EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination (No. 3) 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. 3) 2024* ("the Amendment Determination") is made under subsection 41FDB(7) of the Act. It amends the Principal Determination to align the transition timelines for acceptability of European regulatory approvals with those under *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* ("EU IVD regulation"). The Amendment Determination also introduces requirements to provide evidence that steps are being taken by the manufacturer of a Class 2, Class 3 or Class 4 in vitro diagnostic medical device ("IVD medical device") to transition to compliance with the EU IVD regulation.

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 6 of the Principal Determination prescribes the kind of information that must accompany an application for inclusion of an IVD medical device. Relevantly:

- subsection 6(1) prescribes the kind of information that must accompany an application for inclusion of a Class 2 IVD medical device—being the conformity assessment documents that are specified by an item in the table in Part 1 of Schedule 2;
- subsection 6(3) prescribes the kind of information that must accompany an application for inclusion of a Class 3 IVD medical device—being the conformity assessment documents that are specified by an item in the table in Part 2 of Schedule 2; and
- subsection 6(5) prescribes the kind of information that must accompany an application for inclusion of a Class 4 IVD medical device—being the conformity assessment documents that are specified by an item in the table in Part 3 of Schedule 2.

The tables in Schedule 2 to the Principal Determination set out the information that must accompany an application for inclusion. For each of the tables in Schedule 2, each item sets out conformity assessment documents, relating to the manufacturer's quality management system and to product assessment (if any) that an applicant may seek to rely on to support their application for inclusion. A number of these pathways specify conformity assessment documents that are issued or recognised by comparable overseas regulators, such as notified bodies. Notified bodies are bodies that have been designated by a member state of the European Union ("EU"), and notified to the European Commission, to assess the conformity of medical devices, including IVD medical devices.

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 separately apply for Australian conformity assessment documents.

Purpose

The purpose of the Amendment Determination is to align the transition timelines for acceptability of European regulatory approvals with those under the EU IVD regulation, and introduce a requirement for evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation for Class 2, Class 3 and Class 4 IVD medical devices where the application for inclusion is supported by evidence issued or recognised by a notified body. The amendments reduce regulatory duplication and help ensure continued access to such devices in Australia, while ensuring that steps are being taken by manufacturers to transition to regulation under the EU IVD regulation.

On 25 April 2024, the EU extended its transition timeframes for manufacturers to transition from regulation under Directive 98/79/EC to regulation under the EU IVD regulation. The extended transition timelines apply to manufacturers that meet the exemption criteria outlined in the EU IVD regulation until, relevantly:

- 1 January 2030, for class B IVD medical devices (which are equivalent to Class 2 IVD medical devices in Australia); and
- 1 January 2029, for class C IVD medical devices (which are equivalent to Class 3 IVD medical devices in Australia).
- 1 January 2028, for class D IVD medical devices (which are equivalent to Class 4 IVD medical devices in Australia).

The transition times for IVD medical devices outlined in the Principal Determination are based on the EU transition timelines previously provided for in the EU IVD regulation. However, new transitional timeframes were introduced in the EU IVD regulation by the *Regulation (EU) 2024/1860 of the European Parliament and of the Council of 3 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.* These new timeframes give industry more time to comply with the new requirements in the EU IVD regulation.

The purpose of the Amendment Determination is to make consequential amendments to the Principal Determination to reflect and adopt the new transitional timeframes reflected in the EU IVD regulation as amended.

The amendments in the Amendment Determination also include an additional requirement for certain Class 2, Class 3 and Class 4 IVD medical devices for which an application is made before 1 January 2030, 2029 or 2028, respectively. In addition to providing the conformity assessment documentation set out in the tables in Schedule 2 to the Principal Determination, such applications must also be accompanied by evidence to demonstrate compliance with Article 110(3c) of the EU

IVD regulation. This Article sets out a number of conditions that must be met for devices to transition in the EU from regulation under Directive 98/79/EC to regulation under the EU IVD regulation. Evidence of compliance with such conditions demonstrates that steps are being taken by the manufacturer to transition to compliance with the EU IVD regulation, and that the current conformity assessment documentation issued under Directive 98/79/EC is still valid

The Amendment Determination also makes minor amendments to remove redundant table items that are outdated.

Incorporation by reference

The Amendment Determination incorporates by reference Directive 98/79/EC and the EU IVD regulation. Directive 98/79EC sets out the requirements for IVD medical devices and their accessories. Following a transition period, the EU IVD regulation will replace Directive 98/79/EC.

Directive 98/79/EC is already incorporated by reference and defined in the Principal Determination as in force or existing immediately before the commencement of the Principal Determination. The Amendment Determination incorporates the EU IVD regulation as in force or existing on 1 December 2024. This is in accordance with paragraph 14(1)(b) of the *Legislation Act 2003*, which permits a legislative instrument to incorporate a document (that is not an Act or legislative instrument) as it exists at, or before, the time the instrument commences.

Directive 98/79/EC and the EU IVD regulation are freely available from EUR-Lex at eur-lex.europa.eu/.

Consultation

Between 2 August and 29 August 2024, the TGA consulted with the Regulatory and Technical Consultative Forum for medical devices ("RegTech") and Pathology Technology Australia on the proposals to align with the further extension of EU IVD regulation timelines and introduce requirements to provide evidence of compliance with the requirements in Article 110 (3c) of the EU IVD regulation . RegTech is a forum of key industry bodies and associations that facilitates consultation between the TGA and the medical device industry. Pathology Technology Australia (PTA) is the peak representative body for the IVD medical device industry. Both proposals were endorsed and supported by RegTech and PTA.

The Office of Impact Analysis has advised that an impact analysis is not required in relation to amendments to the Principal Determination as the proposals to align the transition timelines with those under the EU IVD regulation, and to introduce a requirement for evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation for Class 2, Class 3 and Class 4 IVD medical devices, have been assessed as minor (OIA24-08280).

Other details

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

The Amendment Determination 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 Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on 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. 3) 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. 3) 2024* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences on the day after it is registered 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 gives legal effect to the amendments in Schedule 1 to the Amendment Determination.

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 – Section 4 (definition of *EU IVD regulation)*

This item replaces the definition of 'EU IVD regulation' in section 4 to reflect that 'EU IVD regulation" means *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices,* as in force on 1 December 2024 ("EU IVD regulation"). The effect of this amendment is to incorporate the EU IVD regulation, including any amendments made to the EU IVD regulation prior to 1 December 2024.

Items 2, 3 and 4 – At the end of subsection 6(1), at the end of subsection 6(3) and at the end of subsection 6(5)

These items introduce new requirements for applications for inclusion of Class 2, Class 3 and Class 4 in vitro diagnostic medical devices ("IVD medical devices") that are accompanied by conformity assessment documents recognised by a notified body within the meaning of *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices* ("Directive 98/79/EC").

The requirements set out in new paragraphs 6(1)(c), 6(3)(c) and 6(5)(c) apply to applications for inclusion of Class 2, Class 3 and Class 4 IVD medical devices submitted before 1 January 2030, 1 January 2029 and 1 January 2028, respectively. In addition to the information specified in item 2 or 2B in Part 1 of Schedule 2, item 3, 3B or 4 in Part 2 of Schedule 2, and item 3 or 4 in Part 3 of

Schedule 2, such applications must also be accompanied by evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation.

Compliance could be demonstrated by evidence such as:

- a self-declaration by the manufacturer confirming that the conditions for the extension are fulfilled; or
- a 'confirmation letter' issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement; or
- supporting documentation demonstrating that the manufacturer has lodged an application for conformity assessment and/or concluded a written agreement with a notified body also by other means.

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).

Item 5 – Part 1 of Schedule 2 (cell at table item 2, column 3)

This item repeals and replaces the cell in column 3 of table item 2 in Part 1 of Schedule 2. The effect of this amendment is that an application for inclusion of a Class 2 IVD medical device, that is submitted before 1 January 2030, must be accompanied by one of the following documents that is recognised by a notified body:

- a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC; or
- a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC.

Items 6 and 9 Part 1 of Schedule 2 (after table item 2A) and Part 2 of Schedule 2 (after table item 3A)

These items introduce new items in the table in Part 1 and Part 2 of Schedule 2A to prescribe conformity assessment documents relating to the manufacturer's quality management system that must accompany applications for inclusion of Class 2 and Class 3 IVD medical devices that are submitted before 1 January 2030 and 1 January 2029 respectively. Such applications must be supported by an EU declaration of conformity made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022.

Items 7 and 11 Part 1 of Schedule 2 (table item 7) and Part 2 of Schedule 2 (table item 11)

This item repeals table item 7 of Part 1 and table item 11 of Part 2 of Schedule 2. These table items related to applications for inclusion of Class 2 or Class 3 IVD medical devices submitted prior to 26 May 2023 that were accompanied by conformity assessment documents issued by or recognised by an IAF accredited conformity assessment body. These table items are repealed on the basis that this timeframe has now passed.

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

This item repeals and replaces the cell in column 3 of table item 3 in Part 2 of Schedule 2. The effect of this amendment is that an application for inclusion of a Class 3 IVD medical device submitted before 1 January 2029 and accompanied by conformity assessment evidence that is recognised by a notified body, must be accompanied by a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC.

Item 10 Part 2 of Schedule 2 (table item 4)

This item repeals and replaces table item 4 in Part 2 of Schedule 2. The effect of this amendment is that an application for inclusion of a Class 3 IVD medical device submitted before 1 January 2029 and accompanied by conformity assessment evidence that is recognised by a notified body must also be accompanied by:

- a production quality assurance certificate or other document issued under section 3 of Annex VII of Directive 98/79/EC; and
- an EC type-examination certificate issued under Annex V of Directive 98/79/EC.

Items 12 and 13 Part 3 of Schedule 2 (table item 3) and Part 3 of Schedule 2 (table item 4)

These items repeal and replace table items 3 and 4 in Part 3 of Schedule 2. The effect of these amendments is that an application for inclusion of a Class 4 IVD medical device submitted before 1 January 2028 and accompanied by conformity assessment evidence that is recognised by a notified body, must be accompanied by:

- a full quality assurance system certificate or other document issued under section 3 of Annex IV of Directive 98/79/EC and an EC design-examination certificate issued under Annex IV of Directive 98/79/EC; or
- a production quality assurance certificate or other document issued under Annex VII of Directive 98/79/EC and an EC type-examination certificate issued under Annex V of Directive 98/79/EC.

Attachment B

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. 3) 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).

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. 3) 2024* ("the Amendment Determination") is made under subsection 41FDB(7) of the Act. It amends the Principal Determination to align the transition timelines for acceptability of European regulatory approvals with those under *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* ("EU IVD regulation"). The Amendment Determination also introduces requirements to provide evidence that steps are being taken by the manufacturer of a Class 2, Class 3 or Class 4 in vitro diagnostic medical device ("IVD medical device") to transition to compliance with the EU IVD regulation.

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 6 of the Principal Determination prescribes the kind of information that must accompany an application for inclusion of an IVD medical device. Relevantly:

- subsection 6(1) prescribes the kind of information that must accompany an application for inclusion of a Class 2 IVD medical device—being the conformity assessment documents that are specified by an item in the table in Part 1 of Schedule 2;
- subsection 6(3) prescribes the kind of information that must accompany an application for inclusion of a Class 3 IVD medical device—being the conformity assessment documents that are specified by an item in the table in Part 2 of Schedule 2; and

- subsection 6(5) prescribes the kind of information that must accompany an application for inclusion of a Class 4 IVD medical device—being the conformity assessment documents that are specified by an item in the table in Part 3 of Schedule 2.

The tables in Schedule 2 to the Principal Determination set out the information that must accompany an application for inclusion. For each of the tables in Schedule 2, each item sets out conformity assessment documents, relating to the manufacturer's quality management system and to product assessment (if any) that an applicant may seek to rely on to support their application for inclusion. A number of these pathways specify conformity assessment documents that are issued or recognised by comparable overseas regulators, such as notified bodies. Notified bodies are bodies that have been designated by a member state of the European Union ("EU"), and notified to the European Commission, to assess the conformity of medical devices, including IVD medical devices.

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 separately apply for Australian conformity assessment documents.

Purpose

The purpose of the Amendment Determination is to align the transition timelines for acceptability of European regulatory approvals with those under the EU IVD regulation, and introduce a requirement for evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation for Class 2, Class 3 and Class 4 IVD medical devices where the application for inclusion is supported by evidence issued or recognised by a notified body. The amendments reduce regulatory duplication and help ensure continued access to such devices in Australia, while ensuring that steps are being taken by manufacturers to transition to regulation under the EU IVD regulation.

On 25 April 2024, the EU extended its transition timeframes for manufacturers to transition from regulation under Directive 98/79/EC to regulation under the EU IVD regulation. The extended transition timelines apply to manufacturers that meet the exemption criteria outlined in the EU IVD regulation until, relevantly:

- 1 January 2030, for class B IVD medical devices (which are equivalent to Class 2 IVD medical devices in Australia); and
- 1 January 2029, for class C IVD medical devices (which are equivalent to Class 3 IVD medical devices in Australia).
- 1 January 2028, for class D IVD medical devices (which are equivalent to Class 4 IVD medical devices in Australia).

The transition times for IVD medical devices outlined in the Principal Determination are based on the EU transition timelines previously provided for in the EU IVD regulation. However, new transitional timeframes were introduced in the EU IVD regulation by the *Regulation (EU) 2024/1860 of the European Parliament and of the Council of 3 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices.* These new timeframes give industry more time to comply with the new requirements in the EU IVD regulation.

The purpose of the Amendment Determination is to make consequential amendments to the Principal Determination to reflect and adopt the new transitional timeframes reflected in the EU IVD regulation as amended.

The amendments in the Amendment Determination also include an additional requirement for certain Class 2, Class 3 and Class 4 IVD medical devices for which an application is made before

1 January 2030, 2029 or 2028, respectively. In addition to providing the conformity assessment documentation set out in the tables in Schedule 2 to the Principal Determination, such applications must also be accompanied by evidence to demonstrate compliance with Article 110(3c) of the EU IVD regulation. This Article sets out a number of conditions that must be met for devices to transition in the EU from regulation under Directive 98/79/EC to regulation under the EU IVD regulation. Evidence of compliance with such conditions demonstrates that steps are being taken by the manufacturer to transition to compliance with the EU IVD regulation, and that the current conformity assessment documentation issued under Directive 98/79/EC is still valid

The Amendment Determination also makes minor amendments to remove redundant table items that are outdated.

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, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

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 reducing delays in access to medical devices for Australian patients and health practitioners. The amendments will reduce the regulatory burden for medical device sponsors and manufacturers by supporting enhanced international cooperation. This enables medical device sponsors and manufacturers to rely on conformity assessment documentation issued/recognised in the EU, without needing to separately apply for conformity assessment documentation in Australia.

The Amendment Determination would also ensure there is appropriate documentary evidence accompanying an application for inclusion of Class 2, Class 3 and Class 4 IVD medical devices in the Register to enable the application to be processed in a more efficient and timely manner. The information that must accompany an application for inclusion in the Register will assist in assessing the safety and satisfactory performance of medical devices, supporting their timely availability in Australia.

Conclusion

This instrument is compatible with human rights because it supports the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.