

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (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.

The *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* (“Amendment Act”) amended the Act, principally to support the implementation of various recommendations of the Expert Panel Review of Medicines and Medical Device Regulation (“Review”). In addition, the Amendment Act made amendments to provide greater clarity and more accurately reflect administrative practices for considering applications for the inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (“Register”). These amendments reflect, for example, the administrative practice of considering whether an application has met certain ‘preliminary’ requirements before the application is processed further.

These preliminary requirements include that an application has been made in accordance with the relevant form that has been approved in writing by the Secretary (or such other approved manner), for a particular class of therapeutic goods, and is accompanied by the kind of information needed to evaluate the application. Where an application does not meet these requirements, the Secretary has the power to refuse the application prior to its evaluation. The preliminary assessment process enables the effective management of resources by the Department in the review of therapeutic goods, and creates certainty for sponsors as to the requirements.

The Amendment Act inserted a new section 41FDB into the Act, which 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* (“Determination”) is made for the purposes of subsections 41FDB(7) and 41FDB(8) of the Act. 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.

In effect, the Determination supports the implementation of Review recommendations 15 and 17 which encouraged greater use of assessments issued or recognised by comparable overseas regulators. In particular, the Determination specifies conformity assessment documents issued or recognised by comparable overseas regulators that may accompany an application for inclusion of a medical device in Australia.

Relevantly, section 41FD of the Act provides that an applicant for the inclusion of a kind of medical device in the Register must certify that appropriate conformity assessment procedures have been applied to devices of that kind, or requirements comparable to such procedures have been applied to medical devices of that kind to the satisfaction of an overseas regulator. The comparable overseas regulators have been specified in the *Therapeutic Goods (Overseas Regulators) Determination 2018* which is a notifiable instrument freely available from the Federal Register of Legislation at legislation.gov.au

Consultation

In addition to the extensive consultation that was conducted in relation to the Review, the Therapeutic Goods Administration (“TGA”) undertook targeted stakeholder consultation this year on the detailed requirements outlined in this Determination with members of the Regulatory and Technical Consultative Forum for medical devices (“RegTech”). This consultation was conducted in conjunction with related changes for use of assessments and approvals from comparable overseas regulators.

Guidance outlining the requirements with some changes were made, and additional supporting material in the form of questions and answers was developed. This 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>).

Documents incorporated by reference

Schedules 1, 2 and 3 to the Determination specify the kinds of information required to accompany an application form for inclusion of a medical device in the Register by reference to certain matters contained in the *Therapeutic Goods (Medical Devices) Regulations 2002* and specified legislation relating to comparable overseas regulators (within the meaning of section 41BIB of the Act).

The *Therapeutic Goods (Medical Devices) Regulations 2002* are made under the *Therapeutic Goods Act 1989* and are freely available from www.legislation.gov.au. In accordance with section 14 of the *Legislation Act 2003* (“Legislation Act”), these regulations are incorporated as amended from time to time, and so any changes subsequently made to these regulations will be automatically incorporated.

The following table contains a description of the other documents relating to overseas regulators that are incorporated by reference into the Determination and how those documents may be obtained. All of these documents are freely available.

Document	Description	Source
Medical Devices Regulations (SOR/98-282) made under the <i>Food and Drugs Act</i> of Canada	These regulations are made under the <i>Food and Drugs Act</i> of Canada and specify requirements in relation to the manufacture, sale, advertising and importation of medical devices, including in vitro medical devices.	http://laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/
Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)	This directive of the Council of the European Communities sets out the requirements for active implantable medical devices available in the European Union (EU).	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:31990L0385
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	This directive of the Council of the European Communities sets out the requirements for medical devices available in the EU.	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31993L0042
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on <i>in vitro</i> diagnostic medical devices	This directive of the European Parliament and of the Council of the European Union sets out the requirements for <i>in vitro</i> medical devices and their accessories available in the EU.	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:31998L0079
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices	This new EU Medical Devices Regulation entered into force on 25 May 2017. Following a three year transition period, it will replace the EU Medical Devices Directive (Council Directive 93/42/EEC) and the EU Active Implantable Medical Devices Directive (Council Directive 90/385/EEC).	https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32017R0745
Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April	This new EU IVD Medical Devices Regulation entered into force on 25 May 2017. Following a five year	https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:%3A32017R0746

2017 on in vitro diagnostic medical devices	transition period, it will replace the EU IVD Directive (Directive 98/79/EC).	
The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices of Japan	This law (known as <i>Pharmaceutical and Medical Device Act</i> of Japan) sets out, among other things, requirements for the registration and approval of medical devices.	http://www.japaneselawtranslation.go.jp/law/detail/?id=2766&vm=04&re=02
Federal Food, Drug, and Cosmetic Act of the United States	The <i>Federal Food, Drug and Cosmetic Act</i> of the United States provides for the safety of food, drugs and cosmetics. Chapter V of this Act deals with drugs and devices.	https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/federalfooddrugandcosmetictactdcact/default.htm

In accordance with section 14 of the Legislation Act, 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 Determination are set out in Attachment A.

The 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 Determination is a disallowable legislative instrument and commences on the day after it is registered.

Details of the *Therapeutic Goods (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 (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 subsections 41FDB(7) and 41FDB(8) of the Act. These provisions empower the Secretary to determine, by legislative instrument, a kind and form of information that must accompany an application to the Secretary for a kind of medical device to be included in the Register.

Section 4 – Definitions

This section provides definitions for certain terms used in the instrument that are not otherwise defined in the Act. A number of terms are defined by reference to their meaning in the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations).

Section 5 – Kind of information—medical devices other than IVD medical devices

This section is made for subsection 41FDB(7) of the Act and provides that an application for inclusion of a medical device (other than an IVD medical device) must be accompanied by the kind of information specified in the relevant Part of Schedule 1 to the Determination. The requirements of this section are subject to section 8.

Section 6 – Kind of information—IVD medical devices

This section is made for subsection 41FDB(7) of the Act and provides that an application for inclusion of an IVD medical device must be accompanied by the kind of information specified in the relevant Part of Schedule 2 to the Determination. The requirements of this section are subject to section 8.

Section 7 – Kind of information—medical devices used for a special purpose that are a system or procedure pack

This section is made for subsection 41FDB(8) of the Act and provides that an application for inclusion of a medical device used for a special purpose that is a system or procedure pack must be accompanied by the kind of information specified in Part 1 of Schedule 3 to the Determination. Where the medical device is intended by

the manufacturer to be supplied in a sterile state, the application must also be accompanied by one or more documents specified in Part 2 of Schedule 3.

Section 8 – Alternative kinds of information

This section provides that an application for the inclusion of a kind of medical device may, instead of the requirements specified for the particular classification under section 5 or 6, be accompanied by the kind of information specified in that section in relation to a higher level classification.

The note to this section clarifies that the kind of information determined under sections 5 and 6 relate to the minimum conformity assessment procedures that the manufacturer must apply to a kind of device of that classification.

Section 9 – Classes of medical device for which accompanying information is not determined

This section clarifies that no information, other than the information required by the application form, is determined to accompany an application to include the following classes of medical devices in the Register:

- (a) a Class I medical device where the medical device:
 - (i) is not supplied in a sterile state; and
 - (ii) does not have a measuring function;
- (b) a medical device that is intended by the manufacturer to be for export only;
- (c) a Class 1 IVD medical device;
- (d) an in-house IVD medical device other than a Class 4 in-house IVD medical device.

Section 10 – Form of information—all medical devices

This section is made for subsection 41FDB(8) of the Act and provides that all information that is required to accompany an application for a kind of medical device to be included in the Register, must be legible, and either in English or accompanied by a certified translation into English.

Schedule 1 – Medical devices other than IVD medical devices

Schedule 1 specifies the kinds of information that must accompany an application for a kind of medical device to be included in the Register where the medical device is not an IVD medical device.

Schedule 2 – IVD medical devices

Schedule 2 specifies the kinds of information that must accompany an application for a kind of medical device to be included in the Register where the medical device is an IVD medical device.

Schedule 3 – Medical devices used for a special purpose that are a system or procedure pack

Schedule 3 specifies the kinds of information that must accompany an application for a kind of medical device to be included in the Register where the medical device is a medical device used for a special purpose that is a system or procedure pack.

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) 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 (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* is made under subsections 41FDB(7) and 41FDB(8) 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 specify the kind of information that must accompany an application for the inclusion of a kind of medical device in the Australian Register of Therapeutic Goods (the Register), and the form in which that information must be provided. The kind of information determined 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 device.

The *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2018* amended the Act to provide for the preliminary assessment of applications for the registration or inclusion of therapeutic goods. Under paragraph 41FDB(2)(d) of the Act, as amended, an application must be accompanied by information that is of a kind and form determined under subsections 41FDB(7) and 41FDB(8) of the Act.

The only persons on whom requirements under this instrument are imposed are applicants for the inclusion of medical devices in the Register. The requirements are reasonably adapted to the need to ensure that kinds of medical devices satisfy the requirements set out in the Act for inclusion in the Register.

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 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