EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2025

The *Therapeutic Goods Act 1989* ("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 ("TGA") within the Australian Government Department of Health, Disability and Ageing.

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 ("Register"). These include the requirements that an 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 (ii) of the Act refer).

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("Principal Determination") is a legislative instrument made under subsections 41FDB(7) and (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 ("application for inclusion"). If the applicant does not comply with this requirement, the application will not pass preliminary assessment.

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that the appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the kind of medical device. The conformity assessment documents include certificates and other documents that are issued or recognised by the Secretary or, in the alternative, by an '*overseas regulator*' that is determined for the purposes of subsection 41BIB(1) of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2025* ("Amendment Determination") is made under subsection 41FDB(7) of the Act. It makes several amendments to the Principal Determination, primarily to specify the kind of information that must accompany an application for inclusion if the applicant seeks to rely on conformity assessment documents issued by a '*UK approved body*' – that is, an approved body under the Medical Device Regulations 2002 (SI 2002/618) that apply in England, Wales and Scotland ("the UK Regulations").

These amendments are broadly consequential to the withdrawal of the United Kingdom ("UK") from the European Union ("EU") in 2020, also known as 'Brexit'. The *Therapeutic Goods (Overseas Regulators) Amendment Determination 2025* makes related amendments to the *Therapeutic Goods (Overseas Regulators) Determination 2018* ("Overseas Regulators Determination"), the effect of which is to determine such approved bodies to be overseas regulators for the purposes of subsection 41BIB(1) of the Act.

Additionally, the Amendment Determination amends the Principal Determination to:

- specify additional kinds of information that must accompany an application for inclusion, if the application relates to a Class IIa medical device that the United States Food and Drug Administration ("US FDA") has exempted from the requirements of section 510(k) of the *Federal Food, Drug, and Cosmetic Act* of the United States ("US FDC Act"); and

- make a small number of other minor updates, including to repeal the definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*', revise the definition of '*MDSAP certificate*', and implement a small number of other minor, consequential amendments.

Background

For the purposes of subparagraph 41FDB(2)(d)(i) of the Act, the Principal Determination specifies the kind(s) of information that must accompany an application for inclusion in the Register of a medical device. The kind(s) of information specified by the Principal Determination vary according to the classification of the medical device that is the subject of the application for inclusion. For most medical device classifications, however, the arrangements in the Principal Determination provide applicants with multiple pathways for satisfying the requirements in subparagraph 41FDB(2)(d)(i) of the Act.

A number of these pathways specify conformity assessment documents that are issued or recognised by bodies determined by the Overseas Regulators Determination to be '*overseas regulators*' for the purposes of subsection 41BIB(1) of the Act. This reflects that, for certain kinds of medical devices, the TGA will accept 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 applications, and means they do not separately need to apply for Australian conformity assessment documents.

The Overseas Regulators Determination relevantly determines notified bodies to be overseas regulators for the purposes of subsection 41BIB(1) of the Act. Notified bodies are bodies that have been designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices, including in vitro diagnostic ("IVD") medical devices and active implantable medical devices. The Principal Determination specifies the kind(s) of information that must accompany an application for inclusion if the applicant seeks to rely on conformity assessment documents that are issued or recognised by a notified body.

Until the UK's withdrawal from the EU, also known as 'Brexit', the Principal Determination enabled applicants to provide conformity assessment documents that were issued or recognised by UK-based notified bodies in support of their applications for inclusion. However, these arrangements ceased at the conclusion of the implementation period for Brexit on 31 December 2020 at 11pm, at which time UK based notified bodies became '*approved bodies*' as defined in regulation A45 of the UK Regulations ("UK approved bodies").

The Principal Determination does not currently permit the TGA to accept conformity assessment documents issued by UK approved bodies. This is despite the UK regulatory framework for medical devices being largely comparable to the Australian regulatory framework for medical devices. There are concerns that this may jeopardise the continued supply of, or present a barrier to market entry for, medical devices supported by UK approved body evidence, potentially impacting Australian patients if they are not able to access medical devices for the treatment of their health conditions.

Purpose

The primary purpose of the Amendment Determination is to address such concerns by specifying the conformity assessment documents issued by a UK approved body that the TGA will accept in support of an application for inclusion in the Register relating to the following:

- a Class I medical device that the manufacturer intends to be supplied in a sterile state, or that has a measuring function;
- a Class IIa, Class IIb or Class III medical device;

- a Class 2, Class 3 or Class 4 in vitro diagnostic ("IVD") medical device;
- a system or procedure pack that is intended to be supplied in a sterile state and is neither a Class 1 IVD medical device nor intended for export only.

The effect of these amendments is that, if an application for inclusion is made in relation to a kind of medical device with one of these classifications, the applicant may provide the TGA with the conformity assessment document(s) issued by a UK approved body specified in the Principal Determination for the kinds of medical devices with that classification. That is, as an alternative to providing the existing conformity assessment documents specified for such kinds of devices in the Principal Determination. This provides greater flexibility for sponsors and manufacturers of such kinds of medical devices to demonstrate compliance with the conformity assessment procedures that are relevant to those devices.

An additional purpose of the Amendment Instrument is to specify additional kinds of information that must accompany an application for inclusion if:

- the applicant seeks to rely on a Medical Device Single Audit Program ("MDSAP") certificate issued by a recognised or authorised auditing organisation; and
- the US FDA has exempted the medical device that is the subject of the application from the requirements of section 510(k) of the US FDC Act ("section 510(k) requirements").

The Principal Determination already provides a pathway for applicants seeking the inclusion in the Register of Class IIa medical devices to rely on an MDSAP certificate that is issued by a recognised or authorised auditing organisation and conformity assessment documents that are issued by the US FDA (table item 8 in Part 2 of Schedule 1 refers). Under this existing pathway, an applicant seeking the inclusion of a Class IIa medical device that is exempt from section 510(k) requirements is only required to submit an MDSAP certificate that is issued by a recognised or authorised auditing organisation. This is because the US FDA does not issue conformity assessment documents relating to product assessment for medical devices that it exempts from section 510(k) requirements. However, the TGA still requires evidence in such cases to verify that the medical device is so exempt.

Consequently, the Amendment Determination amends the Principal Determination to introduce new table item 8A in Part 2 of Schedule 1. Compliance with this table item requires an application for inclusion to be accompanied by not only the specified conformity assessment document relating to the medical device manufacturer's quality management system — being an MDSAP certificate that is issued by a recognised or authorised auditing organisation — but also a statement that includes the device name or description, regulation number and submission type under US FDA requirements. This is designed to help identify that the device in question is indeed exempt from the section 510(k) requirements in the United States.

Finally, the Amendment Instrument also makes a small number of other minor amendments to the Principal Determination, primarily to repeal the definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*'. This amendment reflects that, under the MDSAP, auditing organisations are initially 'authorised' by a participating regulatory authority to conduct a single audit of a medical device manufacturer's quality management system that will satisfy the requirements of regulatory authorities that participate in the MDSAP. However, this is only an interim arrangement. Subject to the auditing organisation passing the relevant participating regulatory authority's assessment, the auditing organisation may then become a 'recognised' auditing organisation.

In practice, where the Principal Determination requires an application for inclusion to be accompanied by a MDSAP certificate issued by a recognised auditing organisation (as presently defined), the TGA accepts such certificates regardless of whether the issuing auditing organisation is recognised or authorised by a participating regulatory authority. However, the definition could be clearer on its face

in this respect. As such, the amendment to repeal the definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*' is clarificatory, rather than substantive, in nature.

Incorporation by reference

The primary purpose of the Amendment Determination is to specify the kind of information that must accompany an application for inclusion if the applicant seeks to rely on conformity assessment documents that are issued by a UK approved body. To achieve this, the Amendment Determination amends the Principal Determination to incorporate by reference the following:

- the UK Regulations, being the Medical Device Regulations 2002 (SI 2002/618), as in force in England, Wales and Scotland on 1 December 2025;
- the version of *Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of Member States relating to active implantable medical devices* that had effect immediately before 11pm on 31 December 2020, as modified by Schedule 2A to the UK Regulations;
- the version of *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* that had effect immediately before 11pm on 31 December 2020, as modified by Schedule 2A to the UK Regulations;
- the version of *Directive 98/79/EEC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices* that had effect immediately before 11pm on 31 December 2020, as modified by Schedule 2A to the UK Regulations.

In accordance with section 14 of the *Legislation Act 2003*, these documents are incorporated as in force at a particular time. This means that any subsequent changes to these documents will not be automatically applied under the Principal Determination.

In November 2025, the UK Regulations were freely available on the UK legislation website: https://www.legislation.gov.uk. Each of the three EU directives listed above were also freely available at that time on the European Union website: https://european-union.europa.eu/institutions-law-budget/law_en.

Consultation

The recognition of certification issued by UK approved bodies has been developed in liaison with the UK medical device regulator, the Medicines and Healthcare products Regulatory Agency ("MHRA"), which designates and oversees UK approved bodies. Industry stakeholders were informed and updated on this change at the Regulatory and Technical Consultative Forum for medical devices ("RegTech") meetings held during 2024 and 2025. RegTech is a consultative forum designed to prioritise and discuss issues of a regulatory and technical nature relating to the regulation of medical devices, both current and emerging. Its membership includes, for example, the TGA, the Medical Technology Association of Australia, the Australian Dental Industry Association, AusBiotech and Pathology Technology Australia. RegTech members indicated support for the addition of the UK to comparable oversea regulator arrangements, noting that the UK was part of these arrangements prior to their exit from the EU.

The proposal to permit applications for the inclusion of Class IIa medical devices that are exempt from section 510(k) requirements to be accompanied by MDSAP certification and information reflecting the exempt status of the relevant device was consulted on with members of the Medical Technology Association of Australia ("MTAA"), which represents a large number of sponsors and manufacturers of medical devices in Australia. Four members (Zimmer Bionet, Becton Dickinson, Stryker and Medtronic), and MTAA themselves, responded, all of whom supported the proposal.

No consultation was undertaken in relation to the other minor amendments that are made by the Amendment Determination, as these are clarificatory or consequential in nature.

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 1 December 2025.

Attachment A

Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2025*

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 2025* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination commences on 1 December 2025.

Section 3 – Authority

This section provides that the Amendment Determination is made under 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 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 that Schedule, 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] – Section 4

This item amends section 4 of the Principal Determination to introduce definitions of the following:

- '*applied Directive 90/385*';
- '*applied Directive 93/42*'; and
- '*applied Directive 98/79*'.

These expressions are defined by reference to the Medical Device Regulations 2002 (SI 2002/618), as in force in England, Wales and Scotland on 1 December 2025 ("the UK Regulations"). The effect of these definitions is that:

- ***applied Directive 90/385*** means *Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of Member States relating to active implantable medical devices* as it had effect immediately before 11pm on 31 December 2020;
- ***applied Directive 93/42*** means *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices* as it had effect immediately before 11pm on 31 December 2020; and

- ***applied Directive 98/79*** means *Directive 98/79/EEC of the European Parliament and of the Council of 27 October 1998 on in-vitro diagnostic medical devices* as it had effect immediately before 11pm on 31 December 2020.

Importantly, however, as each of these definitions makes clear, a reference to an Annex in applied Directive 90/385, applied Directive 93/42 or applied Directive 98/79 is to be construed in accordance with regulation 2(1A) of the UK Regulations. That is, the reference is to the version of the relevant Annex as in force immediately before 11pm on 31 December 2020, but subject to the modifications made to the Annex by Schedule 2A to the UK Regulations.

Item [2] – Section 4 (definition of *MDSAP certificate*)

This item amends the definition of '*MDSAP certificate*' in section 4 of the Principal Determination to insert "or authorised" after "recognised". This amendment is consequential to the amendments made by item [3] below.

Item [3] – Section 4 (definition of *recognised auditing organisation*)

This item amends section 4 of the Principal Determination to repeal the existing definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*'. The purpose of this amendment is to:

- clarify that the definition encompasses auditing organisations that have either been 'authorised' or 'recognised' by a regulatory authority that participates in the Medical Device Single Audit Program ("MDSAP"); and
- make a small number of minor editorial changes that are intended to more accurately identify the participating regulatory authorities to the MDSAP referred to in the definition, and otherwise improve the clarity and readability of the definition.

Item [4] – Section 4

This item amends section 4 of the Principal Determination to introduce definitions of the following:

- '*UK approved body*';
- '*UK Regulations*'.

The definition of ***UK approved body*** has the meaning given to "approved body" in regulation A45 of the UK Regulations, being a conformity assessment body that:

- has been designated pursuant to the procedure set out in regulation 45 of the UK Regulations (designation etc. of approved bodies); or
- immediately before 11pm on 31 December 2020, was a 'UK notified body' in respect of which no action under regulation 45(5) of the UK Regulations has been taken.

The effect of this definition is that, if, immediately before 11pm on 31 December 2020, a conformity assessment body in the United Kingdom was designated as a '*notified body*' (as defined in section 4 of the Principal Determination), and no action has since been taken to withdraw that designation, that body is a '*UK approved body*' for the purposes of the Principal Determination.

The definition of ***UK Regulations*** means the Medical Devices Regulations 2002 (SI 2002/618), as in force in England, Wales and Scotland on 1 December 2025. This definition does not incorporate by reference the version of the Medical Devices Regulations 2002 that applies in Northern Ireland.

The note to the definition of '*UK Regulations*' makes it clear that the UK Regulations could, in 2025, be viewed on the UK legislation website at https://www.legislation.gov.uk.

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

This item repeals and replaces the cell in column 2 of table item 5 in Division 2 of Part 1 of Schedule 1 to the Principal Determination. This minor amendment is consequential to amendments made by item [3] above.

Item [6] – Division 2 of Part 1 of Schedule 1 (at the end of the table)

This item introduces new table items 6 and 7 to the table in Division 2 of Part 1 of Schedule 1 to the Principal Determination. These table items specify requirements for an application for inclusion of a Class I medical device that the manufacturer intends to be supplied in a sterile state, or that has a measuring function, if the application is accompanied by conformity assessment documents issued by a UK approved body.

Compliance with table item 6 can be demonstrated by producing the following conformity assessment documents (as applicable) relating to the medical device manufacturer's quality management system:

- for a Class I medical device that the manufacturer intends to be supplied in a sterile state (whether or not it has a measuring function)—either of the following:
  - a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; or
  - an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385;
- for a Class I medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state)—one of the following:
  - a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385;
  - a verification certificate of conformity issued under Annex 4 in applied Directive 90/385; or
  - an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385.

Compliance with table item 7 can be demonstrated by producing the following conformity assessment documents (as applicable) relating to the medical device manufacturer's quality management system:

- for a Class I medical device that the manufacturer intends to be supplied in a sterile state (whether or not it has a measuring function)—either of the following:
  - a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; or
  - a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42;
- for a Class I medical device that has a measuring function (and that the manufacturer intends to be supplied in a non-sterile state)—one of the following:
  - a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex;
  - a verification certificate of conformity issued under Annex IV in applied Directive 93/42;
  - a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; or
  - a product quality assurance certificate or other document issued under Annex VI in applied Directive 93/42.

Item [7] – Part 2 of Schedule 1 (after table item 8)

This item introduces new table item 8A to the table in Part 2 of Schedule 1 to the Principal Determination. This table item specifies requirements for an application for inclusion of a Class IIa medical device if:

- the applicant seeks to rely on conformity assessment documents that are issued by a recognised or authorised auditing organisation; and
- the United States Food and Drug Administration ("the US FDA") has exempted the device from the requirements in section 510(k) of the *Federal Food, Drug and Cosmetic Act* of the United States ("the US FDC Act").

Compliance with this pathway can be demonstrated by producing the following conformity assessment documents:

- in relation to the manufacturer's quality management system—a MDSAP certificate issued by a recognised or authorised auditing organisation; and
- in relation to product assessment—a statement that includes the device name or description, regulation number and submission type under US FDA requirements.

Item [8] – Part 2 of Schedule 1 (at the end of the table)

This item introduces new table items 10 and 11 to the table in Part 2 of Schedule 1 to the Principal Determination. These table items specify requirements for an application for inclusion of a Class IIa medical device if the applicant seeks to rely on conformity assessment documents issued by a UK approved body – noting that the application need only comply with one of these table items.

Compliance with table item 10 can be demonstrated by producing the following conformity assessment documents (as applicable) relating to the medical device manufacturer's quality management system:

- for a Class IIa medical device that the manufacturer intends to be supplied in a sterile state—either of the following:
  - a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; or
  - a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42;
- for a Class IIa medical device that the manufacturer intends to be supplied in a non-sterile state—one of the following:
  - a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex;
  - a verification certificate of conformity issued under Annex IV in applied Directive 93/42;
  - a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; or
  - a product quality assurance certificate or other document issued under Annex VI in applied Directive 93/42.

Compliance with table item 11 can be demonstrated by producing the following conformity assessment documents (as applicable) relating to the medical device manufacturer's quality management system:

- for a Class IIa medical device that the manufacturer intends to be supplied in a sterile state—either of the following:
  - a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; or
  - an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385;
- for a Class IIa medical device that the manufacturer intends to be supplied in a non-sterile state—one of the following:
  - a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385;
  - a verification certificate of conformity issued under Annex 4 in applied Directive 90/385; or
  - an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385.

Item [9] – Part 3 of Schedule 1 (at the end of the table)

This item introduces new table items 13, 14 and 15 to the table in Part 3 of Schedule 1 to the Principal Determination. These table items specify requirements for an application for inclusion of a Class IIb medical device if the applicant seeks to rely on conformity assessment documents issued by a UK approved body – noting that the application need only comply with one of these table items.

Compliance with table item 13 can be demonstrated by producing a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex. Such conformity assessment documents relate to the medical device manufacturer's quality management system.

Compliance with table item 14 can be demonstrated by producing the following conformity assessment documents (as applicable) relating to the medical device manufacturer's quality management system:

- for a Class IIb medical device that the manufacturer intends to be supplied in a sterile state—a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42;
- for a Class IIb medical device that the manufacturer intends to be supplied in a non-sterile state—one of the following:
  - a verification certificate of conformity issued under Annex IV in applied Directive 93/42;
  - a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42; or
  - a product quality assurance certificate or other document issued under Annex VI in applied Directive 93/42.

Compliance with table item 15 can be demonstrated by producing a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385. Such conformity assessment documents relate to the medical device manufacturer's quality management system.

Item [10] – Part 4 of Schedule 1 (at the end of the table)

This item introduces new table items 14, 15, 16 and 17 to the table in Part 4 of Schedule 1 to the Principal Determination. These table items specify requirements for an application for inclusion of a Class III medical device if the applicant seeks to rely on conformity assessment documents issued by a UK approved body – noting that the application need only comply with one of these table items.

Compliance with table item 14 can be demonstrated by producing the following conformity assessment documents:

- in relation to the manufacturer's quality management system—a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; and
- in relation to product assessment—a design examination certificate issued under section 4 of Annex II in applied Directive 93/42.

Compliance with table item 15 can be demonstrated by producing a type-examination certificate issued under Annex III in applied Directive 93/42, which relates to product assessment, and the following conformity assessment documents relating to the medical device manufacturer's quality management system (as applicable):

- for a Class III medical device that the manufacturer intends to be supplied in a sterile state—a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42;
- for a Class III medical device that the manufacturer intends to be supplied in a non-sterile state—either of the following:
  - a verification certificate of conformity issued under Annex IV in applied Directive 93/42; or
  - a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42.

Compliance with table item 16 can be demonstrated by producing the following conformity assessment documents:

- in relation to the manufacturer's quality management system—a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; and
- in relation to product assessment—a design examination certificate issued under section 4 of Annex 2 in applied Directive 90/385.

Compliance with table item 17 can be demonstrated by producing a type-examination certificate issued under Annex 3 in applied Directive 90/385, which relates to product assessment, and the following conformity assessment documents relating to the medical device manufacturer's quality management system (as applicable):

- for a Class III medical device that the manufacturer intends to be supplied in a sterile state—an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385;
- for a Class III medical device that the manufacturer intends to be supplied in a non-sterile state—either of the following:
  - a verification certificate of conformity issued under Annex 4 in applied Directive 90/385; or
  - an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385.

Item [11] – Part 1 of Schedule 2 (cell at table item 6, column 2)

This item repeals and replaces the cell in column 2 of table item 6 in Part 1 of Schedule 2 to the Principal Determination. This minor amendment is consequential to amendments made by item [3] above.

Item [12] – Part 1 of Schedule 2 (at the end of the table)

This item introduces new table item 11 to the table in Part 1 of Schedule 2 to the Principal Determination. This table item specifies requirements for an application for inclusion of a Class 2 in vitro diagnostic ("IVD") medical device if the applicant seeks to rely on conformity assessment documents issued by a UK approved body.

Compliance with table item 11 can be demonstrated by producing either of the following conformity assessment documents relating to the medical device manufacturer's quality management system:

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

Item [13] – Part 2 of Schedule 2 (cell at table item 10, column 2)

This item repeals and replaces the cell in column 2 of table item 10 in Part 2 of Schedule 2 to the Principal Determination. This minor amendment is consequential to amendments made by item [3] above.

Item [14] – Part 2 of Schedule 2 (at the end of the table)

This item introduces new table items 15 and 16 to the table in Part 2 of Schedule 2 to the Principal Determination. These table items specify requirements for an application for inclusion of a Class 3 IVD medical device if the applicant seeks to rely on conformity assessment documents issued by a UK approved body – noting that the application need only comply with one of these table items.

Compliance with table item 15 can be demonstrated by producing a full quality assurance system certificate or other document issued under section 3 of Annex IV in applied Directive 98/79. Such conformity assessment documents relate to the medical device manufacturer's quality management system.

Compliance with table item 16 can be demonstrated by producing the following conformity assessment documents:

- in relation to the manufacturer's quality management system—a production quality assurance certificate or other document issued under Annex VII in applied Directive 98/79; and
- in relation to product assessment—a type-examination certificate issued under Annex V in applied Directive 98/79.

Item [15] – Part 3 of Schedule 2 (at the end of the table)

This item introduces new table items 11 and 12 to the table in Part 3 of Schedule 2 to the Principal Determination. These table items specify requirements for an application for inclusion of a Class 4 IVD medical device if the applicant seeks to rely on conformity assessment documents issued by a UK approved body – noting that the application need only comply with one of these table items.

Compliance with table item 11 can be demonstrated by producing the following conformity assessment documents:

- in relation to the manufacturer's quality management system—a full quality assurance system certificate or other document issued under section 3 of Annex IV in applied Directive 98/79; and

- in relation to product assessment—a design-examination certificate issued under Annex IV in applied Directive 98/79.

Compliance with table item 12 can be demonstrated by producing the following conformity assessment documents:

- in relation to the manufacturer's quality management system—a production quality assurance certificate or other document issued under Annex VII in applied Directive 98/79; and
- in relation to product assessment—a type-examination certificate issued under Annex V in applied Directive 98/79.

Item [16] – Part 2 of Schedule 3 (cell at table item 5, column 2)

This item repeals and replaces the cell in column 2 of table item 5 in Part 2 of Schedule 3 to the Principal Determination. This minor amendment is consequential to amendments made by item [3] above.

Item [17] – Part 2 of Schedule 3 (at the end of the table)

This item introduces new table items 6 and 7 to the table in Part 2 of Schedule 3 to the Principal Determination. These table items specify requirements for an application for inclusion of a medical device to which subsections 7(1) and (2) of the Principal Determination apply, if the applicant seeks to rely on conformity assessment documents issued by a UK approved body. Subsections 7(1) and (2) of the Principal Determination apply to medical devices used for a special purpose that are both a system or procedure pack and intended by the manufacturer to be supplied in a sterile state.

Compliance with table item 6 can be demonstrated by producing either of the following conformity assessment documents relating to the medical device manufacturer's quality management system:

- a full quality assurance system certificate or other document issued under Annex II in applied Directive 93/42, excluding section 4 of that Annex; or
- a production quality assurance certificate or other document issued under Annex V in applied Directive 93/42.

Compliance with table item 7 can be demonstrated by producing either of the following conformity assessment documents relating to the medical device manufacturer's quality management system:

- a complete quality assurance system certificate or other document issued under section 3 of Annex 2 in applied Directive 90/385; or
- an assurance of production quality certificate or other document issued under Annex 5 in applied Directive 90/385.

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 2025

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* ("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 ("Register"). These include the requirements that an 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 (ii) of the Act refer).

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* ("Principal Determination") is a legislative instrument made under subsections 41FDB(7) and (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 ("application for inclusion"). If the applicant does not comply with this requirement, the application will not pass preliminary assessment.

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that the appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the kind of medical device. The conformity assessment documents include certificates and other documents that are issued or recognised by the Secretary or, in the alternative, by an '*overseas regulator*' that is determined for the purposes of subsection 41BIB(1) of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2025* ("Amendment Determination") is made under subsection 41FDB(7) of the Act. It makes several amendments to the Principal Determination, primarily to specify the kind of information that must accompany an application for inclusion if the applicant seeks to rely on conformity assessment documents issued by a '*UK approved body*' – that is, an approved body under the Medical Device Regulations 2002 (SI 2002/618) that apply in England, Wales and Scotland ("the UK Regulations").

These amendments are broadly consequential to the withdrawal of the United Kingdom ("UK") from the European Union ("EU") in 2020, also known as 'Brexit'. The *Therapeutic Goods (Overseas Regulators) Amendment Determination 2025* makes related amendments to the *Therapeutic Goods (Overseas Regulators) Determination 2018* ("Overseas Regulators Determination"), the effect of which is to determine such approved bodies to be overseas regulators for the purposes of subsection 41BIB(1) of the Act.

Additionally, the Amendment Determination amends the Principal Determination to:

- specify additional kinds of information that must accompany an application for inclusion, if the application relates to a Class IIa medical device that the United States Food and Drug Administration ("US FDA") has exempted from the requirements of section 510(k) of the *Federal Food, Drug, and Cosmetic Act* of the United States ("US FDC Act"); and
- make a small number of other minor updates, including to repeal the definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*', revise the definition of '*MDSAP certificate*', and implement a small number of other minor, consequential amendments.

Background

For the purposes of subparagraph 41FDB(2)(d)(i) of the Act, the Principal Determination specifies the kind(s) of information that must accompany an application for inclusion in the Register of a medical device. The kind(s) of information specified by the Principal Determination vary according to the classification of the medical device that is the subject of the application for inclusion. For most medical device classifications, however, the arrangements in the Principal Determination provide applicants with multiple pathways for satisfying the requirements in subparagraph 41FDB(2)(d)(i) of the Act.

A number of these pathways specify conformity assessment documents that are issued or recognised by bodies determined by the Overseas Regulators Determination to be '*overseas regulators*' for the purposes of subsection 41BIB(1) of the Act. This reflects that, for certain kinds of medical devices, the TGA will accept 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 applications, and means they do not separately need to apply for Australian conformity assessment documents.

The Overseas Regulators Determination relevantly determines notified bodies to be overseas regulators for the purposes of subsection 41BIB(1) of the Act. Notified bodies are bodies that have been designated by a member state of the European Union, and notified to the European Commission, to assess the conformity of medical devices, including in vitro diagnostic ("IVD") medical devices and active implantable medical devices. The Principal Determination specifies the kind(s) of information that must accompany an application for inclusion if the applicant seeks to rely on conformity assessment documents that are issued or recognised by a notified body.

Until the UK's withdrawal from the EU, also known as 'Brexit', the Principal Determination enabled applicants to provide conformity assessment documents that were issued or recognised by UK-based notified bodies in support of their applications for inclusion. However, these arrangements ceased at the conclusion of the implementation period for Brexit on 31 December 2020 at 11pm, at which time UK based notified bodies became '*approved bodies*' as defined in regulation A45 of the UK Regulations ("UK approved bodies").

The Principal Determination does not currently permit the TGA to accept conformity assessment documents issued by UK approved bodies. This is despite the UK regulatory framework for medical devices being largely comparable to the Australian regulatory framework for medical devices. There are concerns that this may jeopardise the continued supply of, or present a barrier to market entry for, medical devices supported by UK approved body evidence, potentially impacting Australian patients if they are not able to access medical devices for the treatment of their health conditions.

Purpose

The primary purpose of the Amendment Determination is to address such concerns by specifying the conformity assessment documents issued by a UK approved body that the TGA will accept in support of an application for inclusion in the Register relating to the following:

- a Class I medical device that the manufacturer intends to be supplied in a sterile state, or that has a measuring function;
- a Class IIa, Class IIb or Class III medical device;
- a Class 2, Class 3 or Class 4 in vitro diagnostic ("IVD") medical device;
- a system or procedure pack that is intended to be supplied in a sterile state and is neither a Class 1 IVD medical device nor intended for export only.

The effect of these amendments is that, if an application for inclusion is made in relation to a kind of medical device with one of these classifications, the applicant may provide the TGA with the conformity assessment document(s) issued by a UK approved body specified in the Principal Determination for the kinds of medical devices with that classification. That is, as an alternative to providing the existing conformity assessment documents specified for such kinds of devices in the Principal Determination. This provides greater flexibility for sponsors and manufacturers of such kinds of medical devices to demonstrate compliance with the conformity assessment procedures that are relevant to those devices.

An additional purpose of the Amendment Instrument is to specify additional kinds of information that must accompany an application for inclusion if:

- the applicant seeks to rely on a Medical Device Single Audit Program ("MDSAP") certificate issued by a recognised or authorised auditing organisation; and
- the US FDA has exempted the medical device that is the subject of the application from the requirements of section 510(k) of the US FDC Act ("section 510(k) requirements").

The Principal Determination already provides a pathway for applicants seeking the inclusion in the Register of Class IIa medical devices to rely on an MDSAP certificate that is issued by a recognised or authorised auditing organisation and conformity assessment documents that are issued by the US FDA (table item 8 in Part 2 of Schedule 1 refers). Under this existing pathway, an applicant seeking the inclusion of a Class IIa medical device that is exempt from section 510(k) requirements is only required to submit an MDSAP certificate that is issued by a recognised or authorised auditing organisation. This is because the US FDA does not issue conformity assessment documents relating to product assessment for medical devices that it exempts from section 510(k) requirements. However, the TGA still requires evidence in such cases to verify that the medical device is so exempt.

Consequently, the Amendment Determination amends the Principal Determination to introduce new table item 8A in Part 2 of Schedule 1. Compliance with this table item requires an application for inclusion to be accompanied by not only the specified conformity assessment document relating to the medical device manufacturer's quality management system — being an MDSAP certificate that is issued by a recognised or authorised auditing organisation — but also a statement that includes the device name or description, regulation number and submission type under US FDA requirements. This is designed to help identify that the device in question is indeed exempt from the section 510(k) requirements in the United States.

Finally, the Amendment Instrument also makes a small number of other minor amendments to the Principal Determination, primarily to repeal the definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*'. This amendment reflects that, under the MDSAP, auditing organisations are initially 'authorised' by a participating regulatory authority to conduct a single audit of a medical device manufacturer's quality management system that will satisfy the requirements of regulatory authorities that participate in the MDSAP. However, this is only an interim arrangement. Subject to the auditing organisation passing the relevant participating regulatory authority's assessment, the auditing organisation may then become a 'recognised' auditing organisation.

In practice, where the Principal Determination requires an application for inclusion to be accompanied by a MDSAP certificate issued by a recognised auditing organisation (as presently defined), the TGA accepts such certificates regardless of whether the issuing auditing organisation is recognised or authorised by a participating regulatory authority. However, the definition could be clearer on its face in this respect. As such, the amendment to repeal the definition of '*recognised auditing organisation*' and substitute a new definition of '*recognised or authorised auditing organisation*' is clarificatory, rather than substantive, in nature.

Human rights implications

The Amendment Determination 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, 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 enhancing flexibility in relation to the kinds of documentary evidence that may accompany an application for inclusion of medical devices in the Register, to demonstrate the safety and quality of the manufacturing processes used to manufacture such products.

The effect of the Amendment Determination is to enable the TGA to process such applications in a more efficient and timely manner, and reduce regulatory burden for medical device sponsors and manufacturers by supporting enhanced international cooperation. The information will also assist in ensuring the safety and satisfactory performance of these medical devices, as well as their timely availability in Australia. By providing more options for the type of conformity assessment documents that may be submitted with an application for inclusion, the amendments will reduce delays in access to medical devices for Australian patients and health practitioners.

The Amendment Determination also supports the right to health in Article 12 of the ICESCR by reducing the risk that medical devices that are supported by UK conformity assessment evidence may not be made available for patients in Australia if Australian regulatory pathways preclude reliance on such evidence and would involve greater time and cost for device sponsors and manufacturers to bring new and innovative medical technologies to market in Australia.

Conclusion

The Amendment Determination is compatible with human rights because it supports the right to health in Article 12 of the ICESCR, and does not raise any other human rights issues.