EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Consequential Amendments) Determination 2022

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.

Under the Principal Determination, an application for the inclusion of a Class 2 in vitro diagnostic (IVD) medical device, or a Class 3 IVD medical device, may be supported by a document issued 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") or an IAF accredited conformity assessment body, certifying compliance with International Standard ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes* ("ISO 13485"), provided the application is submitted before 26 May 2022. (An IAF accredited conformity assessment body is a body that is accredited to undertake certification for compliance with ISO 13485 by an accreditation body member that is a signatory to the Multilateral Recognition Arrangement of the International Accreditation Forum, Inc., otherwise known as the IAF MLA.) The acceptance of such certification for applications that are submitted before this date was designed to align with the European Union's transitional arrangements specified in *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro medical devices* ("the EU IVD regulation").

However, the significant impact of COVID-19 on the diagnostics industry has resulted in delays in the uptake and full implementation of the EU IVD regulation in Europe. In light of these issues, and to ensure the uninterrupted supply of such IVDs in Europe, the European Parliament has extended the

transitional arrangements initially set out under the EU IVD regulation, through amending legislation implemented under *Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022* ("the EU IVD amendment regulation"). Subsequently this has necessitated an extension to the period in which an ISO13485 certification will be acceptable in Australia, to align with current European arrangements. This will also reduce regulatory duplication and help ensure continued access to these products in Australia.

The transitional arrangements for IVDs in the EU IVD amendment regulation allow Class B (the equivalent of Australian Class 2 IVD) and Class C (the equivalent of Australian Class 3 IVD) medical devices that have been lawfully placed on the market in the European Union before 26 May 2022, to continue to be supplied until 26 May 2027 and 26 May 2026, respectively.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Consequential Amendments) Determination 2022* ("the Amendment Determination") is made under subsection 41FDB(7) of the Act and amends the Principal Determination to:

- extend the period of time in which an application for inclusion of Class 2 and Class 3 IVD medical devices may be supported with an ISO 13485 certificate issued by a notified body within the meaning of Directive 98/79/EC or an IAF accredited conformity assessment body, from 26 May 2022 to 26 May 2023; and
- specify that where the manufacturer has an EU declaration of conformity under Directive 98/79/EC prior to 26 May 2022, an application for inclusion for a Class 2 or Class 3 IVD medical device submitted before 26 May 2027 or 26 May 2026 (respectively) may be supported with an ISO 13485 certification issued by a notified body within the meaning of Directive 98/79/EC, or by an IAF conformity assessment body.

Incorporation by reference

The Amendment Determination makes amendments to the Principal Determination in relation to certain kinds of information that may accompany an application for inclusion of a medical device in the Register by reference to documents relating to comparable overseas regulators. These are:

- *Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices*, which sets out the requirements for in vitro medical devices and their accessories. This document is freely available from EUR-Lex at https://eur-lex.europa.eu/; and
- International Standard ISO 13485:2016 *Medical Devices—Quality management systems—Requirements for regulatory purposes* (ISO 13485). This international standard was issued by the International Organization for Standardization in March 2016. It specifies requirements for quality management systems that enable an organisation to demonstrate that it is able to manufacture medical devices and related services that meet applicable regulatory requirements. Unfortunately, this international standard is not freely available as it is subject to copyright, and it may be purchased from www.iso.org. However, by prior written arrangement with the TGA, a copy of the standard may be made available for viewing free of charge at the TGA office in Fairbairn, ACT.

In accordance with section 14 of the *Legislation Act 2003* ("the Legislation Act"), these documents have been incorporated as in force or existing immediately before the commencement of the Principal Determination (as specified in the definitions of these terms in section 4 of the Principal Determination). This means that any subsequent changes to these documents will not be automatically applied under the Determination.

Consultation

The TGA consulted with relevant stakeholders who may be impacted by the proposed extension to the timeframe for acceptance of ISO 13485 certificates supporting applications for Class 2 and 3 IVDs on two separate occasions.

An initial proposal, which outlined the following 3 possible options available was presented and discussed at the Medical Devices Regulatory and Technical Consultative Forum ("RegTech") meeting on 24 February 2022:

- Option 1, which involved no changes to existing provisions;
- Option 2, which involved extending the acceptance of ISO13485 certificates for a period of 12 months with further allowances for devices that are lawfully supplied in the EU, in line with transition arrangements already in place in Europe; and
- Option 3, which involved allowing for continued acceptance of ISO13485 certificates until 2027 to coincide with the end of the EU IVD regulation transition period.

The proposed options were welcomed, but potentially affected stakeholders requested an opportunity to consider, and discuss in more detail, before confirming their preferred option.

A further meeting for RegTech members was held on 23 March 2022, to allow for more detailed discussions and input from interested parties. This meeting was attended by 15 members of Pathology Technology Australia ("PTA"), including in-person representatives from 13 different Australian sponsors. PTA is the main peak body representing manufacturers and importers of IVD tests and technologies that are used in pathology laboratory, hospital and primary care settings in Australia and its members reportedly cover 95 per cent of diagnostics supplied commercially in Australia. In addition, written feedback was also received from two representatives responding on behalf of the Association of Therapeutic Goods Consultants.

The outcome of the discussions and feedback at the March 2022 meeting was strongly supportive of Option 2. Option 1 was not supported, and while there was some discussion around continuing to accept ISO certification for a longer period under Option 3, industry representatives recognised the higher degree of technical and regulatory deficiencies which occur without having product-related regulatory controls in place. The proposal to proceed with Option 2 was confirmed by an online voting poll conducted at the end of the March 2022 meeting, with no objections received.

The amendments are minor and machinery in nature and follow from the implementation of recommendation 15 of the Expert Panel Review of Medicines and Medical Device Regulation, therefore a Regulation Impact Statement is not required (OPBR Ref 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 and commences on the day after it is registered on the Federal Register of Legislation.

Attachment A

Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Consequential Amendments) Determination 2022*

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 (European Union—Consequential Amendments) Determination 2022* ("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. 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 omits the words "26 May 2022", and substitutes "26 May 2023" in column 3 of table item 2 in Part 1 of Schedule 2 to the Principal Determination.

Item 2 of this Schedule inserts new item 2A in the table in Part 1 of Schedule 2, to specify that an application for inclusion of a Class 2 IVD medical device that is submitted before 26 May 2027, may be supported by an ISO 13485 certification issued by a notified body within the meaning of Directive 98/79/EC, provided the sponsor holds an EU declaration of conformity, made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022.

Item 3 of this Schedule omits the words "26 May 2022", and substitutes "26 May 2023" in column 3 of table item 7 in Part 1 of Schedule 2 to the Principal Determination.

Item 4 of this Schedule adds new item 8 to the end of the table in Part 1 of Schedule 2, to specify that an application for inclusion of a Class 2 IVD medical device that is submitted before 26 May 2027, may be supported by an ISO 13485 certification issued by an IAF accredited conformity assessment

body, provided the sponsor holds an EU declaration of conformity, made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022.

Item 5 of this Schedule omits the words"26 May 2022", and substitutes "26 May 2023" in column 3 of table item 3 in Part 2 of Schedule 2 to the Principal Determination.

Item 6 of this Schedule inserts new item 3A in the table in Part 2 of Schedule 2, to specify that an application for inclusion of a Class 3 IVD medical device that is submitted before 26 May 2026, may be supported by an ISO 13485 certification issued by a notified body within the meaning of Directive 98/79/EC, provided the sponsor holds an EU declaration of conformity, made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022.

Item 7 of this Schedule omits the words "26 May 2022", and substitutes "26 May 2023" in column 3 of table item 11 in Part 2 of Schedule 2 to the Principal Determination.

Item 8 of this Schedule adds new item 12 to the end of the table in Part 2 of Schedule 2, to specify that an application for inclusion of a Class 3 IVD medical device that is submitted before 26 May 2026, may be supported by an ISO 13485 certification issued by an IAF accredited conformity assessment body, provided the sponsor holds an EU declaration of conformity, made by the manufacturer under Annex III of Directive 98/79/EC before 26 May 2022.

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 (European Union—Consequential Amendments) Determination 2022

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.

Under the principal instrument, an application for the inclusion of a Class 2 in vitro diagnostic ("IVD") medical device or a Class 3 IVD medical device in the Australian Register of Therapeutic Goods may be supported by a document issued by a notified body within the meaning of Directive 98/79/EC or an IAF accredited conformity assessment body, certifying compliance with ISO 13485, provided the application is submitted before 26 May 2022. The acceptance of such certification for applications submitted before this date was designed to align with the European Union's *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro medical devices* ("the EU IVD regulation").

However, the significant impact of COVID-19 on the diagnostics industry has resulted in delays in the uptake and full implementation of the EU IVD regulation in Europe. In light of these issues, and to ensure the uninterrupted supply of such IVDs in Europe, the European Parliament has extended the transitional arrangements specified in the EU IVD regulation, through amending legislation implemented under *Regulation (EU) 2022/12 of the European Parliament and of the Council of 25 January 2022* ("the EU IVD amendment regulation"). Subsequently, this necessitates an extension to the period in which an ISO13485 certification will be acceptable in Australia, to align with current European arrangements, reduce regulatory duplication and to ensure continued access to these products in Australia.

The transitional arrangements for IVDs in the EU IVD amendment regulation allow Class B (the equivalent of Australian Class 2 IVD) and Class C (the equivalent of Australian Class 3 IVD) medical devices that have been lawfully placed on the market in the European Union before 26 May 2022, to continue to be supplied until 26 May 2027 and 26 May 2026, respectively.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment (European Union—Consequential Amendments) Determination 2022* ("the amendment instrument") is made under subsection 41FDB(7) of the Act and amends the principal instrument to:

- extend the period of time in which an application for inclusion of Class 2 and Class 3 IVD medical devices may be supported with an ISO 13485 certificate issued by a notified body within the meaning of Directive 98/79/EC or an IAF accredited conformity assessment body, being from 26 May 2022 to 26 May 2023; and
- specify that where the manufacturer has an EU declaration of conformity under Directive 98/79/EC prior to 26 May 2022, an application for inclusion for a Class 2 or Class 3 IVD medical device submitted before 26 May 2027 or 26 May 2026 (respectively), may be supported with an ISO 13485 certification issued by a notified body within the meaning of Directive 98/79/EC or an IAF conformity assessment body.

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 there is appropriate documentary evidence accompanying an application for inclusion of Class 2 IVD medical devices and Class 3 IVD medical devices in the Register to enable the application to be processed by the Secretary of the Department of Health in an effective and timely manner. The information that must accompany an application for inclusion in the Register will assist in 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.