

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Class III, Class AIMD and Class 4 IVD) 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 (“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 (Class III, Class AIMD and Class 4 IVD) 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 reflect the repeal of regulation 4.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”) by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, and to specify conformity assessment documents that will be accepted by the TGA in support of an application for inclusion in the Register for the kinds of medical devices that were previously mentioned in regulation 4.1.

Regulation 4.1 of the MD Regulations was previously made for section 41EA of the Act and specified the kinds of medical devices for which a conformity assessment certificate must have been issued by the Secretary before a valid application could be made for inclusion in the Register. The practical effect of the provision was to preclude an application for inclusion of such devices being supported by a conformity assessment document issued by a comparable overseas regulator.

The devices to which regulation 4.1 applied were:

- medical devices, other than IVD medical devices, that contain tissues of animal origin that have been rendered non-viable (other than those that are intended to come into contact with intact skin only);
- medical devices, other than IVD medical devices, that contain tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body;
- medical devices, other than IVD medical devices, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;
- medical devices, other than IVD medical devices, that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device;
- Class 4 IVD medical devices;
- Class 4 in-house IVD medical devices (other than those to which the conformity assessment procedures set out in Part 6B of Schedule 3 are applied).

The repeal of regulation 4.1 of the MD Regulations means that sponsors and manufacturers of such devices are no longer limited to obtaining conformity assessment certificates issued by the Secretary to demonstrate the safety and quality of their manufacturing processes prior to inclusion in Australia. The Amendment Determination is made in response to this change and permits applications for the inclusion of such devices in the Register to supply certain other kinds of supporting documents to demonstrate such matters, notably, a certificate issued by a notified body in Europe.

This will provide greater flexibility for sponsors and manufacturers of these kinds of higher risk 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

Specific consultation was not undertaken in relation to the Amendment Determination, as its effect is principally to complement and reflect amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002* that were recently made by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, to increase flexibility for device manufacturers and sponsors to demonstrate the conformity assessment of certain kinds of higher risk medical devices. The TGA consulted on this measure in 2016, with stakeholders (including notified bodies in Europe) indicating broad support to enable increased flexibility and Australian conformity assessment bodies to undertake conformity assessment for certain kinds of medical devices.

The amendments are machinery in nature and are related to the amendments made by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021* that facilitate the implementation of recommendation 15 of the Medicines and Medical Devices Review, which was considered to be a RIS-like process (OBPR: 18884).

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 the day after it is registered on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (Class III, Class AIMD and Class 4 IVD) 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 (Class III, Class AIMD and Class 4 IVD) Determination 2021* (“the Amendment Determination”).

Section 2 – Commencement

This section provides that the Amendment Determination commences the day after the Amendment Determination is registered.

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 provides for a definition of “specified medical device” in section 4 of the Principal Determination. This term captures medical devices, which are not IVD medical devices, that were mentioned in the now-repealed regulation 4.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”). Paragraphs (a) to (d) of the definition are drafted in the same terms as the former subparagraphs 4.1(a) to (d) of the MD Regulations.

Item 2 of this Schedule amends subsection 5(7) of the Principal Determination to exclude the application of subsection 5(7) to Class III medical devices that fall within the definition of specified medical devices. This does not change the effect of subregulation 5(7) as it applies to Class III medical devices. It only has the effect that subsection 5(7) does not apply to a Class III medical device if the device is a specified medical device.

Item 3 of this Schedule amends paragraph 5(7)(a) of the Principal Determination to provide that a Class III medical device that is not a specified medical device must be accompanied by a conformity assessment document specified in Division 1 of Part 4 of Schedule 1 to the Principal Determination.

Item 4 of this Schedule introduces subsections 5(8A) and (8B) into the Principal Determination. These new subsections determine the information that is required to accompany an application for inclusion of a Class III medical device that is a specified medical device. These subsections specifically indicate that a conformity assessment document mentioned in the new Division 2 of Part 4 of Schedule 1 to the Principal Determination must be provided.

Item 5 of this Schedule amends subsection 5(9) of the Principal Determination to exclude the application of subsection 5(9) to Class AIMD medical devices that fall within the definition of specified medical devices. This does not change the effect of subsection 5(9) as it applies to Class AIMD medical devices. It only has the effect that subsection 5(9) does not apply to a Class AIMD medical device if the device is a specified medical device.

Item 6 of this Schedule amends paragraph 5(9)(a) of the Principal Determination to provide that a Class AIMD medical device that is not a specified medical device must be accompanied by a conformity assessment document specified in Division 1 of Part 5 of Schedule 1 to the Principal Determination.

Item 7 of this Schedule introduces subsections 5(10A) and (10B) into the Principal Determination. These new sections determine the information required to accompany an application for inclusion of a Class AIMD medical device that is a specified medical device. These subsections specifically indicate that a conformity assessment document mentioned in the new Division 2 of Part 5 of Schedule 1 to the Principal Determination must be provided.

Item 8 of this Schedule makes a consequential amendment to Part 4 of Schedule 1 by inserting a new heading ‘Division 1—Class III medical devices that are not specified medical devices’, which is required due to the amendment made by item 3.

Item 9 of this Schedule introduces Division 2 into Part 4 of Schedule 1 to the Principal Determination and corresponds with the new sections 8A and 8B of the Principal Determination. The table in this Division lists the types of conformity assessment documents, either issued by the Therapeutic Goods Administration (“the TGA”), a notified body within the meaning of Council Directive 93/42/EEC, a notified body within the meaning of Council Directive 90/385/EEC or a notified body within the meaning of the EU medical devices regulation, that may accompany an application for inclusion of a Class III medical device that is a specified medical device in the Register. Under regulation 5.3 of the MD Regulations, an application for inclusion of a Class III medical device (that has not been assessed under the EC Mutual Recognition Agreement or the EFTA Mutual Recognition Agreement) is ordinarily subject to mandatory audit under paragraph 41FH(1)(a) of the Act. However, recent amendments to the MD Regulations, made by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, provide that applications for inclusion of a medical device in the Register are not subject to mandatory audit under paragraph 41FH(1)(a) of the Act if supported by a conformity assessment document issued by a notified body within the meaning of the EU medical devices regulation. Such applications may, however, be selected for audit under paragraph 41FH(1)(b) of the Act.

Item 10 of this Schedule makes a consequential amendment to Part 5 of Schedule 1 by inserting a new heading ‘Division 1—Class AIMD medical devices that are not specified medical devices’, which is required due to the amendment made by item 6.

Item 11 of this Schedule introduces Division 2 into Part 5 of Schedule 1 to the Principal Determination and corresponds with the new subsections 5(10A) and (10B) of the Principal Determination. The table in this Division lists the type of conformity assessment documents, either issued by the TGA, a notified body within the meaning of Council Directive 93/42/EEC, a notified body within the meaning of Council Directive 90/385/EEC or a notified body within the meaning of the EU medical devices regulation, that may accompany an application for inclusion of a Class AIMD medical device that is a specified medical device in the Register. An application for inclusion of a

Class AIMD medical device is ordinarily subject to mandatory audit under paragraph 41FH(1)(a) of the Act together with regulation 5.3 of the MD Regulations. However, recent amendments to the MD Regulations, made by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, provide that applications for inclusion of a medical device in the Register are not subject to mandatory audit under paragraph 41FH(1)(a) of the Act if supported by a conformity assessment document issued by a notified body within the meaning of the EU medical devices regulation. Such applications may, however, be selected for audit under paragraph 41FH(1)(b) of the Act.

Item 12 of this Schedule amends Part 3 of Schedule 2 to the Principal Determination, adding new items 3 to 6 to the end of the table. The effect of this amendment is to expand the types of conformity assessment documents that are capable of satisfying the requirements of subsections 6(5) and (6) of the Principal Determination. Those conformity assessment documents now include documents issued by a notified body within the meaning of Directive 98/79/EC or a notified body within the meaning of the EU IVD regulation, as well as those issued by the TGA (which were previously the only conformity assessment documents capable of satisfying the requirements of subsections 6(5) and (6)). Recent amendments to the MD Regulations, made by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, provide that applications for inclusion of a Class 4 IVD medical device in the Register are now subject to mandatory audit under paragraph 41FH(1)(a) of the Act, unless supported by a conformity assessment document issued by a notified body within the meaning of the EU medical devices regulation. Such applications may still, however, be selected for audit under paragraph 41FH(1)(b) of the Act.

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 (Class III, Class AIMD and Class 4 IVD) 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 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 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 (Class III, Class AIMD and Class 4 IVD) Determination 2021* (“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 reflect the repeal of regulation 4.1 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (“the MD Regulations”) by the *Therapeutic Goods Legislation Amendment (2021 Measures No. 2) Regulations 2021*, and to specify additional conformity assessment documents that will be accepted by the TGA in support of an application for inclusion in the Register for the kinds of medical devices that were previously mentioned in regulation 4.1.

Regulation 4.1 of the MD Regulations was previously made for section 41EA of the Act and specified the kinds of medical devices for which a conformity assessment certificate must have been issued by the Secretary before a valid application could be made for inclusion in the Register. The practical effect of the provision was to preclude an application for inclusion of such devices being supported by a conformity assessment document issued by a comparable overseas regulator.

The devices to which regulation 4.1 applied were:

- medical devices, other than IVD medical devices, that contain tissues of animal origin that have been rendered non-viable (other than those that are intended to come into contact with intact skin only);
- medical devices, other than IVD medical devices, that contain tissues, cells or substances of microbial or recombinant origin and are intended for use in or on the human body;
- medical devices, other than IVD medical devices, incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;

- medical devices, other than IVD medical devices, that incorporate, or are intended to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device;
- Class 4 IVD medical devices;
- Class 4 in-house IVD medical devices (other than those to which the conformity assessment procedures set out in Part 6B of Schedule 3 are applied).

The repeal of regulation 4.1 of the MD Regulations means that sponsors and manufacturers of such devices are no longer limited to obtaining conformity assessment certificates issued by the Secretary to demonstrate the safety and quality of their manufacturing processes prior to inclusion in Australia. The instrument is made in response to this change and permits applications for the inclusion of such devices in the Register to supply certain other kinds of supporting documents to demonstrate such matters, notably, a certificate issued by a notified body in Europe.

This will provide greater flexibility for sponsors and manufacturers of these kinds of higher risk 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 ensuring that there is sufficient documentary evidence accompanying an application for inclusion of the affected kinds of medical devices in the Register, to demonstrate the safety and quality of the manufacturing processes used to manufacture such products.

The conformity assessment documents that may accompany applications for higher risk 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, this measure reduces delay in getting medical devices to market as applicants will not be restricted to one particular kind of conformity assessment document. For example, in the event that an applicant has existing conformity assessment certification from a European notified body, the applicant will no longer be obliged to obtain a separate conformity assessment certificate from the Secretary.

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.