

## EXPLANATORY STATEMENT

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021*

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.

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 kind of medical device. The conformity assessment documents include certificates and other documents that have been issued or recognised by the Secretary and, in the alternative, comparable overseas regulators as defined in section 41BIB of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021* (“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 a declaration of conformity made by a manufacturer:

- under clause 6.6 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the Regulations”) must accompany an application for inclusion in relation to a medical device that is intended by the manufacturer to be for export only; and
- under clause 7.5 of Schedule 3 to the Regulations must accompany an application for inclusion in relation to a system or procedure pack that is classified under the Regulations as a Class 1 in vitro diagnostic (IVD) medical device; and

- under clause 7.5 of Schedule 3 to the Regulations must accompany an application for inclusion in relation to a system or procedure pack that is intended by the manufacturer to be for export only.

Manufacturers of these devices (together, “the relevant medical devices”) must declare a number of matters in accordance with a declaration of conformity under clause 6.6 or 7.5 of Schedule 3 to the Regulations, including in relation to compliance with applicable provisions of the essential principles, and the conformity assessment procedures under the Regulations. The declaration is a pre-existing regulatory requirement.

Prior to the Amendment Determination, the Principal Determination did not determine any kind of accompanying information in relation to applications for inclusion of the relevant medical devices in the Register. The need to determine accompanying information in relation to the relevant medical devices in accordance with the Amendment Determination has become particularly apparent and critical in the context of the public health emergency caused by the outbreak of the disease known as coronavirus disease (“COVID-19”). The COVID-19 pandemic has significantly increased the number of applications for inclusion of low risk medical devices in the Register, in particular, Class I medical devices and Class 1 IVD medical devices. Relevantly, a medical device that is intended by the manufacturer to be for export only is classified as a Class I medical device or Class 1 IVD medical device under clause 5.8 of Schedule 2 or clause 1.8 of Schedule 2A to the Regulations, respectively.

Prior to the pandemic, the TGA would receive approximately 2,500 applications per annum for inclusion of these devices in the Register. This number increased to 4,559 applications as at September 2020. While the surge of applications reflects the efforts of industry to facilitate the availability of critical medical devices in Australia in response to the COVID-19 pandemic, it has also increased the potential for error in the application and inclusion process, particularly on the part of new manufacturers who are not familiar with the conformity assessment procedures that must be applied in relation to medical devices.

The Amendment Determination deals with the potential for these errors by ensuring all manufacturers are appropriately providing information, and relevantly considering and addressing pre-existing regulatory requirements as part of the application process in accordance with the necessary declaration of conformity under clause 6.6 or 7.5 of Schedule 3 to the Regulations. This information will enable the TGA to more efficiently and effectively screen applications and take prompt action where errors have occurred. In so doing, the Amendment Determination takes steps to safeguard the integrity of the application and inclusion process for the relevant medical devices and the accuracy of the Register.

Similar measures were introduced in October and December 2020 in relation to non-measuring and non-sterile Class I medical devices, non-measuring and non-sterile Class I system or procedure packs, and Class 1 IVD medical devices. The Amendment Determination extends those measures to medical devices intended for export only (including system or procedure packs intended for export only) and system or procedure packs that are classified as Class 1 IVD medical devices. These measures represent the next step in improving the application process for low risk medical devices in response to issues that have been heightened by the COVID-19 pandemic.

## **Consultation**

The TGA conducted targeted stakeholder consultation in relation to the measures proposed by the Amendment Determination over a period of 18 months with members of the Regulatory and Technical Consultative Forum for medical devices (“RegTech”). RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry. RegTech members have advocated for improved integrity measures for these low risk medical devices, and strongly supported the proposal.

The Office of Best Practice Regulation (“OBPR”) has advised that the preparation of a regulation impact statement is not required in relation to the changes proposed by the Amendment Determination (OBPR ID: 26445).

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 on 19 May 2021.

**Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021***

**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 (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021* (“the Amendment Determination”).

**Section 2 – Commencement**

This section provides that the Amendment Determination commences on 19 May 2021.

**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”).

Items 1 to 10 of this Schedule repeal and replace ten definitions from section 4 of the Principal Determination, including the definition of “Class 1 IVD medical device” and “Class AIMD medical device”, to provide that those definitions have the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the Regulations”).

Items 11 and 12 of this Schedule add a subsection to the end of sections 5 and 6 of the Principal Determination, to clarify that those sections do not apply to medical devices intended by the manufacturer to be for export only and medical devices used for a special purpose. Relevantly, the new section 6A applies to medical devices intended for export only and section 7 applies to medical devices used for a special purpose that are a system or procedure pack.

Item 13 of this Schedule inserts a new section 6A in the Principal Determination to determine that an application for a medical device that is intended by the manufacturer to be for export only, including an IVD medical device, must be accompanied by a declaration of conformity and a conformity assessment document as specified in the new table in Schedule 2A as inserted by the Amendment Determination.

Items 14 of this Schedule repeals and replaces subsection 7(1A) of the Principal Determination to determine that an application for inclusion of a system or procedure pack that is classified under the Regulations as a Class 1 IVD medical device, or is intended by the manufacturer to be for export only, must be accompanied by a declaration of conformity and a conformity assessment document as specified in Division 1 of Part 1 of Schedule 3 to the Principal Determination.

Items 15 of this Schedule repeals and replaces subsection 7(1) of the Principal Determination to determine that an application for inclusion of a system or procedure pack that is not mentioned in subsection 7(1A) must be accompanied by a declaration of conformity and a conformity assessment document as specified in Division 2 of Part 1 of Schedule 3 to the Principal Determination.

Item 16 of this Schedule is a consequential amendment and replaces “subsection (2)” in paragraph 7(3)(b) of the Principal Determination with “this section”, to ensure that a document accompanying an application in accordance with section 7 of the Principal Determination relates to the kind of device to which the application relates.

Item 17 of this Schedule repeals and replaces section 9 of the Principal Determination to clarify that no kind of information is determined for an application in relation to an in-house IVD medical device other than a Class 4 in-house IVD medical device and a medical device used for a special purpose that is not a system or procedure pack.

Item 18 of this Schedule inserts a new Schedule 2A in the Principal Determination, which contains a table specifying accompanying information (namely, a declaration of conformity made by the manufacturer under clause 6.6 of Schedule 3 to the Regulations) for the purposes of new section 6A inserted by item 13 of this Schedule.

Item 19 of this Schedule adds the words “, Class 1 IVD medical devices, or intended for export only” to the end of the heading of Division 1 of Part 1 of Schedule 3 to the Principal Determination, as a consequence of the amendment made by item 14 of this Schedule.

Item 20 of this Schedule repeals and replaces the heading of Division 2 of Part 1 of Schedule 3 to the Principal Determination, as a consequence of the amendment made by item 15 of this Schedule.

Item 21 of this Schedule repeals and replaces the heading of Part 2 of Schedule 3 to the Principal Determination, as a consequence of the amendments made by items 14 and 15 of this Schedule.

## 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 (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021***

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 *Therapeutic Goods Act 1989* (“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 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 and, in the alternative, comparable overseas regulators as defined in section 41BIB of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Export Only and System or Procedure Packs) Determination 2021* (“the amendment instrument”) is made under subsection 41FDB(7) of the Act, read together with subsection 33(3) of the *Acts Interpretation Act 1901*. The amendment instrument amends the principal instrument to specify that a declaration of conformity made by a manufacturer:

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- under clause 7.5 of Schedule 3 to the Regulations must accompany an application for inclusion in relation to a system or procedure pack that is intended by the manufacturer to be for export only.

Manufacturers of these devices (together, “the relevant medical devices”) must declare a number of matters in accordance with a declaration of conformity under clause 6.6 or 7.5 of Schedule 3 to the Regulations, including in relation to compliance with applicable provisions of the essential principles, and the conformity assessment procedures under the Regulations. The declaration is a pre-existing regulatory requirement.

Prior to the amendment instrument, the principal instrument did not determine any kind of accompanying information in relation to applications for inclusion of the relevant medical devices in the Register. The need to determine accompanying information has become particularly apparent and critical in the context of the public health emergency caused by the outbreak of the disease known as coronavirus disease (“COVID-19”). The COVID-19 pandemic has significantly increased the number of applications for inclusion of low risk medical devices in the Register, in particular, Class I medical devices and Class 1 IVD medical devices. Relevantly, a medical device that is intended by the manufacturer to be for export only is classified as a Class I medical device or Class 1 IVD medical device under clause 5.8 of Schedule 2 or clause 1.8 of Schedule 2A to the Regulations, respectively.

Prior to the pandemic, the TGA would receive approximately 2,500 applications per annum for inclusion of these devices in the Register. This number increased to 4,559 applications as at September 2020. While the surge of applications reflects the efforts of industry to facilitate the availability of critical medical devices in Australia in response to the COVID-19 pandemic, it has also increased the potential for error in the application and inclusion process, particularly on the part of new manufacturers who are not familiar with the conformity assessment procedures that must be applied in relation to medical devices.

The amendment instrument deals with the potential for these errors by ensuring all manufacturers are appropriately providing information, and relevantly considering and addressing pre-existing regulatory requirements as part of the application process in accordance with the necessary declaration of conformity under clause 6.6 or 7.5 of Schedule 3 to the Regulations. This information will enable the TGA to more efficiently and effectively screen applications and take prompt action where errors have occurred. In so doing, the amendment instrument takes steps to safeguard the integrity of the application and inclusion process for the relevant medical devices and the accuracy of 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 (“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 amendment instrument takes positive steps to promote the right to health by ensuring that there is sufficient documentary evidence (in particular, a declaration of conformity made under clause 6.6 or 7.5 of Schedule 3 to the Regulations) accompanying an application for inclusion of the relevant medical devices. In determining accompanying information for these applications, the amendment instrument ensures that manufacturers are relevantly considering and addressing pre-existing regulatory requirements as part of the application process in accordance with the necessary declaration of conformity under clause 6.6 or 7.5 of Schedule 3 to the Regulations. This information will enable the TGA to more efficiently and effectively screen applications and take prompt action where errors have occurred. In so doing, the instrument takes steps to safeguard the integrity of the application and inclusion process for the relevant medical devices and the accuracy of the Register, thereby ensuring the safety and satisfactory performance of medical devices, as well as their timely availability, in Australia.

### **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.