



Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 12 December 2019

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. Sections 1 to 4 and anything in this instrument not elsewhere covered by this table	The day after this instrument is registered.	19 December 2019
2. Schedules 1 to 3	25 August 2020.	25 August 2020
3. Schedule 4	1 February 2020.	1 February 2020
4. Schedule 5	1 January 2020.	1 January 2020
5. Schedule 6	1 January 2021.	1 January 2021
6. Schedule 7	1 January 2020.	1 January 2020
7. Schedule 8	The day after this instrument is registered.	19 December 2019
8. Schedule 9, Parts 1 to 3	1 January 2020.	1 January 2020
9. Schedule 9, Part 4	The day after this instrument is registered.	19 December 2019
10. Schedule 10	The day after this instrument is registered.	19 December 2019

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under the following:

- (a) the *Therapeutic Goods Act 1989*;
- (b) the *Therapeutic Goods (Charges) Act 1989*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Reclassification of medical devices

Part 1—Spinal implantable medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

1 After paragraph 5.3(1)(b)

Insert:

- (c) a medical device that is a spinal fusion implantable device;

Note: Examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

2 Regulation 5.12 (heading)

Omit “relating to certain IVD medical devices”.

3 At the end of subregulation 5.12(1)

Add “or a kind of medical device that is a spinal fusion implantable device”.

4 At the end of subregulation 5.12(1)

Add:

Note: Examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

5 Subclause 3.4(2) of Schedule 2

Omit “and (4A)”, substitute “, (4A) and (4B)”.

6 After subclause 3.4(4A) of Schedule 2

Insert:

(4B) If the device:

- (a) is intended by the manufacturer:
 - (i) to be a motion-preserving device for the spine (such as a spinal disc replacement); or
 - (ii) to come in contact with a person’s spinal column; and
- (b) is not a spinal fusion implantable device;

the device is classified as Class III.

Note: Examples of spinal fusion implantable devices include screws, cages, plates, hooks or rods that are intended to be used during spinal fusion surgical procedures.

Part 2—Active implantable medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

7 Paragraph 1.6(b)

Repeal the paragraph.

8 Paragraph 1.7(1)(f)

Omit “Class AIMD medical device,”.

9 Subregulation 3.1(1) (table)

Repeal the table, substitute:

Medical device classifications					
Item	Column 1 Medical device	Column 2 Class	Column 3 Class	Column 4 Class	Column 5 Class
1	Medical devices other than IVD medical devices	I	IIa	IIb	III
2	IVD medical devices and in-house IVD medical devices	1	2	3	4

10 Paragraph 3.1(2)(a)

Omit “column 3”, substitute “column 2”.

11 Paragraph 3.1(2)(b)

Omit “columns 4 to 6”, substitute “columns 3 to 5”.

12 Paragraph 3.1(2)(c)

Repeal the paragraph.

13 Regulation 3.6 (heading)

Omit “and Class AIMD medical devices”.

14 Subregulation 3.6(1)

Omit “, or a Class AIMD medical device,”.

15 Paragraph 5.3(1)(e)

Repeal the paragraph.

16 Subparagraph 5.10(2)(a)(i)

Repeal the subparagraph.

17 Paragraph 5.11(1)(a)

Repeal the paragraph.

18 Subparagraph 8.1(b)(i)

Omit “Class AIMD medical device,”.

19 Subclause 5.7(1) of Schedule 2

Omit “Class AIMD”, substitute “Class III”.

20 Paragraph 1.1(b) of Schedule 3

Omit “, Class AIMD medical device”.

21 Clause 1.6 of Schedule 3 (heading)

Omit “, Class AIMD medical device”.

22 Subclause 1.6(1) of Schedule 3

Omit “, a Class AIMD medical device,”.

23 Paragraph 1.9(1)(c) of Schedule 3

Omit “, Class AIMD medical device”.

24 Subclause 3.5(1) of Schedule 3

Omit “Class AIMD medical device,”.

25 Paragraph 3.6(1)(b) of Schedule 3

Omit “Class AIMD medical device,”.

26 Subclause 4.7(1) of Schedule 3

Omit “Class AIMD medical device,”.

27 Paragraph 4.8(1)(c) of Schedule 3

Omit “Class AIMD medical device,”.

28 Schedule 4 (table item 1.1, column headed “Kinds of medical devices”, paragraph (c))

Omit “Class AIMD medical device,”.

29 Schedule 5 (table item 1.5)

Omit:

(a) a Class AIMD medical device;

1,340

30 Dictionary (definition of *active implantable medical device* or *AIMD*)

Omit “or *AIMD*”.

31 Dictionary (definition of *Class AIMD medical device*)

Repeal the definition.

32 Dictionary (subparagraph (b)(ii) of the definition of *partial designation conformity assessment body determination (partial QMS or partial devices)*)

Omit “or Class AIMD”.

Part 3—Medical devices that administer medicines or biologicals by inhalation

Therapeutic Goods (Medical Devices) Regulations 2002

33 After subclause 3.1(2) of Schedule 2

Insert:

- (2A) If the device is intended to be used to administer medicines or biologicals by inhalation:
- (a) if the mode of action of the device has an essential impact on the efficacy and safety of the medicines or biologicals—the device is classified as Class IIb; or
 - (b) if the device is intended to treat a life-threatening condition—the device is classified as Class IIb; or
 - (c) if paragraphs (a) and (b) do not apply—the device is classified as Class IIa.

Part 4—Medical devices that are substances for introduction into the body

Therapeutic Goods (Medical Devices) Regulations 2002

34 Clause 2.4 of Schedule 2 (heading)

Omit “skin”, substitute “skin or mucous membrane”.

35 Subclause 2.4(1) of Schedule 2

After “skin”, insert “or a mucous membrane”.

36 Subparagraph 3.1(2)(c)(ii) of Schedule 2

Omit “mucous membrane”, substitute “skin or mucous membrane”.

37 At the end of clause 3.1 of Schedule 2

Add:

(4) If a device is composed of substances, or combinations of substances, that are:

(a) intended to be:

(i) introduced into the human body through a body orifice; or

(ii) applied to the skin; and

(b) absorbed by, or locally dispersed, in the human body after introduction or application;

the device is classified as follows:

(c) if the device, or its products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose—Class III;

(d) if the device achieves its intended purpose in the stomach or lower gastrointestinal tract and the device, or its products of metabolism, are systemically absorbed by the human body—Class III;

(e) if the device is applied to the skin, or in the nasal or oral cavity as far as the pharynx, and achieves its intended purpose on those cavities—Class IIa;

(f) in any other case—Class IIb.

38 Dictionary

Insert:

injured skin or mucous membrane means an area of skin or mucous membrane that has evidence of:

(a) a pathological change; or

(b) a change following:

(i) disease; or

(ii) a wound.

Part 5—Active medical devices for therapy

Therapeutic Goods (Medical Devices) Regulations 2002

39 At the end of clause 4.2 of Schedule 2

Add:

- (4) An active medical device for therapy that includes a diagnostic function the purpose of which is to significantly determine patient management by the device is classified as Class III.

Example: An automated external defibrillator.

Part 6—Medical devices in direct contact with the heart etc.

Therapeutic Goods (Medical Devices) Regulations 2002

40 Clause 1.1 of Schedule 2

Omit “For”, substitute “(1) For the purposes of”.

41 At the end of clause 1.1 of Schedule 2

Add:

- (2) For the purposes of determining whether a medical device is intended to be used continuously, disregard any temporary interruption or removal.

Example: A temporary interruption or removal in order to clean or disinfect the medical device.

42 After subclause 3.2(3) of Schedule 2

Insert:

- (3A) If the device is intended by the manufacturer specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient, the device is classified as Class III.

43 Paragraph 3.3(4)(b) of Schedule 2

Repeal the paragraph, substitute:

- (b) specifically to be used in direct contact with the heart, the central circulatory system or the central nervous system of a patient; or

Part 7—Amendments relating to charges

Therapeutic Goods (Charges) Regulations 2018

44 Paragraph 7(4)(d)

Omit “Class AIMD medical device or”.

45 At the end of the instrument

Add:

Part 3—Application and transitional provisions

Division 1—Transitional provision relating to the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

10 Transitional provision relating to the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*

If, at any time during a charge year, the same medical device is included in the Register as a Class AIMD medical device and a Class III medical device, the charge in respect of the inclusion in the Register of the medical device as a Class III medical device during the charge year is nil.

Schedule 2—Programmed or programmable medical device or software that is a medical device

Part 1—Classification rules

Therapeutic Goods (Medical Devices) Regulations 2002

1 Schedule 2 (note to Schedule heading)

Repeal the note, substitute:

Note: Regulation 3.2 provides for the making of classification rules. Regulation 3.3 sets out the principles for applying those rules.

2 At the end of Part 4 of Schedule 2

Add:

4.5 Programmed or programmable medical device or software that is a medical device for use in relation to diagnosing or screening for a disease or condition

- (1) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to:
 - (a) provide a diagnosis of a disease or condition; or
 - (b) screen for a disease or condition;is classified as:
 - (c) in the case of a disease or condition that:
 - (i) may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or
 - (ii) may pose a high risk to public health;Class III; or
 - (d) in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (c) does not apply—Class IIb; or
 - (e) in any other case—Class IIa.
- (2) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information to a relevant health professional for the purposes of the health professional making a diagnosis of a disease or condition:
 - (a) in the case of a disease or condition that:
 - (i) may lead to the death of a person, or a severe deterioration in the state of a person's health, without urgent treatment; or
 - (ii) may pose a high risk to public health;is classified as Class IIb; or
 - (b) in the case of a serious disease or serious condition or a disease or condition that may pose a moderate risk to public health, and where paragraph (a) does not apply—is classified as Class IIa; or
 - (c) in any other case—is classified as Class I.

4.6 Programmed or programmable medical device or software that is a medical device for use for monitoring the state or progression of a disease or condition etc.

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to provide information that is to be used for monitoring the state or progression of a disease or condition of a person or the parameters in relation to a person:

- (a) in the case where the information to be provided could indicate that the person or another person may be in immediate danger or that there may be a high risk to public health—is classified as Class IIb; or
- (b) in the case where the information to be provided could indicate that the person or another person may be in other danger or that there may be a moderate risk to public health—is classified as Class IIa; or
- (c) in any other case—is classified as Class I.

4.7 Programmed or programmable medical device or software that is a medical device for use in specifying or recommending treatment or intervention

- (1) Subject to subclause (2), a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to specify or recommend a treatment or intervention:
 - (a) in the case where the absence of the treatment or intervention or where the treatment or intervention itself:
 - (i) may lead to the death of a person or a severe deterioration in the state of a person's health; or
 - (ii) may pose a high risk to public health;
is classified as Class III; or
 - (b) in the case where the absence of the treatment or intervention or where the treatment or intervention itself:
 - (i) may otherwise be harmful to a person; or
 - (ii) may pose a moderate risk to public health;
is classified as Class IIb; or
 - (c) in any other case—is classified as Class IIa.
- (2) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to recommend a treatment or intervention (the ***recommended treatment or intervention***) to a relevant health professional for the purposes of the health professional making a decision about the treatment or intervention:
 - (a) in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:
 - (i) may lead to the death of a person or a severe deterioration in the state of a person's health; or
 - (ii) may pose a high risk to public health;
is classified as Class IIb; or
 - (b) in the case where the absence of the recommended treatment or intervention or where the recommended treatment or intervention itself:
 - (i) may otherwise be harmful to a person; or
 - (ii) may pose a moderate risk to public health;

- is classified as Class IIa; or
(c) in any other case—is classified as Class I.

4.8 Programmed or programmable medical device or software that is a medical device that is to provide therapy to a person through the provision of information

A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to provide therapy to a person through the provision of information to the person:

- (a) in the case of therapy that may result in the death of the person or a severe deterioration in the state of the person’s health—is classified as Class III; or
- (b) in the case of therapy that may cause serious harm to the person and where paragraph (a) does not apply—is classified as Class IIb; or
- (c) in the case of therapy that may cause harm to the person and where neither paragraph (a) nor (b) applies—is classified as Class IIa; or
- (d) in any other case—is classified as Class I.

3 Schedule 2A (note to Schedule heading)

Repeal the note, substitute:

Note: Regulation 3.2 provides for the making of classification rules. Regulation 3.3 sets out the principles for applying those rules.

4 Dictionary (at the end of the definition of *active medical device*)

Add:

Software that is a medical device is an *active medical device*.

Part 2—Essential principles

Therapeutic Goods (Medical Devices) Regulations 2002

5 Clause 12.1 of Schedule 1

Repeal the clause, substitute:

12.1 Programmed or programmable medical device or software that is a medical device

- (1) A programmed or programmable medical device, or software that is a medical device, that is intended to make use of either or both of data and information must be designed and produced in a way that ensures that:
 - (a) the safety, performance, reliability, accuracy, precision, useability, security and repeatability of the device are appropriate for the intended purpose of the device; and
 - (b) any consequent risks, or impairment of performance, associated with one or more fault conditions is eliminated or appropriately reduced; and
 - (c) the device is resilient with respect to interactions that could occur during the use of the device and that could result in unsafe performance of the device; and
 - (d) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides suitable warnings in a timely manner:
 - (i) following the disruption to services upon which the device is dependent for the device's operation; and
 - (ii) following the performance of the device being adversely affected; and
 - (e) if relevant to the safety of a patient, or the safety and health of the user or any other person, the device provides a means by which the user can verify correct operation of the device; and
 - (f) if relevant to the safety of a patient, or the safety and health of the user or any other person, the integrity and quality of the data or information is maintained; and
 - (g) if relevant, the privacy of the data or information is maintained.
- (2) A programmed or programmable medical device, or software that is a medical device, must be developed, produced and maintained having regard to the generally acknowledged state of the art (including for design, development life cycle, development environment, version control, quality and risk management, security, verification and validation, change and configuration management and problem resolution).
- (3) A programmed or programmable medical device, or software that is a medical device, that is intended to be used in combination with computing platforms must be designed and developed taking into account the capability, resources and configuration of the platforms and the external factors (including information technology environments) related to the use of the platforms.
- (4) The manufacturer of a programmed or programmable medical device, or software that is a medical device, must provide instructions or information with the device that sets out requirements (including requirements about hardware,

software, information technology environments and security measures) necessary to operate the device as intended.

- (5) A programmed or programmable medical device, or software that is a medical device, must be designed, produced and maintained with regard to best practice in relation to software, security and engineering to provide cybersecurity of the device, including where appropriate the following:
 - (a) protection against unauthorised access, unauthorised influence or unauthorised manipulation;
 - (b) minimisation of risks associated with known cybersecurity vulnerabilities (including either or both of remediation of known vulnerabilities and application of compensating controls);
 - (c) facilitation of the application of updates, patches, compensating controls and other improvements;
 - (d) disclosure of known vulnerabilities in the device or its components and associated mitigations;
 - (e) making available sufficient information for a user to make decisions with respect to the safety of applying, or not applying, updates, patches, compensating controls and other improvements.
- (6) The manufacturer of a programmed or programmable medical device, or software that is a medical device, having regard to the intended purpose of the device, the generally acknowledged state of the art and best practice, must ensure that the data that influences the performance of the device is:
 - (a) representative; and
 - (b) of sufficient quality; and
 - (c) maintained to ensure integrity; and
 - (d) managed to reduce bias.

6 Subclause 13.2(3) of Schedule 1

Repeal the subclause, substitute:

- (3) If it is not practicable to comply with subclause (1) or (2) in relation to the provision of the information required under subregulation 10.2(1) or clause 13.3:
 - (a) for a medical device that is not software—the information must be provided on a leaflet supplied with the device; or
 - (b) for a medical device that is software—the information must be provided on a leaflet supplied with the device or the information must be provided electronically.

7 After clause 13A.4 of Schedule 1

Insert:

13B Software—version numbers and build numbers

- (1) For a medical device that is software, or that incorporates software, the current version number and current build number of the software must be accessible by, and identifiable to, users of the device.
- (2) The current version number and current build number of the software:
 - (a) must be in English; and
 - (b) may also be in any other language.

Schedule 3—Personalised medical devices

Part 1—Definitions

Therapeutic Goods (Medical Devices) Regulations 2002

1 At the end of Part 1

Add:

1.8 Classes of persons that are not manufacturers of a medical device

For the purposes of subsection 41BG(4) of the Act, a class of persons is health professionals, or suitably qualified persons within a healthcare facility, who produce a medical device (the ***final device***) where the following are satisfied:

- (a) a medical device production system is used to produce the final device;
- (b) the medical device production system is included in the Register as a kind of medical device.

2 Dictionary

Insert:

adaptable medical device means a mass-produced medical device that is intended by the manufacturer to be assembled or adapted after it has been supplied, in accordance with the manufacturer's instructions, to:

- (a) address either or both of the anatomical and physiological features of a particular individual; or
- (b) address a pathological condition of a particular individual; or
- (c) otherwise perform as intended by the manufacturer.

3 Dictionary (definition of *custom-made medical device*)

Repeal the definition, substitute:

custom-made medical device means a medical device that:

- (a) is intended by the manufacturer to be for:
 - (i) the sole use of a particular patient (the ***intended recipient***); or
 - (ii) the sole use of a particular health professional (the ***intended recipient***) in the course of the health professional's practice; and
- (b) is manufactured by the manufacturer in accordance with a written request of a health professional (the ***requesting health professional***) and with particular design characteristics specified by that health professional in the request (even if the design is developed in consultation with the manufacturer), where those design characteristics are intended to address:
 - (i) either or both of the anatomical and physiological features of the intended recipient; or
 - (ii) a pathological condition of the intended recipient; and
- (c) the requesting health professional has determined is necessary to address the matters covered by paragraph (b) because there is no kind of medical device included in the Register to address those matters or to address those matters to an appropriate level.

However, a custom-made medical device does not include a patient-matched medical device, an adaptable medical device or other mass-produced medical device.

4 Dictionary

Insert:

mass-produced medical device means a medical device that:

- (a) is manufactured according to standardised dimensions or designs; and
- (b) is not designed for a particular individual; and
- (c) is manufactured in a continuous production process or in a homogenous batch.

medical device production system means a system that consists of raw materials and main production equipment (whether or not the system also consists of software), where the system is intended by the manufacturer to be used (whether or not with ancillary inputs or equipment) by a health professional, or suitably qualified person within a healthcare facility, to produce a particular medical device for use in relation to a patient of the health professional or healthcare facility.

patient-matched medical device means a medical device that:

- (a) is manufactured by the manufacturer, within a specified design envelope, to match:
 - (i) either or both of the anatomical and physiological features of a particular individual; or
 - (ii) a pathological condition of a particular individual; and
- (b) is designed by the manufacturer (even if the design is developed in consultation with a health professional); and
- (c) is manufactured using production processes that are capable of being:
 - (i) either or both validated and verified; and
 - (ii) reproduced.

specified design envelope means minimum and maximum dimensions, performance limits or other relevant factors that:

- (a) characterise a medical device for production purposes; and
- (b) may be based on a standard device template.

Part 2—Reports

Therapeutic Goods (Medical Devices) Regulations 2002

5 After regulation 10.3

Insert:

10.3A Custom-made medical devices—information about supplies

- (1) A person commits an offence if:
- (a) the person is the manufacturer of a custom-made medical device that is manufactured in Australia in a financial year (the *relevant financial year*); and
 - (b) the person does not, before 1 October in the next financial year, give the Secretary a written report that relates to all the custom-made medical devices the person manufactured in the relevant financial year and that complies with subregulation (3).

Penalty: 10 penalty units.

- (2) A person commits an offence if:
- (a) the person is the sponsor of a custom-made medical device that the person imported into Australia in a financial year (the *relevant financial year*); and
 - (b) the person does not, before 1 October in the next financial year, give the Secretary a written report that relates to all the custom-made medical devices the person imported in the relevant financial year and that complies with subregulation (3).

Penalty: 10 penalty units.

- (3) A report under this regulation must:
- (a) be made in accordance with a form approved, in writing, by the Secretary; and
 - (b) contain the information that the form requires.
- (4) Without limiting subregulation (3), the form may require details in relation to supplies of custom-made medical devices covered by paragraph (1)(b) or (2)(b).
- (5) The Secretary must make the form available on the Therapeutic Goods Administration's website.

Part 3—Conformity assessment procedures

Therapeutic Goods (Medical Devices) Regulations 2002

6 Paragraph 7.1(a) of Schedule 3

After “device”, insert “and to provide a copy of the statement with the device”.

7 Subclause 7.2(1) of Schedule 3 (note)

Repeal the note.

8 Paragraph 7.2(2)(c) of Schedule 3

Omit “used only in relation to a particular individual”, substitute “for the sole use of a particular patient”.

9 Paragraph 7.2(2)(e) of Schedule 3

Omit “provided the specification”, substitute “made the request”.

10 Paragraph 7.2(2)(f) of Schedule 3

Omit “or construction of the device as specified by the health professional who provided the specification”, substitute “of the device as specified by the health professional who made the request”.

11 After subclause 7.2(3) of Schedule 3

Insert:

(3A) The manufacturer must provide a copy of the statement with the device.

12 Subclause 7.6(2) of Schedule 3

Repeal the subclause, substitute:

- (2) The manufacturer must keep the statement and documentation for at least:
 - (a) if the device is not an implantable medical device—5 years after the manufacture of the medical device to which the statement and documentation relate; or
 - (b) if the device is an implantable medical device—15 years after the manufacture of the medical device to which the statement and documentation relate.

Part 4—Exemptions

Therapeutic Goods (Medical Devices) Regulations 2002

13 Regulation 1.6

Omit “given to the device by its manufacturer to identify the device and any variants”, substitute “of the device”.

14 Paragraph 3.11(2)(a)

Omit “or 1.5”.

15 At the end of regulation 3.11

Add:

- (3) Despite subregulation (2), this regulation applies to a custom-made medical device.

16 Paragraph 4.3F(e)

Omit “given to the device by the manufacturer”, substitute “of the device”.

17 Paragraph 4A.31(h)

Omit “given to the device by the manufacturer”, substitute “of the device”.

18 Subparagraph 1.8(2)(c)(i) of Schedule 3

Omit “(for example, the product name or model number)”.

19 Subparagraph 3.5(2)(c)(i) of Schedule 3

Omit “(for example, the product name or model number)”.

20 Subparagraph 5.7(2)(c)(i) of Schedule 3

Omit “(for example, the product name or model number)”.

21 Subparagraph 6.6(2)(c)(i) of Schedule 3

Omit “(for example, the product name or model number)”.

22 Subparagraph 6B.6(2)(c)(i) of Schedule 3

Omit “(for example, the product name)”.

23 Part 1 of Schedule 4 (table item 1.5)

Repeal the item.

24 Part 2 of Schedule 4 (at the end of the table)

Add:

- | | | |
|------|--|---|
| 2.12 | Custom-made medical device that is manufactured in Australia | (a) The manufacturer of the device must, at all times, have available: <ul style="list-style-type: none">(i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or(ii) information relating to the design and |
|------|--|---|

- manufacture of the device and to any changes to the device.
- (b) The manufacturer of the device must allow an authorised person to do any of the following:
- (i) enter, at any reasonable time, any premises (including premises outside Australia) at which the manufacturer or any other person deals with the device;
 - (ii) inspect those premises;
 - (iii) if the device is on those premises—inspect the device and examine, take measurements of, conduct tests on or require tests to be conducted on the device;
 - (iv) inspect any thing on those premises that relates to the device and examine, take measurements of, conduct tests on, require tests to be conducted on or take samples of any such thing;
 - (v) make any still or moving image or any recording of those premises or any thing on those premises.
- (c) If asked to do so by an authorised person, the manufacturer of the device must produce to the authorised person any documents relating to the device that the authorised person requires and allow the authorised person to copy the documents.
- (d) The manufacturer of the device must, on request from the Secretary, give the Secretary a copy of the health professional's request for the device within the period requested by the Secretary (which must be at least 10 working days starting on the day on which the Secretary's request is made).
-
- 2.13 Custom-made medical device that is manufactured outside Australia
- (a) The sponsor must have procedures in place to ensure that the manufacturer of the device, at all times, has available:
- (i) sufficient information to substantiate that the conformity assessment procedures have been applied to the device; or
 - (ii) information relating to the design and manufacture of the device and to any changes to the device.
- (b) The sponsor must have procedures in place to ensure that the manufacturer of the device allows an authorised person to do any of the following:
- (i) enter, at any reasonable time, any premises at which the manufacturer or any other person deals with the device;
 - (ii) inspect those premises;
 - (iii) if the device is on those premises—inspect the device and examine, take measurements of, conduct tests on or require tests to be conducted on the device;
 - (iv) inspect any thing on those premises that relates to the device and examine, take
-

measurements of, conduct tests on, require tests to be conducted on or take samples of any such thing;

(v) make any still or moving image or any recording of those premises or any thing on those premises.

(c) The sponsor must have procedures in place to ensure that the manufacturer of the device, if the manufacturer is asked to do so by an authorised person, produces to the authorised person any documents relating to the device that the authorised person requires and allows the authorised person to copy the documents.

(d) The sponsor must, on request from the Secretary, give the Secretary a copy of the health professional's request for the device within the period requested by the Secretary (which must be at least 10 working days starting on the day on which the Secretary's request is made).

2.14 Patient-matched medical device

The sponsor must, before 25 February 2021, notify the Secretary in writing of each kind of medical device covered by the description mentioned in paragraph 11.51(3)(b) that is intended to be supplied in Australia on or after 1 November 2024 and of the following:

- (a) the name and address of the sponsor;
- (b) the name and address of the manufacturer of that kind of medical device;
- (c) the device nomenclature system code of that kind of medical device;
- (d) the medical device classification of that kind of medical device;
- (e) the unique product identifier given to each medical device of that kind.

25 Dictionary

Insert:

unique product identifier of a medical device means the unique product identifier (for example, the product name or model number) given to the device by its manufacturer to identify the device and any variants.

Part 5—Classification rules

Therapeutic Goods (Medical Devices) Regulations 2002

26 After subregulation 3.3(5)

Insert:

- (5A) A medical device production system has the same classification as the medical device the system is intended to produce.

27 Clause 5.4 of Schedule 2

Repeal the clause, substitute:

5.4 Medical devices that record patient images or that are anatomical models etc.

- (1) If:
- (a) a medical device is intended by the manufacturer to be used to record patient images that are to be used for either or both of the following:
 - (i) the diagnosis or monitoring of a disease, injury or disability;
 - (ii) the investigation of the anatomy or of a physiological process; and
 - (b) the images are to be acquired through a method that relies on energy outside the visible spectrum;
- the device is classified as Class IIa.
- (2) A medical device that is an anatomical model (whether physical or virtual) that is intended by the manufacturer to be used for either or both of the following:
- (a) the diagnosis or monitoring of a disease, injury or disability;
 - (b) the investigation of the anatomy or of a physiological process;
- is classified as Class IIa.
- (3) A programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the following:
- (a) the diagnosis or monitoring of a disease, injury or disability;
 - (b) the investigation of the anatomy or of a physiological process;
- is classified as Class IIa.

Part 6—Essential principles

Therapeutic Goods (Medical Devices) Regulations 2002

28 Subclause 13.4(3) of Schedule 1 (at the end of the table)

Add:

- | | |
|----|--|
| 30 | For an adaptable medical device, instructions for assembling or adapting the device which, if followed, will ensure that the device continues to comply with the applicable provisions of the essential principles |
| 31 | For a medical device production system, instructions for the process to be followed in producing the medical device the system is intended to produce which, if followed, will ensure that the device so produced will comply with the applicable provisions of the essential principles |

Schedule 4—IVD companion diagnostics

Therapeutic Goods (Medical Devices) Regulations 2002

1 At the end of regulation 1.6

Add:

; (d) an IVD companion diagnostic.

2 Paragraphs 4.3F(e) and 4A.31(h)

Omit “or (c)”, substitute “, (c) or (d)”.

3 At the end of paragraph 5.3(1)(j)

Add:

; (x) an IVD companion diagnostic.

4 After paragraph 1.3(f) of Schedule 2A

Insert:

(fa) use as an IVD companion diagnostic;

5 Clause 1.3 of Schedule 2A (note)

After “IVD medical device”, insert “(except an IVD companion diagnostic)”.

6 Dictionary

Insert:

IVD companion diagnostic means an IVD medical device:

- (a) that is intended by the manufacturer to be used for the examination of a specimen from the body of an individual:
 - (i) to identify whether the individual would be likely to benefit from the use of a particular medicine or biological; or
 - (ii) to identify whether the individual is likely to be at particular risk of a serious adverse reaction to the use of a particular medicine or biological; or
 - (iii) to monitor the individual’s response to the use of a particular medicine or biological; and
- (b) that is mentioned in product information for the medicine or biological as being essential for the safe and effective use of the medicine or biological; and
- (c) if the medicine or biological comprises blood, a blood component, cells, tissue or an organ, from a donor other than the individual—that is not intended by the manufacturer to be used for the examination of the specimen merely to determine whether the medicine or biological is compatible with the individual.

Schedule 5—Faecal microbiota transplant products

Therapeutic Goods Regulations 1990

1 Regulation 2

Insert:

faecal microbiota transplant product means a thing that:

- (a) comprises, contains or is derived from human stool; and
- (b) is for introduction into a person for a therapeutic use.

2 Before clause 1 of Schedule 16

Insert:

1A Class 1 biologicals

For the purposes of the definition of *Class 1 biological* in regulation 2, a biological is a Class 1 biological if:

- (a) it is a faecal microbiota transplant product; and
- (b) it is not advertised to consumers; and
- (c) it is to be collected under the supervision or direction, or in accordance with the requirements, of a medical practitioner registered, in a State or internal Territory, as a medical practitioner; and
- (d) each later step in the manufacture of it is to be carried out in a hospital by, or under the supervision or direction of, the practitioner (unless the step relates to the storage or testing of the biological, in which case it may instead be carried out by a person under a contract with the hospital in a State or internal Territory); and
- (e) it is for use in a recipient who is a patient of the hospital with the recipient being under the clinical care of the practitioner.

Schedule 6—Consumer medicine information documents

Therapeutic Goods Regulations 1990

1 Subregulations 9A(1) and (1A)

Omit “patient information document”, substitute “consumer medicine information document”.

2 Paragraph 9B(3)(a)

Omit “patient information document”, substitute “consumer medicine information document”.

3 Schedule 12

Repeal the Schedule, substitute:

Schedule 12—Consumer medicine information documents

Note: See subregulation 9A(1).

1 General requirements

A consumer medicine information document about a medicine must:

- (a) be written in English; and
- (b) be clearly legible; and
- (c) be written in language that will easily be understood by patients; and
- (d) be consistent with product information about the product.

2 Specific requirements—document enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine, it must set out all of the information required by the “TGA Consumer Medicine Information (Prescription Medicine) Template” (published by the Therapeutic Goods Administration on its website) but:

- (a) it is not required to set out the information in the same order as the Template; and
- (b) it is not required to include any Consumer Medicine Information (CMI) summary that forms part of that Template.

3 Specific requirements—document not enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is not enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine:

- (a) it must set out all of the information required by the “TGA Consumer Medicine Information (Prescription Medicine) Template” (published by the

Therapeutic Goods Administration on its website) in the same order as the Template; and

- (b) if it is supplied in electronic form, it must be in the form of a PDF file or an HTML file.

4 Schedule 13

Repeal the Schedule, substitute:

Schedule 13—Consumer medicine information documents

Note: See subregulation 9A(1A).

1 General requirements

A consumer medicine information document about a medicine must:

- (a) be written in English; and
- (b) be clearly legible; and
- (c) be written in language that will easily be understood by patients; and
- (d) be consistent with product information about the product.

2 Specific requirements—document enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine, it must set out all of the information required by the “TGA Consumer Medicine Information (Non-prescription Medicine) Template” (published by the Therapeutic Goods Administration on its website) but:

- (a) it is not required to set out the information in the same order as the Template; and
- (b) it is not required to include any Consumer Medicine Information (CMI) summary that forms part of that Template.

3 Specific requirements—document not enclosed within packaging etc.

Also, if the consumer medicine information document about a medicine is not enclosed within, on a surface of, or affixed to a surface of, the packaging of the medicine:

- (a) it must set out all of the information required by the “TGA Consumer Medicine Information (Non-prescription Medicine) Template” (published by the Therapeutic Goods Administration on its website) in the same order as the Template; and
- (b) if it is supplied in electronic form, it must be in the form of a PDF file or an HTML file.

Schedule 7—Handling and testing of samples

Therapeutic Goods Regulations 1990

1 Regulation 2 (definition of *official analyst*)

Repeal the definition.

2 Subregulation 23(1)

Insert:

analyst means a person appointed by the Secretary as an analyst (except an official analyst) under regulation 25.

appropriately fastened and sealed: see subregulation (2).

official analyst means a person appointed by the Secretary as an official analyst under regulation 25.

3 Subregulation 23(1) (definition of *relevant test*)

Repeal the definition.

4 Subregulation 23(1) (definition of *responsible analyst*)

After “means an”, insert “analyst or”.

5 Subregulation 23(2)

Repeal the subregulation, substitute:

- (2) For the purposes of this Part, a sample of therapeutic goods is *appropriately fastened and sealed* if the sample is fastened and sealed:
- (a) in a container or package that is marked with a unique identification number or with the name and address of:
 - (i) the person from whom the sample was taken; or
 - (ii) for a sample delivered under paragraph 28(5)(h) or subsection 41FN(2) of the Act—the sponsor of the goods; and
 - (b) so as to prevent the opening of the container or package, and the removal of the unique identification number or the name and address, without breaking the seal.

6 Regulation 25 (heading)

Repeal the heading, substitute:

25 Appointment of analysts and official analysts and powers of official analysts

7 Subregulation 25(1)

After “to be an”, insert “analyst or an”.

8 Subregulation 25(2)

Repeal the subregulation.

9 Paragraph 25(3)(c)

After “nominate an”, insert “analyst or”.

10 At the end of regulation 25

Add:

- (4) The tests determined under paragraph (3)(b), by an official analyst, for the following matters must be tests covered by regulation 28:
 - (a) determining whether particular therapeutic goods (other than medical devices) are goods that conform with a standard applicable to the goods;
 - (b) determining whether a particular kind of medical device complies with the applicable provisions of the essential principles.
- (5) The tests determined under paragraph (3)(b), by an official analyst, for a matter not covered by subregulation (4), are the tests that the official analyst considers appropriate.

11 Paragraph 26(2)(a)

Omit “packaged,”.

12 Paragraph 26A(1)(a)

Omit “packaged,”.

13 Subparagraphs 26A(1)(b)(i) and (ii)

Omit “packaged,” (wherever occurring).

14 Paragraphs 27(1)(a) and (b)

Omit “packaged,”.

15 Paragraph 27(2)(a)

Omit “relevant tests to the extent the analyst considers necessary”, substitute “performing the tests determined under paragraph 25(3)(b) in relation to the sample”.

16 At the end of paragraph 27(2)(a)

Add:

- (iii) for a sample of medicine listed under section 26A or 26AE of the Act—whether the medicine contains an ingredient that is not specified in a determination under paragraph 26BB(1)(a) of the Act or whether any of the requirements determined under paragraph 26BB(1)(b) of the Act have been contravened; and

17 Regulation 28 (heading)

Repeal the heading, substitute:

28 Tests for determining conformity with a standard or compliance with essential principles

18 Subregulation 28(1)

Omit “relevant”.

19 Paragraph 28(1)(b)

After “British Pharmacopoeia”, insert “, the European Pharmacopoeia or the United States Pharmacopoeia-National Formulary”.

20 Paragraph 28(1)(c)

Repeal the paragraph.

21 Subregulation 28(2)

Omit “relevant”.

22 Regulation 29 (heading)

Repeal the heading, substitute:

29 Certificate of responsible analyst

23 Subregulation 29(1)

Omit “send to the sponsor of the goods a certificate signed by the analyst”, substitute “issue a certificate”.

24 Subregulations 29(2) and (3)

Repeal the subregulations, substitute:

- (2) Within a reasonable time of the completion of the analysis, the responsible analyst must send a copy of the certificate to:
 - (a) the sponsor of the goods; and
 - (b) if the sample was taken under paragraph 25(3)(a) and the person from whom the sample was taken is not the sponsor of the goods—the person from whom the sample was taken.

25 Subregulation 29(4)

Omit “the certificate, and the copy of it referred to in subregulation (2),”, substitute “a copy of the certificate sent under subregulation (2)”.

26 Paragraph 29(4A)(a)

Omit “certificate or copy is sent may ask for the results of the analysis referred to in the certificate”, substitute “copy is sent may ask for the results of the analysis referred to in the copy”.

27 Subregulation 29(5)

Omit “of an official analyst”.

28 Paragraph 29(6)(a)

Omit “of an official analyst”.

29 Subregulation 29(6)

Omit “and purporting to be signed by an official analyst”.

30 Subregulation 29(6)

Omit “and to have been issued under subregulation (1) or (2), as the case requires”.

31 Regulation 30 (heading)

Repeal the heading, substitute:

30 Review of results of examination and analysis

32 Paragraph 30(1)(a)

Repeal the paragraph, substitute:

- (a) to whom a copy of a certificate, setting out the results of the examination and analysis of goods, is sent under subregulation 29(2); and

33 Subregulation 30(2)

Omit “certificate, or the copy of the certificate, as the case may be”, substitute “copy of the certificate”.

34 Subregulation 30(4)

Omit “an analyst”, substitute “a person (the *third party*)”.

35 Paragraph 30(4)(a)

Omit “analyst”, substitute “third party”.

36 Subregulation 30(5)

Omit “relevant tests in relation to the goods”, substitute “tests determined by an official analyst under paragraph 25(3)(b) on the basis of which the certificate referred to in paragraph (1)(a) of this regulation was issued”.

37 Subregulation 30(6)

Omit “, at the request of the sponsor of the goods,”.

38 Paragraph 30(6)(a)

Omit “the official analyst”, substitute “an official analyst”.

39 Subregulation 30(6)

Omit “to an analyst agreed”, substitute “to a person agreed (who may be an analyst or official analyst)”.

40 Subregulation 30(6)

After “and the official analyst”, insert “referred to in subregulation (5)”.

41 Subregulation 30(6)

Omit “an analyst nominated”, substitute “a person nominated (who may be an analyst or official analyst)”.

42 Subregulation 30(7)

Omit “forwarded to an analyst referred to in subregulation (6), the analyst”, substitute “sent to a person as mentioned in subregulation (6), the person”.

43 Paragraph 30(7)(a)

Omit “any relevant tests”, substitute “the tests determined by an official analyst under paragraph 25(3)(b) on the basis of which the certificate referred to in paragraph (1)(a) of this regulation was issued”.

44 Paragraphs 30(7)(b) and (c)

Omit “analyst”, substitute “person”.

45 Paragraph 30(7)(c)

Omit “sponsor of the goods”, substitute “person who requested the review”.

46 Subregulation 30(9)

Omit “official analyst”, substitute “responsible analyst”.

47 Subregulation 30(9)

Omit “analyst referred to in”, substitute “person to whom a sample is sent as mentioned in”.

48 Subregulation 30(10)

Omit “of an analyst”.

49 Paragraph 30(11)(a)

Omit “an analyst”, substitute “a person”.

50 Paragraph 30(11)(b)

Omit “analyst”, substitute “person”.

51 Subregulation 30(11)

Omit “, or a copy of the certificate, and to have been issued under that subregulation”, substitute “or a copy of the certificate”.

Schedule 8—Fee waivers for certain requests relating to prescription opioids

Therapeutic Goods Regulations 1990

1 After subregulation 45(6)

Insert:

Fee waivers for prescription opioids

- (7) The Secretary must waive a fee prescribed in Schedule 9 in relation to a request (an *opioid reform request*) that satisfies all of the following:
 - (a) it is made in relation to prescription opioids that are registered goods;
 - (b) it is made in the period beginning on the commencement of this subregulation and ending at the end of 31 December 2020;
 - (c) it is made under subsection 9D(2) or (3) of the Act;
 - (d) it is made solely for an opioid reform purpose (see subregulation (8)) or solely for an opioid reform purpose and an associated variation of product information purpose (see subregulation (9)).
- (8) For the purposes of subregulation (7), an opioid reform request is made for an opioid reform purpose if it is made:
 - (a) under subsection 9D(2) of the Act, to do either or both of the following:
 - (i) add a warning, or precaution, in relation to the goods that does not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;
 - (ii) reduce the class of persons for whom the goods are suitable; or
 - (b) under subsection 9D(3) of the Act, to introduce a smaller pack size in relation to the goods.
- (9) For the purposes of subregulation (7), an opioid reform request is made for an associated variation of product information purpose if:
 - (a) the opioid reform request is made under subsection 9D(3) of the Act; and
 - (b) paragraphs 9D(3)(b) to (c) of the Act are satisfied in relation to the request; and
 - (c) the request is made for the purpose of varying product information in relation to the prescription opioids so that the product information is in the form approved under section 7D of the Act in relation to the prescription opioids.

Schedule 9—Other amendments

Part 1—Fee waiver for requests to vary product information for medicine

Therapeutic Goods Regulations 1990

1 At the end of regulation 45

Add:

Fee waiver for requests to vary product information for medicine

- (13) The Secretary must waive a fee prescribed in Schedule 9 in relation to a request that a person makes under subsection 9D(3) of the Act if:
- (a) the request is in relation to therapeutic goods that are registered; and
 - (b) the therapeutic goods are medicine; and
 - (c) paragraphs 9D(3)(b) to (c) of the Act are satisfied in relation to the request; and
 - (d) the request is made solely for the purpose of varying product information in relation to the medicine so that the product information is in the form approved under section 7D of the Act in relation to the medicine; and
 - (e) the request is made in the period beginning on 1 January 2020 and ending at the end of 31 December 2020.

Part 2—Clinical trials

Therapeutic Goods Regulations 1990

2 Regulation 2

Insert:

Practice Guideline has the meaning given by paragraph 12AB(2)(a).

3 Regulation 2 (definition of *Practice Guidelines*)

Repeal the definition.

4 Paragraph 12AB(2)(a)

Omit “the Guidelines for Good Clinical Practice (the *Practice Guidelines*)”, substitute “the Guideline for Good Clinical Practice (the *Practice Guideline*)”.

5 Paragraph 12AB(2)(a)

Omit “published jointly by the International Conference on Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use and the Committee for Medicinal Products”, substitute “published by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use”.

6 Subregulation 12AC(1)

After “clinical trial mentioned in regulation 12AB”, insert “or item 3 of the table in Schedule 5A”.

7 Paragraph 12AD(a)

Omit “Practice Guidelines”, substitute “Practice Guideline”.

8 Schedule 5A (at the end of the cell at table item 3, column 3)

Add:

- ; and (i) the sponsor must comply with requests by an authorised officer, whether made before or after the start of the trial, to give information about the conduct of the trial (whether or not the sponsor is conducting the trial); and
- (j) if a body or organisation is conducting the trial for the sponsor, that body or organisation must comply with requests by an authorised officer, whether made before or after the start of the trial, to give information about the conduct of the trial; and
- (k) the sponsor (if the sponsor is conducting the trial), or the body or organisation conducting the trial for the sponsor, must allow an authorised officer to do the things mentioned in regulation 12AC

Part 3—Nappy rash products

Therapeutic Goods Regulations 1990

9 Schedule 5 (after table item 8A)

Insert:

- 8B unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action)

10 Schedule 7 (after table item 11)

Insert:

- 11A unmedicated preparations for topical use for protecting against, or providing relief from, nappy rash symptoms by acting only as a barrier for the skin (whether or not the preparations also have a moisturising action)

Part 4—Other amendments

Therapeutic Goods Regulations 1990

11 Regulation 2 (note 2 to the definition of *Australian Approved Names List*)

Omit “TGA Approved Terminology for Medicines”, substitute “TGA Approved Terminology for Therapeutic Goods”.

Note: This item updates the title of a document.

12 Subparagraph 16M(1)(b)(i)

Omit “subregulation 16J(3)”, substitute “subregulation 16J(4)”.

Note: This item fixes an incorrect cross-reference.

13 Subparagraph 16M(1)(b)(ii)

Omit “subregulation 16J(4)”, substitute “subregulation 16J(3)”.

Note: This item fixes an incorrect cross-reference.

Schedule 10—Application, saving and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

1 In the appropriate position in Part 11

Insert:

Division 11.10—Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

Subdivision A—Definitions

11.38 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

finally determined: an application is finally determined at the first time both the following conditions are met:

- (a) a decision has been made whether or not to grant the application;
- (b) there is no longer any possibility of a change in the outcome of the decision.

unique product identifier, in relation to a medical device, means the unique product identifier given to the device by its manufacturer to identify the device and any variants.

Subdivision B—Reclassification of medical devices

11.39 Definitions

In this Subdivision:

inclusion day for an entry of a kind of transitional medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

pre-commencement entry: an entry of a kind of transitional medical device in the Register is a *pre-commencement entry* if that kind of medical device is included in the Register because of an application made before 25 August 2020 (whether the inclusion day for the entry occurred before, on or after 25 August 2020).

transitional AIMD device means a transitional medical device of a kind mentioned in column 1 of item 2 of the table in the definition of *transitional medical device*.

transitional medical device means a medical device of a kind mentioned in column 1 of an item in the following table if:

- (a) the medical device is, immediately before 25 August 2020, included in the Register and classified as a class of medical device mentioned in column 2 of the item; or
- (b) on 25 August 2020:
 - (i) the medical device was the subject of a class of application mentioned in column 2 of the item for inclusion in the Register; and
 - (ii) the application had not been finally determined.

Transitional medical device		
Item	Column 1 Kind of medical device	Column 2 Class of medical device or application
1	a medical device of a kind described in subclause 3.4(4B) of Schedule 2	Class IIb
2	an active implantable medical device	Class AIMD
3	a medical device of a kind described in subclause 3.1(2A) of Schedule 2	Class I or Class IIa
4	a medical device of a kind described in subclause 3.1(4) of Schedule 2	Class I, Class IIa or Class IIb
5	a medical device of a kind described in subclause 4.2(4) of Schedule 2	Class IIa or Class IIb
6	a medical device of a kind described in subclause 3.2(3A) of Schedule 2	Class IIa or Class IIb

11.40 Transitional medical devices—application of amendments

Applications and entries other than for transitional medical devices

- (1) The amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations apply on and after 25 August 2020 in relation to the following:
 - (a) an application for a kind of medical device to be included in the Register that is made on or after 25 August 2020;
 - (b) a kind of medical device that is included in the Register as a result of such an application.

Applications and entries for transitional medical devices

- (2) Subject to subregulations (3) and (5), the amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations apply in relation to a transitional medical device on and after 1 November 2024.
- (3) The amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations do not apply in relation to a transitional medical device before the day applicable under subregulation (4) if:
 - (a) a person applies under the Act:
 - (i) on or after the inclusion day for the entry of the transitional medical device; and
 - (ii) on or after 25 August 2020; and
 - (iii) before 1 November 2024;

- to have a kind (the *new kind*) of medical device included in the Register; and
 - (b) the person gives to the Secretary a notice under regulation 11.41 in relation to the transitional medical device; and
 - (c) the unique product identifier of the device of the new kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.
- (4) For the purposes of subregulation (3), the day is the day after the day on which:
- (a) the person withdraws the application mentioned in paragraph (3)(a); or
 - (b) that application lapses under section 41FK of the Act; or
 - (c) that application is finally determined.
- (5) If:
- (a) a person is required under regulation 11.41 to give a notice to the Secretary in relation to a transitional medical device; and
 - (b) the person fails to give the notice in accordance with that regulation before the later of:
 - (i) 25 February 2021; and
 - (ii) the day occurring 2 months after the inclusion day for the entry of the transitional medical device;
- then the amendments made by Parts 1 to 6 of Schedule 1 to the amending regulations apply in relation to the transitional medical device on and after the later of those days.

11.41 Transitional medical devices—Secretary must be notified of unique product identifiers of devices supplied under pre-commencement entries

- (1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (2) if:
- (a) a kind of medical device is included in the Register in relation to the person; and
 - (b) the entry of that kind of medical device is a pre-commencement entry; and
 - (c) a medical device of that kind is a transitional medical device.
- (2) The notice must:
- (a) be in writing; and
 - (b) state:
 - (i) the unique device number assigned to that kind of device under section 41FL of the Act; and
 - (ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and
 - (c) be given to the Secretary before the later of:
 - (i) 25 February 2021; and
 - (ii) the day occurring 2 months after the inclusion day for the entry of the transitional medical device.

11.42 Transitional medical devices—selecting applications for auditing

Subregulation 5.3(1) does not apply to an application for inclusion of a kind of medical device in the Register as a Class III medical device if the application is for a transitional AIMD device.

11.43 Waiver of certain application fees

- (1) This regulation applies in relation to an application to include in the Register a transitional AIMD device as a Class III medical device.
- (2) The Secretary must waive the fee set out in paragraph (b) of column 2 in item 1.5 of the table in Part 1 of Schedule 5 in relation to the application.
- (3) This regulation ceases to have effect at the end of 24 August 2021.

Subdivision C—Programmed or programmable medical device or software that is a medical device**11.44 Definitions**

In this Subdivision:

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

transitional kind of medical device means a kind of medical device included in the Register because of an application made before 25 August 2020 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

11.45 Programmed or programmable medical device or software that is a medical device—classification rules

Applications and entries other than a transitional kind of medical device

- (1) Clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, apply on and after 25 August 2020 in relation to the following:
 - (a) an application for a kind of medical device to be included in the Register that is made on or after 25 August 2020;
 - (b) a kind of medical device that is included in the Register as a result of such an application.

Transitional kind of medical device

- (2) Subject to subregulations (3) and (5), clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, apply in relation to a transitional kind of medical device on and after 1 November 2024.
- (3) Clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, do not apply in relation to a transitional kind of medical device before the day applicable under subregulation (4) if:
 - (a) the person applies under the Act:
 - (i) on or after the inclusion day for the entry of the transitional kind of medical device; and

- (ii) on or after 25 August 2020; and
 - (iii) before 1 November 2024;
 - to have a kind (the *new kind*) of medical device included in the Register; and
 - (b) the person gives to the Secretary a notice under regulation 11.46 in relation to the transitional kind of medical device; and
 - (c) the unique product identifier of the devices of the new kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.
- (4) For the purposes of subregulation (3), the day is the day after the day on whichever of the following events occurs first:
- (a) the person withdraws the application mentioned in paragraph (3)(a);
 - (b) that application lapses under section 41FK of the Act;
 - (c) that application is finally determined.
- (5) If:
- (a) a person is required under regulation 11.46 to give a notice to the Secretary in relation to a transitional kind of medical device; and
 - (b) the person fails to give the notice in accordance with that regulation before the later of:
 - (i) 25 February 2021; and
 - (ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device;
- then clauses 4.5 to 4.8 of Schedule 2, as added by Schedule 2 to the amending regulations, apply in relation to the transitional kind of medical device on and after the later of those days.

11.46 Secretary must be notified in relation to a transitional kind of medical device

- (1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (2) if:
- (a) a kind of medical device is included in the Register in relation to the person; and
 - (b) the kind of medical device so included is a transitional kind of medical device; and
 - (c) medical devices of that kind are programmed or programmable medical devices or software.
- (2) The notice must:
- (a) be in writing; and
 - (b) state:
 - (i) the unique device number assigned to that kind of device under section 41FL of the Act; and
 - (ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and
 - (c) be given to the Secretary before the later of:
 - (i) 25 February 2021; and
 - (ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device.

11.47 Programmed or programmable medical device or software that is a medical device—essential principles

- (1) Clause 13B of Schedule 1, as inserted by Schedule 2 to the amending regulations, applies on and after 25 August 2020 in relation to the following:
 - (a) an application for a kind of medical device to be included in the Register that is made on or after 25 August 2020;
 - (b) a kind of medical device that is included in the Register as a result of such an application.
- (2) Clause 13B of Schedule 1, as inserted by Schedule 2 to the amending regulations, applies in relation to a transitional kind of medical device on and after 1 November 2024.

Subdivision D—Personalised medical devices**11.48 Definitions**

In this Subdivision:

inclusion day for an entry of a kind of medical device in the Register means the day on which the inclusion of that kind of device in the Register commences.

transitional kind of medical device means a kind of medical device included in the Register because of an application made before 25 August 2020 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

11.49 Personalised medical devices—reports

- (1) Subregulation 10.3A(1), as inserted by Schedule 3 to the amending regulations, applies in relation to a custom-made medical device that is manufactured on or after 25 August 2020.
- (2) Subregulation 10.3A(2), as inserted by Schedule 3 to the amending regulations, applies in relation to a custom-made medical device that is imported into Australia on or after 25 August 2020.

11.50 Personalised medical devices—conformity assessment procedures

- (1) The amendments of clause 7.2 of Schedule 3 made by Schedule 3 to the amending regulations apply in relation to a custom-made medical device that is manufactured on or after 25 August 2020.
- (2) The repeal and substitution of subclause 7.6(2) of Schedule 3 made by Schedule 3 to the amending regulations applies in relation to a medical device that is manufactured on or after 25 August 2020.

11.51 Personalised medical devices—exemptions

- (1) Item 1.5 of the table in Part 1 of Schedule 4, as in force immediately before 25 August 2020, continues to apply on and after that day in relation to the following:
 - (a) a custom-made medical device (within the meaning of these Regulations as in force immediately before that day) that is manufactured before that day;

- (b) a custom-made medical device (within the meaning of these Regulations as in force immediately before that day) that is manufactured on or after that day, where the request from the health professional was made before that day.
- (2) Items 2.12 and 2.13 of the table in Part 2 of Schedule 4, as added by Schedule 3 to the amending regulations, apply in relation to a custom-made medical device that is manufactured on or after 25 August 2020, where the request from the health professional is made on or after that day.
- (3) Item 2.14 of the table in Part 2 of Schedule 4, as added by Schedule 3 to the amending regulations, applies in relation to a patient-matched medical device if:
 - (a) it is manufactured on or after 25 August 2020 and before 1 November 2024; and
 - (b) before 25 August 2020, information was given to the Secretary under regulation 10.3 and the patient-matched medical device is covered by the description of the kinds of medical devices referred to in paragraph 10.3(1)(b) or (2)(c).

11.52 Personalised medical devices—classification rules

Applications and entries other than a transitional kind of medical device

- (1) Clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, applies on and after 25 August 2020 in relation to the following:
 - (a) an application for a kind of medical device to be included in the Register that is made on or after 25 August 2020;
 - (b) a kind of medical device that is included in the Register as a result of such an application.

Transitional kind of medical device

- (2) Subject to subregulations (3) and (5), clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, applies in relation to a transitional kind of medical device on and after 1 November 2024.
- (3) Clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, does not apply in relation to a transitional kind of medical device before the day applicable under subregulation (4) if:
 - (a) the person applies under the Act:
 - (i) on or after the inclusion day for the entry of the transitional kind of medical device; and
 - (ii) on or after 25 August 2020; and
 - (iii) before 1 November 2024;to have a kind (the **new kind**) of medical device included in the Register; and
 - (b) the person gives to the Secretary a notice under regulation 11.53 in relation to the transitional kind of medical device; and
 - (c) the unique product identifier of the devices of the new kind is the unique product identifier, or one of the unique product identifiers, stated in the notice.

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- (4) For the purposes of subregulation (3), the day is the day after the day on whichever of the following events occurs first:
- (a) the person withdraws the application mentioned in paragraph (3)(a);
 - (b) that application lapses under section 41FK of the Act;
 - (c) that application is finally determined.
- (5) If:
- (a) a person is required under regulation 11.53 to give a notice to the Secretary in relation to a transitional kind of medical device; and
 - (b) the person fails to give the notice in accordance with that regulation before the later of:
 - (i) 25 February 2021; and
 - (ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device;
- then clause 5.4 of Schedule 2, as substituted by Schedule 3 to the amending regulations, applies in relation to the transitional kind of medical device on and after the later of those days.

11.53 Secretary must be notified in relation to a transitional kind of medical device

- (1) For the purposes of subsection 41FN(5A) of the Act, a person must give to the Secretary a notice in accordance with subregulation (5) if:
- (a) a kind of medical device is included in the Register in relation to the person; and
 - (b) the kind of medical device so included is a transitional kind of medical device; and
 - (c) medical devices of that kind are medical devices that are covered by subregulation (2), (3) or (4).
- (2) This subregulation covers a medical device that is intended by the manufacturer to be used to record patient images that are to be used for either or both of the following:
- (a) the diagnosis or monitoring of a disease, injury or disability;
 - (b) the investigation of the anatomy or of a physiological process;
- where the images are to be acquired through a method that relies on energy outside the visible spectrum.
- (3) This subregulation covers a medical device that is an anatomical model (whether physical or virtual) that is intended by the manufacturer to be used for either or both of the following:
- (a) the diagnosis or monitoring of a disease, injury or disability;
 - (b) the investigation of the anatomy or of a physiological process.
- (4) This subregulation covers a programmed or programmable medical device, or software that is a medical device, that is intended by the manufacturer to be used to generate a virtual anatomical model that is to be used for either or both of the following:
- (a) the diagnosis or monitoring of a disease, injury or disability;
 - (b) the investigation of the anatomy or of a physiological process.
- (5) The notice must:

- (a) be in writing; and
- (b) state:
 - (i) the unique device number assigned to that kind of device under section 41FL of the Act; and
 - (ii) the unique product identifier given to each medical device (if any) of that kind that the person supplies in Australia; and
- (c) be given to the Secretary before the later of:
 - (i) 25 February 2021; and
 - (ii) the day occurring 2 months after the inclusion day for the entry of the transitional kind of medical device.

Subdivision E—IVD companion diagnostics

11.54 IVD companion diagnostics

Applications required to be audited

- (1) The amendment of paragraph 5.3(1)(j) by Schedule 4 to the amending regulations applies to applications made on or after 1 February 2020.

Classification and kind of medical device

- (2) Despite the amendments made by Schedule 4 to the amending regulations on 1 February 2020, until 1 July 2022 those amendments:
 - (a) do not affect the classification of a device covered by subregulation (3), (4) or (5); and
 - (b) do not affect whether such a device is of the same kind as another device.
- (3) This subregulation covers an IVD companion diagnostic that, immediately before 1 February 2020, was either a Class 4 in-house IVD medical device or an IVD medical device other than an in-house IVD medical device, and:
 - (a) was included in the Register; or
 - (b) was the subject of an application for inclusion in the Register that had not been finally determined.
- (4) This subregulation covers an IVD companion diagnostic that, immediately before 1 February 2020, was either a Class 4 in-house IVD medical device or an IVD medical device other than an in-house IVD medical device, that:
 - (a) was not included in the Register but was covered by a conformity assessment certificate having effect; or
 - (b) was proposed to be covered by a conformity assessment certificate for which an application had been made but not finally determined.
- (5) This subregulation covers an IVD companion diagnostic that, immediately before 1 February 2020, was:
 - (a) a Class 1 in-house IVD medical device; or
 - (b) a Class 2 in-house IVD medical device; or
 - (c) a Class 3 in-house IVD medical device.
- (6) Subregulation (2) does not prevent the making and determination on or after 1 February 2020 and before 1 July 2022 of an application for inclusion in the Register of a device covered by subregulation (3), (4) or (5) in accordance with these Regulations as amended by Schedule 4 to the amending regulations.

- (7) Paragraph (h) of item 1.5 of the table in Part 1 of Schedule 5 does not apply to an application described in subregulation (6) of this regulation (made within the period described in that subregulation).

Note: This means that an application described in subregulation (6) can pass the preliminary assessment without payment of any fee.

Therapeutic Goods Regulations 1990

2 In the appropriate position in Part 9

Insert:

Division 12—Application and transitional provisions relating to the Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019

Subdivision A—Definitions

69 Definitions

In this Division:

amending regulations means the *Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019*.

finally determined: an application is finally determined at the first time both the following conditions are met:

- (a) a decision has been made whether or not to grant the application;
- (b) there is no longer any possibility of a change in the outcome of the decision.

Subdivision B—Faecal microbiota transplant products

70 Faecal microbiota transplant products—Division 4 of Part 3-2A of the Act

Exemption

- (1) For the purposes of subsection 32CA(2) of the Act, faecal microbiota transplant products are exempt from the operation of Division 4 of Part 3-2A of the Act.
- (2) The exemption mentioned in subregulation (1) is subject to compliance with the condition that, if the sponsor of the faecal microbiota transplant products knows that particular information relating to an event or occurrence indicates that use of the products as intended by the sponsor may have an unintended harmful effect, the sponsor must give the information to the Secretary within the period specified by regulation 16AB.

When exemption ceases

- (3) Subregulation (1) ceases to have effect on 1 January 2021, subject to subregulations (4) and (5).
- (4) If a sponsor of faecal microbiota transplant products applies, on or before 31 December 2020, for inclusion of the products in the Register,

subregulation (1) ceases to have effect in relation to the products when the application is finally determined, lapses or is withdrawn, if that happens on or after 1 January 2021.

- (5) If a sponsor of faecal microbiota transplant products applies, on or before 31 December 2020, for an approval under section 32CK of the Act in relation to the products, subregulation (1) ceases to have effect in relation to the products when the application is finally determined or is withdrawn, if that happens on or after 1 January 2021.

71 Faecal microbiota transplant products—Part 3-3 of the Act

- (1) For the purposes of this regulation, a biological is a *transitional biological* if it is:
- (a) a faecal microbiota transplant product; and
 - (b) a biological other than a Class 1 biological.

Exemption

- (2) For the purposes of subsection 34(1) of the Act, transitional biologicals are exempt from the operation of Part 3-3 of the Act.

When exemption ceases

- (3) Subregulation (2) ceases to have effect on 1 January 2021, subject to subregulation (4).
- (4) If, on or before 31 December 2020, each person who carries out a step in the manufacture of transitional biologicals applies for a licence authorising the person to carry out the step on premises referred to in the application, subregulation (2) ceases to have effect in relation to the transitional biologicals produced by those persons carrying out the steps on those premises when the last of those applications is finally determined or is withdrawn, if that happens on or after 1 January 2021.

Subdivision C—Consumer medicine information documents

72 Consumer medicine information documents

- (1) Subject to this regulation, the amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations apply in relation to medicines supplied on and after 1 January 2021.

Transitional medicines

- (2) Subject to subregulation (3), the amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations do not apply in relation to supplies of a medicine of a kind (a *transitional medicine*) that immediately before 1 January 2021 was:
- (a) a registered good; or
 - (b) an exempt good under section 18 of the Act; or
 - (c) an exempt good under section 18A of the Act; or
 - (d) the subject of an approval or authority under section 19 of the Act; or
 - (e) the subject of an approval under section 19A of the Act.

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- (3) The amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations apply in relation to supplies of transitional medicines on and after 1 January 2026.

Medicines where applications not finally determined

- (4) Subject to subregulation (5), the amendments of regulations 9A and 9B and Schedules 12 and 13 made by Schedule 6 to the amending regulations do not apply in relation to supplies of a medicine of a kind (a **transitional application medicine**) while either of the following applies to the transitional application medicine:
- (a) it is the subject of an application for registration that was made before 1 January 2021 and that immediately before that date was not finally determined;
 - (b) it is included in the Register as a result of such an application.
- (5) The amendments made to regulations 9A and 9B, and Schedules 12 and 13 by Schedule 6 to the amending regulations apply in relation to a supply of a transitional application medicine:
- (a) if at a time before 1 January 2026 subregulation (4) ceases to apply in relation to the transitional application medicine—at that time; or
 - (b) in any other case—on and after 1 January 2026.

Subdivision D—Handling and testing of samples

73 Handling and testing of samples

The repeal and substitution of subregulation 23(2) made by Schedule 7 to the amending regulations, the amendment of paragraph 25(3)(c) made by that Schedule, subregulations 25(4) and (5) as added by that Schedule and the amendments of paragraph 27(2)(a) and of regulations 28, 29 and 30 made by that Schedule apply in relation to samples taken or delivered on or after 1 January 2020.

Subdivision E—Fee waivers and refunds for certain requests relating to prescription opioids

74 Fee waivers and refunds for certain requests relating to prescription opioids

- (1) The insertion of subregulations 45(7) to (9) by Schedule 8 to the amending regulations applies in relation to requests made on or after the commencement of those subregulations.
- (2) If, on or after 31 August 2019 and before the commencement of subregulations 45(7) to (9):
- (a) a person made a request (an **opioid reform request**) that:
 - (i) was made in relation to prescription opioids that were registered goods; and
 - (ii) was made under subsection 9D(2) or (3) of the Act; and
 - (iii) was made solely for an opioid reform purpose (see subregulation (3)) or solely for an opioid reform purpose and an associated variation of product information purpose (see subregulation (4)); and

- (b) the person paid the fee prescribed in Schedule 9 to these Regulations in relation to the request;
the Secretary must, on behalf of the Commonwealth, refund to the person an amount equal to the fee paid.
- (3) For the purposes of subregulation (2), an opioid reform request was made for an opioid reform purpose if it was made:
- (a) under subsection 9D(2) of the Act, to do either or both of the following:
 - (i) add a warning, or precaution, in relation to the goods that did not include any comparison of the goods with any other therapeutic goods by reference to quality, safety or efficacy;
 - (ii) reduce the class of persons for whom the goods were suitable; or
 - (b) under subsection 9D(3) of the Act, to introduce a smaller pack size in relation to the goods.
- (4) For the purposes of subregulation (2), an opioid reform request was made for an associated variation of product information purpose if:
- (a) the opioid reform request was made under subsection 9D(3) of the Act; and
 - (b) paragraphs 9D(3)(b) to (c) of the Act were satisfied in relation to the request; and
 - (c) the request was made for the purpose of varying product information in relation to the prescription opioids so that the product information would be in the form approved under section 7D of the Act in relation to the prescription opioids.

Subdivision F—Clinical trials

75 Clinical trials

- (1) These Regulations have effect as if a written assurance given before 1 January 2020 under paragraph 12AB(2)(a) that clinical trials would be conducted in accordance with the Practice Guidelines were, on and after 1 January 2020, a written assurance that clinical trials would be conducted in accordance with the Practice Guideline.
- (2) The amendment of subregulation 12AC(1) made by Part 2 of Schedule 9 to the amending regulations applies in relation to things done on or after 1 January 2020 in relation to a clinical trial that began before, on or after 1 January 2020.
- (3) The amendment of paragraph 12AD(a) made by Part 2 of Schedule 9 to the amending regulations applies in relation to uses on or after 1 January 2020 in relation to a clinical trial that began before, on or after 1 January 2020.
- (4) The amendment of Schedule 5A made by Part 2 of Schedule 9 to the amending regulations applies in relation to:
- (a) requests made on or after 1 January 2020 to give information acquired before, on or after 1 January 2020; and
 - (b) things mentioned in regulation 12AC done on or after 1 January 2020; in relation to a clinical trial that began before, on or after 1 January 2020.