EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018

The *Therapeutic Goods Act 1989* ("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.

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 41BIBof the Act).

The *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("Amendment Determination") amends the Principal Determination to include an additional kind of conformity assessment document that may accompany an application for inclusion in the Australian Register of Therapeutic Goods (Register) in relation to Class 2 and Class 3 IVD medical devices. That document is issued by a European notified body within the meaning of Directive 98/79/EC of the European Parliament, certifying compliance with International Standard ISO 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*. It was originally intended to have been included in the Principal Determination but was inadvertently omitted at the time of the Principal Determination's making.

Consultation

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

As part of that process, the TGA conducted targeted stakeholder consultation earlier this year with members of the Regulatory and Technical Consultative Forum for medical devices ("RegTech"). The consultation detailed the kinds of conformity assessment documents that must accompany an application for inclusion in the Register. The consultation included reference to the documents specified in both the Principal Determination and this subsequent Amendment Determination. Consequently, no further consultation was considered necessary for the purposes of this Amendment Determination.

Following consultation earlier this year, guidance outlining the new requirements, with some changes, was made, and additional supporting material, in the form of questions and answers, was developed. The guidance and supporting material were discussed again at the RegTech meeting on 10 August 2018. RegTech members strongly supported the proposal and only provided minor comments, which were taken into consideration before the guidance was finalised. The guidance was published on the TGA website on 20 August 2018 (http://www.tga.gov.au/comparable-overseas-regulators-medical-device-applications). It includes express reference to the additional kind of information that is the subject of this amendment.

Documents incorporated by reference

The 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 a European notified body within the meaning of Directive 98/79/EC of the European Parliament. This is achieved by repealing and substituting two items in Schedule 2 of the Principal Determination and, in so doing, referencing the following documents:

- 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

- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices— this directive of the European Parliament and of the Council of the European Union sets out the requirements for *in vitro* medical devices and their accessories available in the European Union. It is freely available at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:31998L0079.

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.

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.

Attachment A

Details of the *Therapeutic Goods Amendment (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018*

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 2018.*

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 inserts a new definition of ***ISO 13485*** into section 4 of the Principal Determination. ISO 13485 is defined as meaning International Standard 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes*, issued by the International Organization for Standardization in March 2016, as in force or existing immediately before the commencement of this instrument. The note to this definition provides that ISO 13485 is published at: https://www.iso.org.

Item 2 of Schedule 1 repeals and substitutes item 2 of the table in Part 1 of Schedule 2 to the Principal Determination to specify an additional kind of conformity assessment document, issued by a European notified body within the meaning of Directive 98/79/EC, certifying compliance with ISO 13485. The effect of this repeal and substitution is to enable an application for inclusion of a Class 2 IVD medical device to be accompanied by the additional document so determined.

Similarly, item 3 of Schedule 1 repeals and substitutes item 3 of the table in Part 2 of Schedule 2 to the Principal Determination to specify the same conformity assessment document, issued by a European notified body within the meaning of Directive 98/79/EC, certifying compliance with ISO 13485. The effect of this repeal and substitution is to enable an application for inclusion of a Class 3 IVD medical device to be accompanied by the additional document so determined.

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 2018

This 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 2018* is made under subsection 41FDB(7) of the *Therapeutic Goods Act 1989* ("Act") by a delegate of the Secretary of the Department of Health. The purpose of the instrument is to amend the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("Principal Determination") 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 ("Register"). This information was inadvertently omitted from the Principal Determination.

The additional kind of information determined in this instrument is a document certifying compliance with International Standard 13485:2016 *Medical devices—Quality management systems—Requirements for regulatory purposes* ("ISO 13485"), issued by a European notified body within the meaning of Directive 98/79/EC of the European Parliament. This document demonstrates 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 may be accompanied by this document.

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.

Hongxia Jin, delegate of the Secretary of the Department of Health