

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024

The *Therapeutic Goods Act 1989* (“the 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 (“the TGA”) within the Australian Government Department of Health and Aged Care.

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

Relevantly, subsections 41FDB(7) and (8) of the Act provide that the Secretary may, by legislative instrument, determine a kind and form of information (respectively) for the purposes of an application mentioned in subparagraphs 41FDB(2)(d)(i) and (ii) of the Act for inclusion of a medical devices of a particular classification in the Register.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* (“the Principal Determination”) is made under subsections 41FDB(7) and (8) of the Act. The Principal Determination determines the kind and form of information that must accompany an application for kinds of medical devices of a particular classification to be included in the Register.

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the kind of medical device. The conformity assessment documents include certificates and other documents that have been issued or recognised by the Secretary and, in the alternative, by a comparable overseas regulator as defined in section 41BIB of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024* (“the Amendment Determination”) is made under subsection 41FDB(7) of the Act, and makes a number of amendments to the Principal Determination.

The Amendment Determination amends the Principal Determination principally to:

1. remove references, and requirements relating, to ‘specified medical devices’;
2. require that applications for inclusion of a Class III medical devices be accompanied by a clinical evaluation report, and instructions for use, where the application is not accompanied by a conformity assessment certificate issued by the TGA;

3. require additional conformity assessment documents to be provided with an application for inclusion of certain IVD medical devices in the Register as these devices will no longer be subject to a mandatory application audit;
4. enable the provision of information supporting an application for inclusion of an IVD medical device in the Register that provides evidence of assessment of the medical device by Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency, the US Food and Drug Administration (FDA), Health Canada or the Health Science Authority of Singapore;
5. remove references to applications made before 2019; and
6. . remove requirements relating to AIMD classified medical devices.

Specified medical devices

The Amendment Determination amends the Principal Determination, to remove provisions relating to 'specified medical devices', that is medical devices that contain medicines or materials of animal, microbial, recombinant or human origin, as defined in the Principal Determination. This has the effect that the documentation required in support of an application for inclusion in the Register for such devices will no longer be differentiated on the basis of the device containing any of those substances. The kinds of documentation required will be based upon the classification of the medical device as provided for in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

This amendment in the Amendment Determination is a consequence of an amendment to the *Therapeutic Goods (Medical Devices) Regulations 2002* by the *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024*, to reclassify (and in most cases down-classify) kinds of medical devices that only contain tissues, cells, or substances of microbial or recombinant origin; and certain tissues or cells of animal origin that have been rendered non-viable, or their derivatives. This amendment was made to align Australia's risk classification rules for medical devices that contain the materials identified above, with those implemented by comparable overseas jurisdictions.

Accordingly, the conformity assessment documents that must support an application for inclusion of such devices is those that apply according to the classification of those devices and provision for such devices will no longer separately be provided in the Principal Determination.

IVD medical devices

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024* amends regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (commencing 1 July 2024) to limit the kinds of medical devices that will be subjected to a mandatory audit for the purposes of paragraph 41FH(2)(a) of the Act. The effect of the amendment is to limit mandatory application audits to only applications for inclusion of those kinds of medical devices that pose the greatest risk of harm to users, and provide greater flexibility for the Secretary to select (at the Secretary's discretion) any other applications for audit.

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024* also made an amendment to set out additional circumstances in which an application does not need to be selected for a mandatory application audit, including where the kind of device:

- is the subject of a medical device licence issued by Health Canada under the *Medical Devices Regulations (Canada)*;
- is the subject of an order approving an application for premarket approval from the US Food and Drug Administration under the *Federal Food, Drug, and Cosmetic Act (United States of America)*;
- is the subject of a pre-market certification or approval issued by the Japanese Ministry of Health, Labour and Welfare, or the Japanese Pharmaceuticals and Medical Devices Agency, under *The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Japan)*;
- is the subject of an entry in the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under the *Health Products Act 2007 (Singapore)*; or
- has been certified in accordance with the Australia-UK Mutual Recognition Agreement, the EC Mutual Recognition Agreement, or the EFTA Mutual Recognition Agreement.

As a result of these amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002*, the Amendment Determination amends the Principal Determination to enable evidence from a comparable overseas regulator to support an application for inclusion of a medical device in the Register for a Class 2, 3 or 4 IVD medical device. Conformity assessment documents from Japan’s Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency can be provided with an application for inclusion of a Class 2, 3 and 4 IVD medical device. Further, conformity assessment documents from Health Canada, the US FDA, and Health Science Authority of Singapore may be provided with an application for inclusion of a Class 4 IVD medical device in the Register. For a Class 3 IVD medical device, additional conformity assessment documents from a notified body are required, as well as from a notified body and Health Canada for a Class 2 IVD medical device.

The amendments enable an application for inclusion to be supported by conformity assessment documents from additional overseas regulators, and also requires additional information from certain overseas regulators to support an application for inclusion in the Register. This is because those medical devices will no longer be subject to a mandatory application audit where these overseas regulators have assessed the medical device. As the devices are not subject to a mandatory application audit, additional evidence from the overseas regulatory must be provided with the application for inclusion in the Register.

Clinical evaluation report and instructions for use

The clinical evaluation report and instructions for use have been routinely requested by the TGA from applicants, in order to properly assess whether an application for inclusion of the device in the Register should undergo an application audit. To remove the administrative burden of having to request these documents, and to avoid delays from having to request these documents from applicants, the Amendment Determination amends the Principal Determination to require these documents be provided with the application for a Class III medical devices. This will enable the TGA to process applications without delays from waiting for these documents to be provided on request.

A clinical evaluation report and instructions for use will only be required if the application is not accompanied by a conformity assessment certificate issued by the TGA, as these documents would have already been reviewed as part of the assessment of an application for a conformity assessment certificate.

AIMD medical devices and applications prior to 2019

The Amendment Determination removes references to AIMD medical devices as there is no longer an AIMD classification for medical devices. The AIMD classification was abolished in 2019 with an associated transitional period where AIMD medical devices were reclassified to Class III medical devices. The TGA no longer receives applications for inclusion of AIMD medical devices in the Register (as they are now applications for inclusion of Class III medical devices in the Register). The Amendment Determination therefore repeals redundant provisions that refer to the AIMD classification.

Similarly, the Amendment Determination removes references to conformity assessment documents that were needed to support an application made prior to 2019 as these provisions are no longer relevant.

Incorporation by reference

The Amendment Determination does not incorporate any documents by reference into the Principal Determination. Rather the Amendment Determination makes reference to certain overseas legislation to identify the documentation that must accompany an application for inclusion of a medical device in the register. References to the relevant legislation are simply to the fact of specifying the documents that have been procedure by the relevant overseas regulator in accordance with that legislation.

Consultation

In October 2023, public consultation was undertaken on changes to the application audit framework to limit the mandatory audits to high risk medical devices. 26 submissions were received and the proposal was supported by medical device industry stakeholders. Additionally, targeted consultation with the Regulatory and Technical Consultative Forum for medical devices (RegTech Forum) was undertaken on further regulatory changes to the Regulations to limit mandatory audits through improved reliance and acceptance of comparable overseas regulator approvals, which was endorsed by RegTech. In addition, feedback on the changes to the Principal Determination was sought through targeted consultation with peak IVD representative bodies which was also endorsed.

Responses to this public consultation on changes to the application audit framework also identified that 'specified medical devices' should be accepted for approval based on approvals from other comparable overseas regulators without limiting these approvals to those from the EU. This change is incorporated into the Amendment Determination.

The Office of Impact Assessment (OIA) advised that the proposed changes to the reclassification of medical devices containing microbial, recombinant, or animal origin substances do not require an impact assessment (IA) (OIA23-05988). The OIA also advised that a IA is not required for establishing a new application audit framework for medical

devices (OIA23-04966). As the other changes in the Amendment Determination are consequential and machinery only, an IA has not been prepared.

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

The Amendment Determination is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 1 July 2024.

Details of the *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024*

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 2024* (“the Amendment Determination”).

Section 2 – Commencement

This section provides that the Amendment Determination commences on 1 July 2024.

Section 3 – Authority

This section provides that the legislative authority for making the Amendment Determination is subsection 41FDB(7) of the *Therapeutic Goods Act 1989* (“the Act”).

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that provision.

Section 4 – Schedules

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

Schedule 1 – Amendments

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

Item 1 – Section 4 (definitions of *active implantable medical device* and *Class AIMD medical device*)

This item amends section 4 of the Principal Determination to repeal the definitions of “active implantable medical device” and “Class AIMD medical device”.

Item 2 – Section 4

This item introduces definitions for ‘clinical evaluation report’, generic device group, and other terms that are defined in the *Therapeutic Goods (Medical Devices) Regulations 2002* such as instructions for use and point of care testing.

Item 3 – Section 4 (definition of *specified medical device*)

This item amends section 4 of the Principal Determination to repeal the definition of “specified medical device”.

Item 4 – subsection 5(7)

This item replaces subsection 5(7) of the Principal Determination to provide that this subsection also applies to medical devices that were formerly defined as a ‘specified medical device’, and to require the submission of a clinical evaluation report and instructions for use for an application for inclusion of a Class III medical device in the Register, unless there is a TGA conformity assessment certificate for the medical device.

Item 5 – Subsections 5(8A) to (10B)

This item repeals subsections 5(8A to (10B) as those provisions are no longer needed since they relate to AIMD medical device (which have been reclassified as Class III medical devices) and ‘specified medical devices’ which will no longer have particular requirements in the Principal Determination.

Items 6, 7 and 9 - Part 2 of Schedule 1 (cell at item 7, column 3), Part 3 of Schedule 1 (cell at item 9, column 3) and Division 1 of Part 4 of Schedule 1 (cell at item 10, column 3)

These items replace the text in the relevant cell to simply refer to a MDSAP certificate, with the effect of remove requirements that relate to applications made prior to 2019. This amendment does not otherwise change the effect of the items.

Item 8 - Division 1 of Part 4 of Schedule 1 (heading)

This item repeals the heading of Division 1 of Part 4 of Schedule 1 to the Principal Determination as that Division will no longer apply only to medical devices that are not a ‘specified medical device’.

Item 10 - Division 2 of Part 4 of Schedule 1

This item repeals Division 2 of Part 4 of Schedule 1 to the Principal Determination to remove the requirements for ‘specified medical devices’. That category of devices is being removed from the Principal Determination, and other provisions will apply to those devices as relevant.

Item 11 – Part 5 of Schedule 1

This item repeals Part 5 of Schedule 1 to the Principal Determination as that Part relates to AIMD medical devices which have been reclassified as Class III medical devices, and the AIMD classification no longer exists.

Item 12 - Part 1 of Schedule 2 (cell at item 3, column 4)

This item introduces requirements for Class 2 IVD medical devices where an application for inclusion of the device in the Register is supported by conformity assessment documents from a notified body. The new requirement applies to an IVD medical device for self-testing or an IVD medical device for point of care testing, and requires an application to be accompanied by an assessment of technical documentation referred to in section 5.1 of Annex IX of the EU IVD regulation.

Item 13 - Part 1 of Schedule 2 (cell at item 4, column 3)

This item replaces the text in column 3 of item 4 in Part 1 of Schedule 2 to the Principal Determination to refer only to a MDSAP certificate. The effect of this amendment is that where overseas regulator evidence is being relied upon to support an application for inclusion in the Register specifically from Health Canada, a MDSAP certificate must accompany the application.

Item 14 – Part 1 of Schedule 2 (cell at item 4, column 4)

This item introduces a requirement in column 4 of item 4 in Part 1 of Schedule 2 to the Principal Determination that an application for inclusion of a Class 2 IVD medical device in the Register must be accompanied by a Class II medical device licence issued under the Canadian medical devices regulations, where overseas regulator evidence from Health Canada is being relied up on to support the application. This additional information will need to be provided as these devices will no longer be subject to a mandatory audit.

Item 15 – Part 1 of Schedule 2 (at the end of the table)

This item introduces new item 10 to the table in Part 1 of Schedule 2 to permit an application for inclusion of a Class 2 IVD medical device in the Register to be supported by overseas regulator evidence from Japan’s Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency.

The conformity assessment document relating to the manufacturer’s quality management system that must be provided is either a MDSAP certificate, or a quality management system certificate for the purposes of the Japanese PMD Act. The conformity assessment document relating to product assessment that must be provided for an IVD medical device for self-testing or an IVD medical device for point of care testing is either a pre-market certification issued under the Japanese PMD Act or a pre-market approval issued under the Japanese PMD Act.

Item 16 - Part 2 of Schedule 2 (cell at item 5, column 4)

This item introduces a requirement in column 4 of item 5 of Part 2 of Schedule 2 to the Principal Determination that an application for inclusion of a Class 3 IVD medical device in the Register must be accompanied by a conformity assessment document relating to product assessment where evidence from a notified body within the meaning of the EU IVD regulation is being relied upon.

The conformity assessment document relating to product assessment that must be provided for an IVD medical device for self-testing or an IVD medical device for point of care testing is an assessment of technical documentation set out in section 5.1 of Annex IX of the EU IVD regulation. The conformity assessment document relating to product assessment that must be provided for an IVD companion diagnostic is an assessment of technical documentation set out in section 5.2 of Annex IX of the EU IVD regulation. The conformity assessment document relating to product assessment that must be provided for all other Class 3 IVD medical devices is the assessment of technical documentation as set out in section 4 of Annex IX of the EU IVD regulation for at least one representative device in a generic device group.

Item 17 - Part 2 of Schedule 2 (cell at item 7, column 3)

This item replaces the text in column 3 of item 4 in Part 1 of Schedule 2 to the Principal Determination to refer only to a MDSAP certificate. The effect of this amendment is that where overseas regulator evidence is being relied upon to support an application for inclusion in the Register specifically from Health Canada, a MDSAP certificate must accompany the application.

Item 18 – Part 2 of Schedule 2 (cell at item 7, column 4)

This item introduces a requirement in column 4 of item 7 in Part 2 of Schedule 2 to the Principal Determination that an application for inclusion of a Class 3 IVD medical device in the Register must be accompanied by a Class III medical device licence issued under the Canadian medical devices regulations, where overseas regulator evidence from Health Canada is being relied up on to support the application. This additional information will need to be provided as these devices will no longer be subject to a mandatory audit.

Item 19 - Part 2 of Schedule 2 (cell at item 9, column 4)

This item introduces a requirement in column 4 of item 9 in Part 2 of Schedule 2 to the Principal Determination that an application for inclusion of a Class 3 IVD medical device in the Register must be accompanied by an order approving an application for premarket approval under section 515 of the US FDC Act, where overseas regulator evidence from the US FDA is being relied up on to support the application. This amendment is to clarify that such an order is also considered a conformity assessment document relating to product assessment.

Item 20 - Part 2 of Schedule 2 (at the end of the table)

This item introduces new item 14 to the table in Part 2 of Schedule 2 to permit an application for inclusion of a Class 3 IVD medical device in the Register to be supported by overseas regulator evidence from Japan’s Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency.

The conformity assessment document relating to the manufacturer’s quality management system that must be provided is either a MDSAP certificate, or a quality management system certificate for the purposes of the Japanese PMD Act. The conformity assessment document relating to product assessment that must be provided for an IVD medical device for self-testing or an IVD medical device for point of care testing is either a pre-market

certification issued under the Japanese PMD Act or a pre-market approval issued under the Japanese PMD Act.

Item 21 – Part 3 of Schedule 2 (at the end of the table)

This item introduces new items 7 to 10 to the table in Part 3 of Schedule 2 to permit an application for inclusion of a Class 4 IVD medical device in the Register to be supported by overseas regulator evidence from 4 other comparable overseas regulators.

Item 7 permits such an application to be supported by evidence from Japan’s Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency. The conformity assessment document relating to the manufacturer’s quality management system that must be provided is either a MDSAP certificate, or a quality management system certificate for the purposes of the Japanese PMD Act. The conformity assessment document relating to product assessment that must be provided is a pre-market approval issued under the Japanese PMD Act.

Item 8 permits such an application to be supported by evidence from the US FDA. The conformity assessment document relating to the manufacturer’s quality management system, and conformity assessment document relating to product assessment, that must be provided is an order approving an application for premarket approval under section 515 of the US FDC Act.

Item 9 permits such an application to be supported by evidence from Health Canada. The conformity assessment document relating to the manufacturer’s quality management system that must be provided is a MDSAP certificate. The conformity assessment document relating to product assessment that must be provided is a Class IV medical device licence issued under Canadian medical device regulations.

Item 10 permits such an application to be supported by evidence from the Health Science Authority of Singapore. The conformity assessment document relating to the manufacturer’s quality management system that must be provided is an extract from, or copy of, the entry in the Singapore Register of Health Products as a Class D IVD.

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 2024

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

Relevantly, subsections 41FDB(7) and (8) of the Act provide that the Secretary may, by legislative instrument, determine a kind and form of information (respectively) for the purposes of an application mentioned in subparagraphs 41FDB(2)(d)(i) and (ii) of the Act for inclusion of a medical devices of a particular classification in the Register.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Determination 2018* (“the Principal Determination”) is made under subsections 41FDB(7) and (8) of the Act. The Principal Determination determines the kind and form of information that must accompany an application for kinds of medical devices of a particular classification to be included in the Register.

The kinds of information specified in the Principal Determination relate to the conformity assessment documents that are required to demonstrate that appropriate conformity assessment procedures have been applied by the manufacturer to its quality management system and the kind of medical device. The conformity assessment documents include certificates and other documents that have been issued or recognised by the Secretary and, in the alternative, by a comparable overseas regulator as defined in section 41BIB of the Act.

The *Therapeutic Goods (Medical Devices—Information that Must Accompany Application for Inclusion) Amendment Determination 2024* (“the Amendment Determination”) is made under subsection 41FDB(7) of the Act, and makes a number of amendments to the Principal Determination.

The Amendment Determination amends the Principal Determination principally to:

7. remove references, and requirements relating, to ‘specified medical devices’;
8. require that applications for inclusion of a Class III medical devices be accompanied by a clinical evaluation report, and instructions for use, where the application is not accompanied by a conformity assessment certificate issued by the TGA;

9. require additional conformity assessment documents to be provided with an application for inclusion of certain IVD medical devices in the Register as these devices will no longer be subject to a mandatory application audit;
10. enable the provision of information supporting an application for inclusion of an IVD medical device in the Register that provides evidence of assessment of the medical device by Japan's Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency, the US Food and Drug Administration (FDA), Health Canada or the Health Science Authority of Singapore;
11. remove references to applications made before 2019; and
12. . remove requirements relating to AIMD classified medical devices.

Specified medical devices

The Amendment Determination amends the Principal Determination, to remove provisions relating to 'specified medical devices', that is medical devices that contain medicines or materials of animal, microbial, recombinant or human origin, as defined in the Principal Determination. This has the effect that the documentation required in support of an application for inclusion in the Register for such devices will no longer be differentiated on the basis of the device containing any of those substances. The kinds of documentation required will be based upon the classification of the medical device as provided for in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

This amendment in the Amendment Determination is a consequence of an amendment to the *Therapeutic Goods (Medical Devices) Regulations 2002* by the *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024*, to reclassify (and in most cases down-classify) kinds of medical devices that only contain tissues, cells, or substances of microbial or recombinant origin; and certain tissues or cells of animal origin that have been rendered non-viable, or their derivatives. This amendment was made to align Australia's risk classification rules for medical devices that contain the materials identified above, with those implemented by comparable overseas jurisdictions.

Accordingly, the conformity assessment documents that must support an application for inclusion of such devices is those that apply according to the classification of those devices and provision for such devices will no longer separately be provided in the Principal Determination.

IVD medical devices

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024* amends regulation 5.3 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (commencing 1 July 2024) to limit the kinds of medical devices that will be subjected to a mandatory audit for the purposes of paragraph 41FH(2)(a) of the Act. The effect of the amendment is to limit mandatory application audits to only applications for inclusion of those kinds of medical devices that pose the greatest risk of harm to users, and provide greater flexibility for the Secretary to select (at the Secretary's discretion) any other applications for audit.

The *Therapeutic Goods Legislation Amendment (2024 Measures No. 2) Regulations 2024* also made an amendment to set out additional circumstances in which an application does not need to be selected for a mandatory application audit, including where the kind of device:

- is the subject of a medical device licence issued by Health Canada under the *Medical Devices Regulations (Canada)*;
- is the subject of an order approving an application for premarket approval from the US Food and Drug Administration under the *Federal Food, Drug, and Cosmetic Act (United States of America)*;
- is the subject of a pre-market certification or approval issued by the Japanese Ministry of Health, Labour and Welfare, or the Japanese Pharmaceuticals and Medical Devices Agency, under *The Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Japan)*;
- is the subject of an entry in the Register of Health Products kept and maintained by the Health Sciences Authority of Singapore under the *Health Products Act 2007 (Singapore)*; or
- has been certified in accordance with the Australia-UK Mutual Recognition Agreement, the EC Mutual Recognition Agreement, or the EFTA Mutual Recognition Agreement.

As a result of these amendments to the *Therapeutic Goods (Medical Devices) Regulations 2002*, the Amendment Determination amends the Principal Determination to enable evidence from a comparable overseas regulator to support an application for inclusion of a medical device in the Register for a Class 2, 3 or 4 IVD medical device. Conformity assessment documents from Japan’s Ministry of Health, Labour and Welfare or the Japanese Pharmaceuticals and Medical Devices Agency can be provided with an application for inclusion of a Class 2, 3 and 4 IVD medical device. Further, conformity assessment documents from Health Canada, the US FDA, and Health Science Authority of Singapore may be provided with an application for inclusion of a Class 4 IVD medical device in the Register. For a Class 3 IVD medical device, additional conformity assessment documents from a notified body are required, as well as from a notified body and Health Canada for a Class 2 IVD medical device.

The amendments enable an application for inclusion to be supported by conformity assessment documents from additional overseas regulators, and also requires additional information from certain overseas regulators to support an application for inclusion in the Register. This is because those medical devices will no longer be subject to a mandatory application audit where these overseas regulators have assessed the medical device. As the devices are not subject to a mandatory application audit, additional evidence from the overseas regulatory must be provided with the application for inclusion in the Register.

Clinical evaluation report and instructions for use

The clinical evaluation report and instructions for use have been routinely requested by the TGA from applicants, in order to properly assess whether an application for inclusion of the device in the Register should undergo an application audit. To remove the administrative burden of having to request these documents, and to avoid delays from having to request these documents from applicants, the Amendment Determination amends the Principal Determination to require these documents be provided with the application for a Class III medical devices. This will enable the TGA to process applications without delays from waiting for these documents to be provided on request.

A clinical evaluation report and instructions for use will only be required if the application is not accompanied by a conformity assessment certificate issued by the TGA, as these documents would have already been reviewed as part of the assessment of an application for a conformity assessment certificate.

AIMD medical devices and applications prior to 2019

The Amendment Determination removes references to AIMD medical devices as there is no longer an AIMD classification for medical devices. The AIMD classification was abolished in 2019 with an associated transitional period where AIMD medical devices were reclassified to Class III medical devices. The TGA no longer receives applications for inclusion of AIMD medical devices in the Register (as they are now applications for inclusion of Class III medical devices in the Register). The Amendment Determination therefore repeals redundant provisions that refer to the AIMD classification.

Similarly, the Amendment Determination removes references to conformity assessment documents that were needed to support an application made prior to 2019 as these provisions are no longer relevant.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health.

In General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument 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 the relevant kinds of medical devices in the Register, to demonstrate the safety and quality of the manufacturing processes used to manufacture such products. Expanding the kinds of conformity assessment documents that may accompany applications for medical devices will enable the TGA to process such applications in a more efficient and timely manner, and reduces 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 document 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.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.