# EXPLANATORY STATEMENT

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 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 61 of the Act provides that the Secretary may release specified kinds of therapeutic goods information to the public, and to certain organisations, bodies or authorities. Subsection 61(1) of the Act provides that therapeutic goods information means, for the purposes of the section, information relating to therapeutic goods, which is held by the Department and relates to the performance of the Department's functions.

Under subsection 61(5C) of the Act, the Secretary may release to the public kinds of therapeutic goods information specified under subsection 61(5D) of the Act. Subsection 61(5D) provides that the Minister may, by legislative instrument, specify kinds of therapeutic goods information for the purposes of subsection 61(5C) of the Act.

The *Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 2022* ("the Specification") is a legislative instrument made under subsection 61(5D) of the Act. It specifies kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The Specification authorises the release to the public of therapeutic goods information provided to the TGA by a sponsor (or person authorised to act on behalf of a sponsor) in an Online Notification Form, which relates to the transition of a medical device from certain European Directives to the new *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017* ("the EU Medical Devices Regulation"). The Specification also repeals the *Therapeutic Goods (Transition to EU Medical Devices Regulation—Stakeholder Testing) (Information) Specification 2022* ("the Stakeholder Testing Specification"), which is no longer required.

**Background**

Section 41FD of the Act sets out a number of matters in relation to which an applicant for the inclusion of a kind of medical device in the Australian Register of Therapeutic Goods ("the Register") must certify. Relevantly, paragraph 41FD(f) provides that an applicant must certify that appropriate conformity assessment procedures have been applied to devices of that kind, or requirements comparable to such procedures have been applied to medical devices of that kind.

The conformity assessment procedures are specified in the *Therapeutic Goods (Medical Devices) Regulations 2002* and set out the requirements relating to the application of quality management systems in the manufacture of medical devices, and other requirements relating to obligations of manufacturers of medical devices.

Section 41FDA of the Act requires that, when certifying the matter referred to in paragraph 41FD(f), the applicant must also state whether the certification is based on a conformity assessment certificate (issued by the Secretary), an Australian conformity assessment body certificate or an overseas regulator conformity assessment document.

An 'overseas regulator conformity assessment document' is a certificate or other document that is issued by an overseas regulator after that regulator is satisfied that requirements, comparable to the

conformity assessment procedures, have been applied to a medical device by the manufacturer. The comparable overseas regulators have been specified in the *Therapeutic Goods (Overseas Regulators) Determination 2018* ("the Overseas Regulators Determination"), which is a notifiable instrument made under section 41BIB of the Act and is freely available from the Federal Register of Legislation at www.legislation.gov.au.

Under the Overseas Regulators Determination, an overseas regulator includes a body that has been designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices ("a notified body").

The regulation of medical devices in Europe is undergoing transition to the new *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices* ("EU Medical Devices Regulation"), which repeals and replaces the following directives ("EU Council Directives"):

- *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)* of the Council of the European Communities ("Council Directive 90/385/EEC");
- *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* of the Council of the European Communities ("Council Directive 93/42/EEC").

The EU Medical Devices Regulation fully applies from 26 May 2021, after a four-year transition period. However, the transition may continue up until May 2024 for medical devices with a conformity assessment document issued by a notified body under Council Directive 90/385/EEC or Council Directive 93/42/EEC ("an EU MDD certificate").

Most medical devices included in the Register are supported by an EU MDD certificate, and sponsors of these devices are expected to transition to the new EU Medical Devices Regulation to ensure that they can continue to supply their products in Australia. Transition to the EU Medical Devices Regulation has introduced a range of changes for manufacturers of medical devices including, for example:

- more stringent requirements to demonstrate medical device safety for patients and users, including requirements for clinical evidence;
- additional requirements for the quality management systems of manufacturers;
- detailed technical document requirements;
- changes to classification rules for some medical devices.

As a result of the transition, many sponsors and manufacturers will be required to obtain alternative conformity assessment documentation to support the inclusion of their devices in the Register and enable continued supply of the devices in Australia. Under subparagraph 41FN(3)(b)(i) of the Act, it is a condition of inclusion that the sponsor has available sufficient information to substantiate that the conformity assessment procedures have been applied to the kind of medical device, or that requirements, comparable to those procedures, have been applied to the kind of medical device to the satisfaction of an overseas regulator.

Issues arising for some manufacturers and sponsors in relation to the transition include delays in having an overseas regulator conformity assessment document issued by a notified body under the EU Medical Devices Regulation, or changes to products included in the Register as a result of the new requirements under the EU Medical Devices Regulation.

To help minimise regulatory burden, cost and impacts on supply, a risk-based and streamlined approach that does not compromise safety, quality or performance of medical devices supplied in Australia is being adopted by the TGA in relation to managing the transition of medical devices to the EU Medical Devices Regulation. This includes ensuring that patients and health professionals in Australia are kept up to date about any changes affecting medical devices that are available or in

use in Australia. As part of this approach, the TGA has developed an Online Assessment Tool and an Online Notification Form for sponsors of relevant medical devices (other than IVD medical devices), or persons acting on their behalf, to update the TGA and patients, health professionals and others about changes involving their devices.

The Online Assessment Tool will assist sponsors to determine the actions that may be needed in order to ensure that they comply with the Act in transitioning to compliance with the EU Medical Devices Regulation. The Online Notification Form has been developed for sponsors who choose to utilise the TGA's web publication service to provide market notifications to health professionals and the public, in relation to changes to medical devices arising as a result of the transition to the EU Medical Devices Regulation. There is no requirement for sponsors to use the Online Notification Form, rather it is provided to assist sponsors who seek (on a voluntary basis) to utilise the TGA's web publication service to streamline the provision of market notifications to the public (in particular, this is designed to ensure that such information is available for patients, health professionals and other users of medical devices).

The Stakeholder Testing Specification supported an initial, limited release of information, prior to the proposed public release of the information, so that the information could be evaluated and tested by informed users such as health professionals, private and public hospitals, medical device sponsors and patients, in order to provide feedback to the TGA.

The Specification is a separate legislative instrument under subsection 61(5D) of the Act that supports the public release of the information in the Online Notification Form. The Specification supports the release of the same information that was specified in the Stakeholder Testing Specification, with a small number of additional data fields (including manufacturer name, sponsor name, Global Medical Device Nomenclature code, Global Trade Item Number, and names of the kind of medical device) that were identified as part of the stakeholder testing. The Specification also repeals the Stakeholder Testing Specification, which is no longer needed as the information specified in the Stakeholder Testing Specification may be released under the Specification.

**Incorporation by reference**

The Specification incorporates by reference the Online Notification Form, which is published by the TGA for the purpose of assisting sponsors to utilise the TGA's web publication service to provide market notifications to health professionals, other stakeholders and the public, in relation to device related changes arising as a result of the transition to the EU Medical Devices Regulation. The Online Notification Form may be accessed via the TGA – Citizen Space website at https://consultations.tga.gov.au/tga/ef19f496/. In accordance with section 14 of the *Legislation Act 2003* ("the Legislation Act"), the form is incorporated as in force or existing at the commencement of the Specification.

The Specification also defines a number of matters by reference to the following documents:

- *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)* of the Council of the European Communities, which sets out the requirements for active implantable medical devices available in the European Union;
- *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* of the Council of the European Communities, which sets out the requirements for medical devices available in the European Union;
- *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices,* which sets out safety and performance requirements for medical devices for human use in the European Union, and replaces Council Directive 93/42/EEC and Council Directive 90/385/EEC.

These three documents have been incorporated as in force or existing at the commencement of the Specification in accordance with section 14 of the Legislation Act, and are freely available from EUR-Lex at https://eur-lex.europa.eu/.

**Consultation**

Prior to the making of the Stakeholder Testing Specification, the TGA conducted three stakeholder workshops with sponsors and members of the Regulatory and Technical Consultative Forum for medical devices ("RegTech") on 6 April, 13 May and 21 June 2022. RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry. In these workshops, stakeholders were supportive of the notion of streamlined market notifications and were in favour of an optional TGA web publishing service, to which sponsors could direct end-users to obtain information about changes relating to their devices that are being implemented as part of the transition to the new EU Medical Devices Regulation.

An email-only beta release was issued to RegTech members in relation to the Online Assessment Tool and Online Notification Form on 29 June 2022. RegTech members were advised that information collected from sponsors in the Online Notification From would not be published publicly, but would be shared with select stakeholders in order to obtain feedback for the purpose of informing improvements for a final release of the online tool and form in the coming months. No issues were raised by stakeholders in relation to this approach.

Following the making of the Stakeholder Testing Specification, feedback was received from four stakeholders. Those stakeholders identified additional information fields that would be helpful to end users in identifying the relevant medical device, and those additional information fields have been included in the Specification.

A regulation impact statement was not required in relation to the development of the Specification, as the matter of specifying kinds of therapeutic goods information under section 61 of the Act is the subject of a standing exemption from the regulation impact statement process (OBPR ID 15070).

Details of the Specification are set out in **Attachment A**.

The Specification is 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 Specification is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 5 December 2022.

**Attachment A**

**Details of the *Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 2022***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 2022* ("the Specification").

**Section 2 – Commencement**

This section provides that the Specification commences on 5 December 2022.

**Section 3 – Authority**

This section provides that the legislative authority for making the Specification is subsection 61(5D) of the *Therapeutic Goods Act 1989* ("the Act").

**Section 4 – Definitions**

This section notes that the meaning of certain terms used in the Specification, e.g. 'medical device' and 'overseas regulator conformity assessment document', are defined in subsection 3(1) of the Act. Other terms have been defined for the purposes of the Specification, including 'EU MDD certificate', 'EU MDR certificate', 'GMDN code', 'GTIN', 'relevant kind of medical device' and 'transition'.

This section also provides that several expressions have the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002*, including 'intended purpose' and 'instructions for use'.

**Section 5 – Release of therapeutic goods information**

This section provides that the kinds of therapeutic goods information set out in the table in Schedule 1, are specified for the purpose of subsection 61(5C) of the Act. The effect of this section is to enable the Secretary to release to the public therapeutic goods information of the kind set out in the table in Schedule 1 to the Specification.

**Section 6 – Repeals**

This section provides that the instruments specified in Schedule 2 are repealed.

**Schedule 1 – Therapeutic goods information**

This Schedule specifies the kinds of therapeutic goods information, for the purposes of section 5 of the Specification, which may be released to the public by the Secretary under subsection 61(5C) of the Act. The kind of information specified includes information provided to the TGA by a sponsor (or person authorised to act on behalf of a sponsor) in the online notification form in relation to the transition of a relevant kind of medical device, which may be released to the public.

**Schedule 2—Repeals**

This Schedule repeals the *Therapeutic Goods (Transition to EU Medical Devices Regulation—Stakeholder Testing) (Information) Specification 2022.*

**Attachment B**

## Statement of Compatibility with Human Rights

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

***Therapeutic Goods (Transition to EU Medical Devices Regulation) (Information) Specification 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 (Transition to EU Medical Devices Regulation) (Information) Specification 2022* ("the instrument") is a legislative instrument made under subsection 61(5D) of the *Therapeutic Goods Act 1989* ("the Act"). It specifies the kinds of therapeutic goods information that the Secretary may release to the public under subsection 61(5C) of the Act.

The instrument authorises the release to the public of therapeutic goods information provided to the TGA by a sponsor (or person authorised to act on behalf of a sponsor) in an Online Notification Form, which relates to the transition of a medical device to the new *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017* ("the EU Medical Devices Regulation"). The instrument also repeals the *Therapeutic Goods (Transition to EU Medical Devices Regulation—Stakeholder Testing) (Information) Specification 2022* ("the Stakeholder Testing Specification") which is no longer required.

The regulation of medical devices in Europe is undergoing transition to the new EU Medical Devices Regulation, which repeals and replaces the following directives ("EU Council Directives"):

- *Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)* of the Council of the European Communities ("Council Directive 90/385/EEC");
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Most medical devices included in the Australian Register of Therapeutic Goods ("the Register") are supported by an EU MDD certificate, and sponsors of these devices are expected to transition to the new EU Medical Devices Regulation in order to continue to supply their products in Australia. Transition to the EU Medical Devices Regulation has introduced a range of changes for manufacturers of medical devices including, for example:

- more stringent requirements to demonstrate medical device safety for patients and users, including requirements for clinical evidence;
- additional requirements for the quality management systems of manufacturers;
- detailed technical document requirements;
- changes to classification rules for some medical devices.

As a result of the transition, many sponsors and manufacturers will be required to obtain alternative conformity assessment documentation to support the inclusion of their devices in the Register and enable continued supply of the devices in Australia.

Issues arising for some manufacturers and sponsors in relation to the transition include delays in having an overseas regulator conformity assessment document issued by a notified body under the EU Medical Devices Regulation, or changes to products included in the Register as a result of the new requirements under the EU Medical Devices Regulation.

To help minimise regulatory burden, cost and impact on supply, a risk-based and streamlined approach that does not compromise safety, quality or performance of medical devices supplied in Australia, is being adopted by the TGA in relation to managing the transition of medical devices to the EU Medical Devices Regulation from a regulatory perspective, including ensuring that patients and health professionals in Australia are kept up to date about any changes affecting medical devices that are in use in Australia. As part of this approach, the TGA has developed an Online Assessment Tool and Online Notification Form for sponsors of relevant medical devices (other than IVD medical devices), and persons acting on their behalf, to update the TGA and patients, health professionals and others about changes involving their devices.

**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 steps to promote the right to health by supporting the release of information about relevant changes to medical devices that are transitioning to the new EU Medical Devices Regulation, ensuring that patients and health professionals in Australia are kept up to date about any changes affecting medical devices that are in use in Australia (for example, changes to the class of persons for which the device is suitable or changes to the intended purpose).

**Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR.