

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 2) 2024

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy or performance, 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.

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”). Relevantly, paragraph 41FDB(2)(d) provides that such an application must be accompanied by information that is of a kind determined under subsection (7) and is in a form determined under subsection (8).

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* (“the Principal Determination”) is a legislative instrument made under subsections 41FDB(7) and (8) of the Act. It determines the kind of information, and the form of information, that must accompany an application for a kind of medical device to be included in the Register (“application for inclusion”).

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 2) 2024* (“the Amendment Determination”) is made under subsection 41FDB(7) of the Act. It makes a small number of amendments to the Principal Determination, which are broadly intended to:

- update the kind of information that must accompany an application for inclusion of a Class IIa or Class III medical device, if the applicant seeks to rely on conformity assessment documents that are issued by the United States Food and Drug Administration (“the US FDA”); and
- make two minor corrections to the Principal Determination.

Background

The Principal Determination requires an application for inclusion of a kind of medical device in the Register to be accompanied by conformity assessment documents which demonstrate that the manufacturer has applied appropriate conformity assessment procedures to its quality management system and to the particular kind of medical device. If an application for inclusion is not accompanied by the kind of information prescribed in the Principal Determination, the application will not pass preliminary assessment, and the Secretary must refuse the application (subsection 41FDB of the Act refers).

Section 5 of the Principal Determination prescribes the kind of information that must accompany an application for inclusion of a medical device that is not an in-vitro diagnostic (IVD) medical device. Relevantly:

- subsection 5(3) prescribes the kind of information that must accompany an application for inclusion of a Class IIa medical device—being the conformity assessment

documents that are specified by an item in the table in Part 2 of Schedule 1 to the Principal Determination; and

- subsection 5(7) prescribes the kind of information that must accompany an application for inclusion of a Class III medical device—being the conformity assessment documents that are specified by an item in the table in Part 4 of Schedule 1 to the Principal Determination.

The tables in Schedules 1 and 2 set out the information that must accompany an application for inclusion. For each of the tables in Schedules 1 and 2 to the Principal Determination, each item sets out conformity assessment documents, relating to the manufacturer’s quality management system and to product assessment (if any), issued by a particular regulatory body that an applicant may seek to rely on to support their application. A number of these pathways specify conformity assessment documents that are issued by comparable overseas regulators, such as the US FDA. This reflects that for certain kinds of devices, the TGA will consider evidence from a comparable overseas regulator in support of an application for inclusion. This reduces regulatory burden for applicants who can rely on overseas conformity assessment documents in support of their application, and do not need to apply for Australian conformity assessment documents.

Purpose

The principal purpose of the Amendment Determination is to reduce regulatory burden for persons applying for inclusion in the Register of a Class IIa medical device that the US FDA has exempted from the requirements in section 510(k) of the *Federal Food, Drug and Cosmetic Act* of the United States (“the US FDC Act”). The Amendment Determination amends Part 2 of Schedule 1 to the Principal Determination to make it clear that an application for inclusion of such a device in the Register only needs to be accompanied by a Medical Device Single Audit Program (“MDSAP”) certificate issued by a recognised auditing organisation. This reflects that, in such cases, conformity assessment documents issued by the US FDA relating to product assessment are not available to the applicant.

Applications for inclusion of medical devices that are not exempt from the requirements in section 510(k) of the US FDC Act are still required to be supported by either a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act or an order granting a request for classification under section 513 of the US FDC Act (a De Novo classification request).

The Amendment Determination also provides improved flexibility for persons who, when applying for the inclusion in the Register of a Class III medical device, seek to rely on conformity assessment documents issued by the US FDA. It does so by amending Part 4 of Schedule 1 to the Principal Determination to broaden the range of US FDA conformity assessment documents relating to product assessment that an applicant may rely on to support their application for inclusion. The effect of this amendment is that, where an applicant seeks to rely on a MDSAP certificate issued by a recognised auditing organisation to demonstrate that the appropriate conformity assessment procedures have been applied to the manufacturer’s quality management system, the applicant must also submit either of the following:

- an order approving an application for premarket approval under section 515 of the US FDC Act; or

- a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act.

That is, instead of submitting an order approving an application for premarket approval under section 515, an applicant could instead provide a determination of substantial equivalence made with respect to a notification submitted under section 510(k).

Finally, the Amendment Determination makes a small number of amendments to section 5 of the Principal Determination. The purpose of these amendments is to make two minor corrections to the Principal Determination. Specifically, the Amendment Determination inserts the heading “Class III medical devices” before subsection 5(7) of the Principal Determination and omits the reference in paragraph 5(7)(a) to the now-repealed Division 1 of Part 4 of Schedule 1 to the Principal Determination.

Incorporation by reference

The Amendment Determination does not incorporate or prescribe any matters by reference to the provisions of the US FDC Act. Instead, references to sections 510(k) and 515 of the US FDC Act are simply references to the fact of whether certain regulatory decisions have been made by the US FDA in accordance with those provisions.

Consultation

Between August and September 2024, the TGA engaged in targeted consultation with 17 industry participants about the proposed amendment to Part 2 of Schedule 1 to the Principal Determination. The TGA received 5 responses in total—from Zimmer Biomet Australia, Becton Dickinson Australia, Stryker, Medtronic, and a representative of the Medical Technology Association of Australia—each of which was broadly supportive of the proposal.

The amendment to Part 4 of Schedule 1 to the Principal Determination was inadvertently omitted from the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024* (July 2024 Instrument). Consultation on this amendment was undertaken as part of the TGA’s consultation on the amendments proposed to the application audit framework in the July 2024 Instrument.

No consultation was undertaken in relation to the minor, editorial amendments that are made by the Amendment Instrument, as these are intended simply to improve the readability of the Principal Determination.

Other details

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

In 2023, the Office of Impact Analysis (“OIA”) advised that an impact analysis was not required for the TGA’s proposed reforms to the application audit framework for medical devices, including in relation to the proposed amendment to Part 4 of Schedule 1 to the Principal Determination (OIA23-04966).

The TGA did not engage with the OIA in relation to the amendment to Part 2 of Schedule 1 to the Principal Determination, as this amendment is de-regulatory in nature. The amendments to section 5 of the Principal Determination are minor and machinery as they simply make editorial corrections.

The Amendment Determination is compatible with the human rights and freedoms that are 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 the day after registration on the Federal Register of Legislation.

Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 2) 2024*

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 Determination (No. 2) 2024* (“the Amendment Determination”).

Section 2 – Commencement

This section provides that the Amendment Determination commences the day after registration on the Federal Register of Legislation.

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. The Amendment Determination 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 – Before subsection 5(7)

This item amends subsection 5(7) of the Principal Determination to insert a subsection heading “*Class III medical devices*”. This heading was inadvertently repealed by the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024* (“the July 2024 Instrument”).

Item 2 – Paragraph 5(7)(a)

This item amends paragraph 5(7)(a) of the Principal Determination to omit the reference to Division 1 of Part 4 of Schedule 1. This reference is redundant as the effect of the relevant

amendment in the July 2024 Instrument was that Part 4 of Schedule 1 to the Principal Determination no longer contains Divisions.

Item 3 – Part 2 of Schedule 1 (cell at table item 8, column 4)

This item updates the requirements for Class IIa medical devices where an application for inclusion of the device in the Australian Register of Therapeutic Goods (“the Register”) is supported by conformity assessment documents from the United States Food and Drug Administration (“the US FDA”). It does so by amending column 4 of table item 8 in Part 2 of Schedule 1 to the Principal Determination.

In complying with the requirements of table item 8, an application for the inclusion of a Class IIa medical device in the Register must be accompanied by the following conformity assessment documents:

- in relation to the manufacturer’s quality management system—a Medical Device Single Audit Program (“MDSAP”) certificate issued by a recognised auditing organisation; and
- in relation to product assessment—either of the following:
 - a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the *Federal Food, Drug and Cosmetic Act* of the United States (“the US FDC Act”); or
 - an order granting a request for classification under section 513 of the US FDC Act (i.e., a De Novo classification request).

A notification submitted by a person under section 510(k) of the US FDC Act is essentially a premarket submission to the US FDA that the device to be marketed is substantially equivalent (in terms of safety and efficacy) to a device that is already lawfully marketed in the United States. However, the US FDA may exempt certain kinds of medical devices (including medical devices that are regulated as Class IIa medical devices in Australia) from the notification requirements in section 510(k) of the US FDC Act, on the basis that this is not required to provide reasonable assurance as to the safety or performance of the device.

The relevant effect of a Class IIa medical device being exempt from the requirements in section 510(k) of the US FDC Act is that no conformity assessment documents in relation to product assessment are issued by the US FDA in respect of that device. Therefore, persons wishing to apply for inclusion of such a device in the Register are unable to provide the TGA with all the conformity assessment documents that are specified in table item 8 in Part 2 of Schedule 1 to the Principal Determination.

The amendment made by this item clarifies that the documents specified in column 4 of item 8 in Part 2 of Schedule 1 are only required for medical devices that are not exempted by the US FDA from section 510(k) requirements. Therefore, where the application for inclusion relates to a Class IIa medical device that has been exempted from the requirements in section 510(k) of the US FDC Act, the application need not be accompanied by a conformity assessment document relating to product assessment. In such cases, the application only needs to be accompanied by a MDSAP certificate issued by a recognised auditing organisation as a conformity assessment document relating to the manufacturer’s quality management system.

Item 4 – Part 4 of Schedule 1 (cell at table item 11, column 4)

This item amends table item 11 in Part 4 of Schedule 1 to the Principal Determination, which specifies the requirements for Class III medical devices where an application for inclusion of the device in the Register is supported by conformity assessment documents from the US FDA. The purpose of this amendment is to effectively broaden the range of conformity assessment documents relating to product assessment that an applicant may submit to the TGA in support of their application.

In complying with the requirements in table item 11, an application for inclusion in the Register of a Class III medical device must be accompanied by the following conformity assessment documents:

- in relation to the manufacturer’s quality management system—a MDSAP certificate issued by a recognised auditing organisation; and
- in relation to product assessment—an order approving an application for premarket approval under section 515 of the US FDC Act.

This item amends the cell at column 4 of table item 11 to specify a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act. Such a determination is an alternative to an order approving an application for premarket approval under section 515 of the US FDC Act, and represents a decision of the US FDA that the relevant device meets minimum benchmarks for safety and performance.

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 Determination (No. 2) 2024

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

Section 41FDB of the *Therapeutic Goods Act 1989* (“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”). Relevantly, paragraph 41FDB(2)(d) provides that such an application must be accompanied by information that is of a kind determined under subsection (7) and is in a form determined under subsection (8).

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- make two minor corrections to the Principal Determination.

Background

The Principal Determination requires an application for inclusion of a kind of medical device in the Register to be accompanied by conformity assessment documents which demonstrate that the manufacturer has applied appropriate conformity assessment procedures to its quality management system and to the particular kind of medical device. If an application for inclusion is not accompanied by the kind of information prescribed in the Principal Determination, the application will not pass preliminary assessment, and the Secretary must refuse the application (subsection 41FDB of the Act refers).

Section 5 of the Principal Determination prescribes the kind of information that must accompany an application for inclusion of a medical device that is not an in-vitro diagnostic (IVD) medical device. Relevantly:

- subsection 5(3) prescribes the kind of information that must accompany an application for inclusion of a Class IIa medical device—being the conformity assessment documents that are specified by an item in the table in Part 2 of Schedule 1 to the Principal Determination; and
- subsection 5(7) prescribes the kind of information that must accompany an application for inclusion of a Class III medical device—being the conformity assessment documents that are specified by an item in the table in Part 4 of Schedule 1 to the Principal Determination.

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Purpose

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Applications for inclusion of medical devices that are not exempt from the requirements in section 510(k) of the US FDC Act are still required to be supported by either a determination of substantial equivalence made with respect to a notification submitted under section 510(k) of the US FDC Act or an order granting a request for classification under section 513 of the US FDC Act (a De Novo classification request).

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Human rights implications

The Amendment Determination 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 Amendment Determination 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. The effect of the Amendment Determination will be to enable the TGA to process such applications in a more efficient and timely manner, and reduce regulatory burden for medical device sponsors and manufacturers by supporting enhanced international cooperation.

The information will also 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 amendments will reduce delays in access to medical devices for Australian patients and health practitioners.

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.