

## EXPLANATORY STATEMENT

### *Therapeutic Goods Act 1989*

#### *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class I Medical Devices) Determination 2020*

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) refers).

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 which 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—Class I Medical Devices) Determination 2020* (“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 primarily to specify that a declaration of conformity made by a manufacturer under clauses 6.6 or 7.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the Regulations”) must accompany an application for inclusion in relation to a Class I medical device or Class I system or procedure pack (respectively) that the manufacturer intends to be supplied in a non-sterile state and that does not have a measuring function (“the relevant Class I medical devices”). Manufacturers of these devices must declare a number of matters in accordance with a declaration of conformity under clauses 6.6 or 7.5 of Schedule 3 to the Regulations, including in relation to the application of and 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 Class I medical devices in the Register. The need to determine accompanying information in relation to the relevant

Class I medical devices in accordance with the Amendment Determination has arisen 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 Class I medical devices in the Register, from an average of 150 applications per month to a peak of over 1,200 applications in April 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 members who are not familiar with conformity assessment procedures that must be applied in relation to the relevant Class I 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 clauses 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 Class I medical devices and the accuracy of the Register.

The Amendment Determination otherwise makes a small number of minor amendments to the Principal Determination that are stylistic and editorial in nature. These amendments are intended to improve readability, without introducing any substantive changes.

### **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 the relevant Class I medical devices, and strongly supported the proposal.

The Prime Minister has granted an exemption from the requirement to complete a regulatory impact analysis in the form of a Regulation Impact Statement for all urgent and unforeseen Australian Government measures made in response to COVID-19. The Amendment Determination is made in response to the public health emergency and relies on this exemption (OBPR ID: 26445).

The Amendment Determination does not incorporate any documents by reference.

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 1 October 2020.

**Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (COVID-19 Measures—Class I Medical Devices) Determination 2020***

**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—Class I Medical Devices) Determination 2020* (“the Amendment Determination”).

**Section 2 – Commencement**

This section provides that the Amendment Determination commences on 1 October 2020.

**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 inserts a new subsection 5(1A) in the Principal Determination to determine that an application for a Class I medical device that the manufacturer intends to be supplied in a non-sterile state and that does not have a measuring function must be accompanied by a declaration of conformity and a conformity assessment document as specified in the new table in Division 1 of Part 1 of Schedule 1 as inserted by the Amendment Determination.

Item 2 of this Schedule repeals and replaces subsection 5(1) of the Principal Determination to clarify that the accompanying information determined in that subsection relates to an application for a Class I medical device that the manufacturer intends to be supplied in a sterile state or that has a measuring function.

Items 3 and 4 of this Schedule insert references to subsections 5(1) and 5(1A) in subsections 5(2)(a) and 5(2)(b) of the Principal Determination respectively, as a consequence of the amendments made by items 1 and 2 of this Schedule.

Items 5 and 6 of this Schedule omit references to section 8 in subsections 5(3), (5), (7) and (9) and subsections 6(1), (3), (5) and (7) of the Principal Determination, to more accurately reflect that those

subsections are not subject to section 8, but that section 8 provides alternative kinds of accompanying information.

Item 7 of this Schedule inserts a new subsection 7(1A) in the Principal Determination to determine that an application for a Class I system or procedure pack that the manufacturer intends to be supplied in a non-sterile state and does not have a measuring function must be accompanied by a declaration of conformity and a conformity assessment document as specified in the new table in Division 1 of Part 1 of Schedule 1 as inserted by the Amendment Determination.

Item 8 of this Schedule repeals and replaces subsection 7(1) of the Principal Determination as a consequence of the amendment made by item 7 of this Schedule, to provide that the kind of accompanying information for the relevant system or procedure packs under that subsection are specified in the table in Division 2 of Part 1 of Schedule 3.

Items 9 and 10 of this Schedule amend subsections 8(1) and (2) of the Principal Determination to improve the clarity of expression in those provisions, which relate to the alternative kinds of information that may be provided under sections 5 and 6 of the Principal Determination respectively.

Item 11 of this Schedule repeals paragraph 9(a) of the Principal Determination, as a consequence of the Amendment Determination determining accompanying information for applications in relation to a Class I medical devices that the manufacturer intends to be supplied in a non-sterile state and do not have a measuring function.

Item 12 of this Schedule inserts two new Division headings in Part 1 of Schedule 1. In addition, item 12 inserts a new 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 the new subsection 5(1A) inserted by item 1 of this Schedule.

Item 13 of this Schedule inserts two new Division headings in Part 1 of Schedule 3. In addition, item 12 inserts a new table specifying accompanying information (namely, a declaration of conformity made by the manufacturer under clause 7.5 of Schedule 3 to the Regulations) for the purposes of the new subsection 7(1A) inserted by item 7 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—Class I Medical Devices) Determination 2020***

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 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 which 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—Class I Medical Devices) Determination 2020* (“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 primarily to specify that a declaration of conformity made by a manufacturer under clauses 6.6 or 7.5 of Schedule 3 to the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the Regulations”) must accompany an application for inclusion in relation to a Class I medical device or Class I system or procedure pack (respectively) that the manufacturer intends to be supplied in a non-sterile state and that does not have a measuring function (“the relevant Class I medical devices”). Manufacturers of these devices must declare a number of matters in accordance with a declaration of conformity under clauses 6.6 or 7.5 of Schedule 3 to the Regulations, including in relation to the application of and 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 Class I medical devices in the Register. The need to determine accompanying information in relation to the relevant Class I medical devices in accordance with the amendment instrument has arisen 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 Class I medical devices in the Register, from an average of 150 applications per month to a peak of over 1,200 applications in April 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 members who are not familiar with conformity assessment procedures that must be applied in relation to the relevant Class I 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 clauses 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.

### **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 clauses 6.6 or 7.5 of Schedule 3 to the Regulations) accompanying an application for inclusion of the relevant Class I medical devices in the Register. 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 clauses 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 Class I 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.