD medical device, or a Class 2 IVD or Class 3 IVD medical device. This has the effect that such a document will be accepted by the Therapeutic Goods Administration ("the TGA") in support of an application for inclusion in the Register for kinds of medical devices with those classifications, as an alternative to the existing conformity assessment documents specified for such kinds of devices in the principal instrument.

The instrument reflects related amendments made to the *Therapeutic Goods (Overseas Regulators) Determination 2018* by the *Therapeutic Goods (Overseas Regulators) Amendment (Singapore) Determination 2022*, to determine the Health Sciences Authority of Singapore as a (comparable) overseas regulator for the purposes of section 41BIB of the Act.

The effect of the instrument, together with the determination of the Health Sciences Authority of Singapore as a comparable overseas regulator, will be to provide greater flexibility for sponsors and manufacturers of Class IIa, Class IIb, Class III and Class AIMD medical devices, and Class 2 IVD and Class 3 IVD medical devices, regarding the kinds of conformity assessment documents that may be provided with an application for inclusion. Additional administrative measures have also been established to ensure such applications may be selected for audit in relation to the documentary evidence provided to substantiate the safety and quality of the device, prior to the device's inclusion 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 enhancing flexibility in relation to the kinds of documentary evidence that may accompany an application for inclusion of the relevant kinds of medical devices in the Register, to demonstrate the safety and quality of the manufacturing processes used to manufacture such products.

Expanding the kinds of conformity assessment documents that may accompany applications for Class IIa, Class IIb, Class III and Class AIMD medical devices, and Class 2 IVD and Class 3 IVD medical devices, as a consequence of this instrument will enable the TGA to process such applications in a more effective and timely manner. The information will assist in ensuring the safety and satisfactory performance of these medical devices, as well as their timely availability, in Australia. By providing more options for the type of conformity assessment document that may be submitted with an application for inclusion, the instrument will reduce delays in access to such medical devices for Australian patients and health practitioners.

The instrument also takes positive steps to promote the right to health through supporting enhanced international cooperation with Singapore in relation to the regulation and approval of higher risk medical devices.

Conclusion

This legislative 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.