EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019

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 the preliminary assessment requirements in relation to an application to the Secretary for a kind of medical device to be included in the Register. These include requirements that the application be accompanied by information that is of a kind determined under subsection 41FDB(7), and in a form determined under subsection 41FDB(8), for the relevant classification of medical device (subparagraphs 41FDB(2)(d)(i) and 41FDB(2)(d)(ii) refers).

Subsections 41FDB(7) and 41FDB(8) of the Act relevantly 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* ("Principal Determination") was made for the purposes of subsections 41FDB(7) and 41FDB(8) of the Act and commenced on 10 October 2018. As above, it 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 this Determination relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the particular kind of medical device. The conformity assessment documents include certificates and other documents which have been issued or recognised by the Secretary and, in the alternative, comparable overseas regulators, as defined in section 41BIB of the Act. The *Therapeutic Goods (Overseas Regulators) Determination 2018* ("Overseas Regulators Determination") specifies the bodies that have been determined by the Secretary to be an overseas regulator for the purposes of section 41BIB of the Act.

The *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019* ("Amendment Determination") amends the Principal Determination primarily to include an additional kind of conformity assessment document that may accompany an application for inclusion in the Australian Register of Therapeutic Goods ("the Register") in relation to Class 2 and Class 3 IVD medical devices. That document is issued by an "IAF accredited conformity assessment body", certifying compliance with International Standard ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*. The practical effect is to enable manufacturers with current ISO 13485 certification from an IAF accredited conformity assessment body sufficient time to obtain certification under the new *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro*

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diagnostic medical devices ("EU IVD Regulation") or an MDSAP certificate. (An MDSAP certificate is a certification document issued by a recognised auditing organisation under the Medical Devices Single Audit Program following the completion of an audit of a manufacturer's quality management system).

The *Therapeutic Goods Amendment (Overseas Regulators) Determination 2019* amends the Overseas Regulators Determination to determine an IAF accredited conformity assessment body as an overseas regulator for the purposes of section 41BIB of the Act. This is defined as 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.

ISO 13485 certification issued by an IAF accredited conformity assessment body may only accompany an application for inclusion of a Class 2 or Class 3 IVD medical device that is submitted before 26 May 2022. That date corresponds with the end of the transition period in relation to the new EU IVD Regulation. From 26 May 2022, technical documentation and processes relating to the manufacture of IVD medical devices will be required to meet the requirements of the EU IVD Regulation (or other certification documentation that has been determined under subsection 41FDB(7) of the Act), and certificates issued under ISO 13485 by an IAF accredited conformity assessment body will no longer be accepted.

Similarly, the transition period applies in relation to ISO 13485 certification 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"). Consequently, the Amendment Determination also amends Schedule 2 to the Principal Determination to clarify that a document certifying compliance with ISO 13485 that is issued by such a body may only accompany an application for inclusion submitted before 26 May 2022.

The Amendment Determination further clarifies that documentation relating to product assessment demonstrating that appropriate conformity assessment procedures have been applied by the manufacturer to the particular kind of device is not determined to be required under the Principal Instrument in relation to applications for inclusion of Class 2 or Class 3 IVD medical devices, which are accompanied by a MDSAP certificate recognised by Health Canada, or a quality management system ("QMS") certificate for the purposes of the Canadian medical devices regulations (item 4 in Part 1 of Schedule 2 and item 7 in Part 2 of Schedule 2 to the Principal Determination refer).

In addition, the requirement in paragraph (b) of those items that an application must have been submitted before 1 January 2019 in relation to a QMS certificate for the purposes of the Canadian medical devices regulations has been removed. These amendments are required as a result of differences in the classification of IVD medical devices in Australia and Canada, and also to allow sufficient time for manufacturers to transition to alternative arrangements. These amendments are also consistent with the current treatment of MDSAP certificates issued by a recognised auditing organisation under the Principal Determination.

Consultation

The TGA conducted extensive consultation in relation to the Expert Panel Review of Medicines and Medical Device Regulation ("Review"). The Review included recommendations to streamline processes for including medical devices in the Register in order to improve access by Australian consumers. In response, the Government introduced

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measures to make greater use of marketing approvals issued by comparable overseas regulators (see Review Recommendation 15).

The TGA conducted targeted stakeholder consultation on 28 February 2019 with members of the Regulatory and Technical Consultative Forum for medical devices ("RegTech") in relation to the amendments proposed by the Amendment Determination. No further consultation was considered necessary for the purposes of making this Amendment Determination, noting that the effect of the amendment provides a beneficial outcome to industry by expanding the kind of conformity assessment documents that may be provided with relevant applications for inclusion.

Documents incorporated by reference

The primary purpose of the Amendment Determination is to specify an additional kind of information that may accompany an application for inclusion in the Register of a Class 2 or Class 3 IVD medical device, being a document certifying compliance with International Standard ISO 13485:2016 issued by an IAF accredited conformity assessment body. This is achieved by repealing and substituting two items in Schedule 2 of the Principal Determination and, in so doing, referencing the following:

- 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. The standard may be purchased from http://www.iso.org. It is not freely available and is subject to copyright. The cost of obtaining the standard is a matter for industry. The TGA has no control over these costs. 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 Symonston, ACT; and
- Multilateral Recognition Arrangement of the International Accreditation Forum, Inc., otherwise known as the IAF MLA—the purpose of the IAF MLA is to allow accreditations and certificates issued by certification and registration bodies accredited by members of the MLA to be recognised by other members of the MLA. Details in relation to the IAF and the MLA are available from the IAF website at www.iaf.nu. The structure and scope of the IAF MLA is detailed in the IAF Procedures Document *Structure of the IAF MLA and List of IAF Endorsed Normative Documents* which is available at the following link on the IAF website: https://www.iaf.nu/upFiles/IAF_PR_MLA_Structure_Normative_Documents_23102015_Publication_Version.pdf. A list of IAF accreditation body members and signatories to the IAF MLA is available at: https://www.iaf.nu/articles/IAF_MEMBERS_SIGNATORIES/4.

In accordance with section 14 of the *Legislation Act 2003*, these documents are incorporated as in force or existing immediately before the commencement of this Determination. This means that any subsequent changes to these documents will not be automatically applied under the Determination.

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

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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 and commences on the day after it is registered.

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Attachment A

Details of the *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019.*

Section 2 – Commencement

This section provides that the instrument commences on the day after it is registered.

Section 3 – Authority

This section provides that the instrument is made under subsection 41FDB(7) of the Act. This provision empowers the Secretary to determine, by legislative instrument, a kind of information that may accompany an application to the Secretary for a kind of medical device to be included in the Register.

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 – Amendments

This section provides that each instrument that is specified in a Schedule to this instrument is amended as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

Schedule 1 amends the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("Principal Determination").

Item 1 of Schedule 1 clarifies that the term 'Act' in section 3 of the Principal Determination is the *Therapeutic Goods Act 1989*.

Item 2 of Schedule 1 inserts a definition of ***IAF accredited conformity assessment body*** into section 4 of the Principal Determination. IAF accredited conformity assessment body is defined as meaning 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. A definition of ISO 13485 is currently included in section 4 of the Principal Determination.

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Item 3 of Schedule 1 repeals and substitutes item 2 of the table in Part 1 of Schedule 2 to the Principal Determination to clarify that ISO 13485 certification issued by a notified body within the meaning of Directive 98/79/EC may only accompany an application for inclusion of a Class 2 IVD medical device submitted before 26 May 2022. Item 7 of the Schedule repeals and substitutes item 3 of the table in Part 2 of Schedule 2 to the Principal Determination in order to make the same provision in relation to an application for inclusion of a Class 3 IVD medical device.

Item 4 of Schedule 1 repeals and substitutes item 4 of the table in Part 1 of Schedule 2 to the Principal Determination to clarify that documentation relating to product assessment demonstrating that appropriate conformity assessment procedures have been applied by the manufacturer to the particular kind of device is not required where an MDSAP certificate recognised by Health Canada, or a quality management system certificate for the purposes of the Canadian medical devices regulations, accompanies an application for inclusion of a Class 2 IVD medical device.

Likewise, item 8 of Schedule 1 repeals and substitutes item 7 of the table in Part 2 of Schedule 2 to the Principal Determination to make similar provision in relation to applications for inclusion of Class 3 IVD medical devices. In addition, items 4 and 8 of Schedule 1 remove the requirement that an application must have been submitted before 1 January 2019 in order to be able to be accompanied by a quality management system certificate for the purposes of the Canadian medical devices regulations.

Item 5 of Schedule 1 contains a minor formatting amendment.

Item 6 of Schedule 1 specifies an additional kind of conformity assessment document certifying compliance with ISO 13485, issued by an IAF accredited conformity assessment body. The effect of new item 7 in the table in Part 1 of Schedule 2 to the Principal Determination is to enable an application for inclusion of a Class 2 IVD medical device submitted before 26 May 2022 to be accompanied by the additional document so determined.

Similarly, item 9 of Schedule 1 inserts a new item 11 into the table in Part 2 of Schedule 2 to the Principal Determination to specify the same conformity assessment document, issued by an IAF accredited conformity assessment body, certifying compliance with ISO 13485. The effect of this new item is to enable an application for inclusion of a Class 3 IVD medical device submitted before 26 May 2022 to be accompanied by the additional document so determined.

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Attachment B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011.

Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019

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 Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2019* is made under subsection 41FDB(7) of the *Therapeutic Goods Act 1989* ("the Act") by a delegate of the Secretary of the Department of Health. The primary purpose of the instrument is to amend the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("the principal instrument") to specify an additional kind of information that may accompany an application for the inclusion of a Class 2 or Class 3 IVD medical device in the Australian Register of Therapeutic Goods ("the Register").

The additional kind of information determined in this instrument is a document certifying compliance with International Standard ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes* ("ISO 13485"), issued by an IAF accredited conformity assessment body. ISO 13485 demonstrates that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system. The instrument is necessary to ensure that applications for inclusion in the Register of Class 2 and Class 3 IVD medical devices submitted before 26 May 2022 may be accompanied by this document.

The practical effect is to enable manufacturers with current ISO 13485 certification from an IAF accredited conformity assessment body sufficient time to obtain certification under the new *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") or a certificate issued by a recognised auditing organisation under the Medical Devices Single Audit Program ("MDSAP certification").

The instrument also amends the principal instrument to consistently apply this transition period in relation to ISO 13485 certification 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*.

In addition, the instrument makes further amendments in relation to information recognised by Health Canada that is currently specified in the principal instrument, and which will also allow time for relevant manufacturers to transition to alternative arrangements.

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Human rights implications

The instrument engages the right to health in Article 12(1) 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 stated 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 that 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 a Class 2 and Class 3 IVD medical device 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 instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.

Miranda Lauman, delegate of the Secretary of the Department of Health

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