



Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

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 28 October 2021

David Hurley
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health and Aged Care

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1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*.

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.	29 October 2021
2. Schedule 1, Part 1	25 November 2021.	25 November 2021
3. Schedule 1, Parts 2 and 3	The day after this instrument is registered.	29 October 2021
4. Schedule 1, Part 4	Immediately after the commencement of Schedule 1 to the <i>Therapeutic Goods Legislation Amendment (2019 Measures No. 1) Regulations 2019</i> .	25 November 2021
5. Schedule 1, Parts 5 and 6	The day after this instrument is registered.	29 October 2021
6. Schedule 1, Part 7	25 November 2021.	25 November 2021
7. Schedule 1, Parts 8 to 12	The day after this instrument is registered.	29 October 2021

Note: This table relates only to the provisions of this instrument as originally made.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 *Therapeutic Goods 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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—Amendments

Part 1—System or procedure packs

Therapeutic Goods (Medical Devices) Regulations 2002

1 Paragraph 3.10(3)(aa)

Repeal the paragraph, substitute:

- (aa) if one or more medicines, biologicals or other therapeutic goods are included in the system or procedure pack:
 - (i) if all of those medicines and biologicals are entered on the Register; and
 - (ii) if all of those other therapeutic goods are entered on the Register, or are covered by subregulation 12(1) of the *Therapeutic Goods Regulations 1990* to the extent that they are tampons, menstrual cups or disinfectants; and
 - (iii) if there has been no modification of the packaging of any of those medicines, biologicals or other therapeutic goods; and
 - (iv) if there has been no modification of any of those medicines, biologicals or other therapeutic goods; and

2 Paragraphs 3.10(3)(b) and (c)

Omit “for use”.

3 Subregulation 3.10(4)

Repeal the subregulation (including the note), substitute:

- (4) If a system or procedure pack is intended by the manufacturer to be supplied in a sterile state:
 - (a) the full quality assurance procedures (other than clause 1.6); or
 - (b) the production quality assurance procedures (other than clause 4.7);must also be applied to the system or procedure pack in relation to the aspects of the manufacturing process that relate to ensuring that the system or procedure pack is supplied and maintained in a sterile state.

Note: If a medicine is included in the system or procedure pack, the manufacturer of the system or procedure pack must ensure that the method to be used for sterilisation or re-sterilisation is appropriate or is in accordance with the approved indications of the medicine.

4 Paragraph 7.5(2)(e) of Schedule 3

Before “state”, insert “except in relation to a medical device covered by paragraph (ia)—”.

5 Paragraph 7.5(2)(e) of Schedule 3

Omit “evidence”.

6 Subparagraph 7.5(2)(e)(i) of Schedule 3

Repeal the subparagraph, substitute:

- (i) a conformity assessment document, a declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) for each medical

device in the system or procedure pack for which such a document, declaration or statement is required; and

7 Subparagraph 7.5(2)(e)(ii) of Schedule 3

Before “that”, insert “evidence”.

8 Paragraph 7.5(2)(g) of Schedule 3

Omit “for use specified by the manufacturers of those items”, substitute “of the medicine, biological or other therapeutic goods”.

9 Paragraph 7.5(2)(h) of Schedule 3

Repeal the paragraph, substitute:

- (h) state that the mutual compatibility of each medical device, medicine, biological or other therapeutic goods, and any other goods, in the system or procedure pack has been verified in accordance with:
 - (i) the instructions for use of each medical device included in the system or procedure pack, being the instructions for use provided by the manufacturer of the device; and
 - (ii) the approved indications of each medicine, biological and other therapeutic goods (if any) included in the system or procedure pack; and
- (ha) state that the manufacturer of the system or procedure pack has manufactured the system or procedure pack in accordance with the instructions referred to in subparagraph (h)(i) and the indications referred to in subparagraph (h)(ii); and

10 After paragraph 7.5(2)(i) of Schedule 3

Insert:

- (ia) if the manufacturer of the system or procedure pack has modified the packaging of any medical device included in the system or procedure pack or modified any medical device included in the system or procedure pack—state the matters covered by subclause (2A); and

11 Paragraph 7.5(2)(k) of Schedule 3

Repeal the paragraph, substitute:

- (k) if the system or procedure pack is intended by the manufacturer to be supplied in a sterile state—state that the full quality assurance procedures (other than clause 1.6), or the production quality assurance procedures (other than clause 4.7), have been applied to the system or procedure pack in accordance with:
 - (i) the instructions for use of each medical device included in the system or procedure pack, being the instructions for use provided by the manufacturer of the device; and
 - (ii) the approved indications of each medicine, biological and other therapeutic goods (if any) included in the system or procedure pack; and

12 After subclause 7.5(2) of Schedule 3

Insert:

- (2A) For the purposes of paragraph (2)(ia), the matters are the following:

Schedule 1 Amendments

Part 1 System or procedure packs

- (a) that the modification has not affected the quality, safety or performance of the medical device;
 - (b) if the modification has not been done in accordance with the instructions for use of the medical device provided by the manufacturer of the device—that the manufacturer of the system or procedure pack has:
 - (i) if a conformity assessment document, a declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) is required for the medical device—such a document, declaration or statement for the medical device, as affected by the modification; and
 - (ii) evidence that the medical device, as affected by the modification, complies with the applicable provisions of the essential principles.
- (2B) If the manufacturer of a system or procedure pack has modified the packaging of any medical device included in the system or procedure pack or modified any medical device included in the system or procedure pack:
- (a) the manufacturer of the system or procedure pack must ensure that the modification does not affect the quality, safety or performance of the medical device; and
 - (b) if the modification has not been done in accordance with the instructions for use of the medical device provided by the manufacturer of the device—the manufacturer of the system or procedure pack must have:
 - (i) if a conformity assessment document, a declaration of conformity under clause 6.6 or a statement under subclause 7.2(2) is required for the medical device—such a document, declaration or statement for the medical device, as affected by the modification; and
 - (ii) evidence that the medical device, as affected by the modification, complies with the applicable provisions of the essential principles.

13 Dictionary

Insert:

approved indications, of a medicine, biological or other therapeutic goods, means:

- (a) if the medicine, biological or other therapeutic goods are entered on the Register—the indications included in the Register in relation to the medicine, biological or other therapeutic goods; or
- (b) otherwise—the indications in relation to the medicine, biological or other therapeutic goods.

Note: For ***indications***, see subsection 3(1) of the Act.

Part 2—Reports about adverse events or occurrences for medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

14 At the end of subregulation 5.7(1)

Add:

Note: See also regulation 5.8A (which deals with the giving of a report after information is given within a period covered by paragraph (1)(a), (b) or (c) of this regulation).

15 After regulation 5.8

Insert:

5.8A Conditions applying automatically—giving of report about adverse events or occurrences (Act s 41FN)

- (1) For the purposes of subsection 41FN(5A) of the Act, if the person in relation to whom a kind of medical device is included in the Register gives information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the period covered by paragraph 5.7(1)(a), (b) or (c) of these Regulations, the person must give a written report to the Secretary in accordance with this regulation.
- (2) The person must give the report to the Secretary before the end of the period of 120 days beginning on the day the person gave that information to the Secretary.
- (3) The report must:
 - (a) deal with any updates to that information since that information was given; and
 - (b) set out details of the action the person has taken, or the manufacturer of the kind of medical device has taken, to investigate the event or other occurrence concerned; and
 - (c) set out details of the action the person has taken, or the manufacturer of the kind of medical device has taken, to alleviate the impact of the event or other occurrence concerned for patients or for users of the kind of medical device; and
 - (d) set out details of similar events or occurrences that have occurred in the last 3 years, in relation to the kind of medical device, of which the person is aware.

Part 3—Patient implant cards and patient information leaflets

Therapeutic Goods (Medical Devices) Regulations 2002

16 After Division 9.1 of Part 9

Insert:

Division 9.1A—Reduced fee for consent to import, supply or export implantable medical devices—patient implant cards and patient information leaflets

9.1AA Working out the reduced fee

(1) If:

- (a) an application is covered by paragraph (a) of item 1.15 of the table in Part 1 of Schedule 5; and
- (b) the application is made solely in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1;

the amount of the fee is not worked out in accordance with Part 1 of Schedule 5. Instead, the amount of the fee is \$30.

(2) If:

- (a) an application is covered by paragraph (b) of item 1.15 of the table in Part 1 of Schedule 5; and
- (b) the application is made solely in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1;

the amount of the fee is not worked out in accordance with Part 1 of Schedule 5. Instead, the amount of the fee is worked out in accordance with the following method statement:

Method statement

Step 1. Work out the number of separate entries in the Register in relation to the devices concerned.

Step 2. The amount of the fee is the number at step 1 multiplied by \$30.

17 Clause 13A of Schedule 1 (heading)

Repeal the heading, substitute:

13A Patient information about implantable medical devices or active implantable medical devices to be made available

18 Paragraph 13A.1(b) of Schedule 1

Omit “or connector”, substitute “, connector or similar article”.

19 Clause 13A.2 of Schedule 1 (heading)

Repeal the heading, substitute:

13A.2 Patient implant cards etc. for implantable devices

20 Subclause 13A.2(1) of Schedule 1

Repeal the subclause, substitute:

- (1) Either:
- (a) a card (a *patient implant card*) that includes the information covered by subclause (2) and that satisfies clause 13A.4 must be made available for provision to the patient concerned; or
 - (b) information covered by subclause (2) that is in electronic form and that satisfies clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.

21 Subclause 13A.2(2) of Schedule 1

Omit “The card must include the information mentioned in the following table”, substitute “The information covered by this subclause is the information in the following table”.

22 Subclause 13A.2(2) of Schedule 1 (table heading)

Repeal the heading, substitute:

Information to be made available for provision to patient

23 Subclause 13A.2(2) of Schedule 1 (table, heading to column headed “Information to be included”)

Repeal the heading, substitute:

Information

24 Clause 13A.3 of Schedule 1 (heading)

Repeal the heading, substitute:

13A.3 Patient information leaflets etc. for implantable devices

25 Subclause 13A.3(1) of Schedule 1

Repeal the subclause, substitute:

- (1) Either:
- (a) a leaflet (a *patient information leaflet*) that includes the information covered by subclauses (2) and (3) and that satisfies subclause (4) and clause 13A.4 must be made available for provision to the patient concerned; or
 - (b) information covered by subclauses (2) and (3) that is in electronic form and that satisfies subclause (4) and clause 13A.4 must be made available in a way that is readily accessible by the patient concerned.

26 Subclause 13A.3(2) of Schedule 1

Omit “The leaflet must include the following information”, substitute “The information covered by this subclause is the following information”.

27 Subclause 13A.3(3) of Schedule 1

Omit “In particular, the leaflet must include the information mentioned in the following table”, substitute “The information covered by this subclause is the information in the following table”.

28 Subclause 13A.3(3) of Schedule 1 (table heading)

Repeal the heading, substitute:

Information to be made available for provision to patient

29 Subclause 13A.3(3) of Schedule 1 (table, heading to column headed “Information to be included”)

Repeal the heading, substitute:

Information

30 Subclause 13A.3(4) of Schedule 1

Omit “The information in the leaflet”, substitute “The information covered by subclauses (2) and (3)”.

31 Clause 13A.4 of Schedule 1 (heading)

Repeal the heading, substitute:

13A.4 General requirements for information to be made available for patients

32 Subclause 13A.4(1) of Schedule 1

Omit “The information required by clause 13A.2 or 13A.3 to be included in a patient implant card or patient information leaflet”, substitute “The information covered by subclause 13A.2(2) or 13A.3(2) or (3)”.

33 Subclause 13A.4(2) of Schedule 1

Omit “number, letter, symbol, or letter or number in a symbol, used in a patient implant card or patient information leaflet”, substitute “number, letter or symbol, or letter or number in a symbol, that is part of the information covered by subclause 13A.2(2) or 13A.3(2) or (3)”.

34 Paragraph 13A.4(2)(b) of Schedule 1

Before “at least”, insert “if the number, letter or symbol, or letter or number in a symbol, is included in a patient implant card or patient information leaflet—”.

35 Part 1 of Schedule 5 (table item 1.15, column headed “Matter”, paragraph (a))

After “relating to”, insert “a medical device that is not included in the Register or to”.

36 Part 1 of Schedule 5 (table item 1.15, column headed “Amount (\$)”)

Before “500” (first occurring), insert “Subject to regulation 9.1AA,”.

37 Part 1 of Schedule 5 (table item 1.15, column headed “Amount (\$)”)

Before “500 for the first”, insert “Subject to regulation 9.1AA,”.

Part 4—Reclassification of medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

38 Subclause 3.1(1) of Schedule 2

After “surgically invasive medical device”, insert “or a medical device covered by clause 5.10 or 5.11”.

39 Subclause 3.1(2A) of Schedule 2

Repeal the subclause.

40 Subclause 3.1(4) of Schedule 2

Repeal the subclause.

41 Subclause 3.2(3A) of Schedule 2

After “If the device is”, insert “not a reusable surgical instrument and the device is”.

42 Subclause 3.4(4B) of Schedule 2

Repeal the subclause, substitute:

- (4B) If the device is intended by the manufacturer to be a motion-preserving device for the spine (such as a spinal disc replacement), the device is classified as Class III.

43 At the end of Part 5 of Schedule 2

Add:

5.10 Medical devices that administer medicines or biologicals by inhalation

If a medical 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.

5.11 Medical devices that are substances to be introduced into the body or applied to and absorbed by the skin

If a medical device is composed of substances, or combinations of substances, that are intended to be:

- (a) introduced into the human body through a body orifice; or
- (b) applied to and absorbed by the skin;

the device is classified as follows:

- (c) if the device is introduced into the nasal or oral cavity as far as the pharynx, or is applied to and absorbed by the skin, and achieves its intended purpose in that cavity or on the skin—Class IIa;

Schedule 1 Amendments

Part 4 Reclassification of medical devices

(d) in any other case—Class IIb.

Part 5—Medical devices assembled or adapted at point of care

Therapeutic Goods (Medical Devices) Regulations 2002

44 At the end of Part 9

Add:

Division 9.4—Other refunds or waivers of fees

9.9 Other refunds or waivers of fees

Refunds

- (1) For the purposes of paragraph 63(3)(b) of the Act, the Secretary must, on behalf of the Commonwealth, refund the fee covered by item 1.6A of the table in Part 1 of Schedule 5 if:
 - (a) the request referred to in that item was made on or after 21 August 2021 and before the commencement of this regulation; and
 - (b) that request was for revocation of the cancellation of an entry of a kind of medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument was in force before that commencement.

Waivers

- (2) For the purposes of paragraph 63(3)(b) of the Act, the Secretary must, on behalf of the Commonwealth, waive the fee covered by item 1.6A of the table in Part 1 of Schedule 5 if:
 - (a) the request referred to in that item is made on or after the commencement of this regulation and before the end of 31 December 2022; and
 - (b) that request is for revocation of the cancellation of an entry of a kind of medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time.
- (3) For the purposes of paragraph 63(3)(b) of the Act, the Secretary must, on behalf of the Commonwealth, waive the fee covered by item 1.5 of the table in Part 1 of Schedule 5 if:
 - (a) the application referred to in that item is made on or after the commencement of this regulation and before the end of 31 December 2022; and
 - (b) that application is for inclusion in the Register of a kind of medical device covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time; and
 - (c) the person making that application had made a request before the commencement of this regulation under paragraph 41GL(d) of the Act for cancellation of the entry of the kind of device that is the subject of that application.

Schedule 1 Amendments

Part 5 Medical devices assembled or adapted at point of care

45 Part 1 of Schedule 4 (after table item 1.3A)

Insert:

1.3B Medical device that is:

- (a) manufactured by a health professional or by a person acting under the written instructions of a health professional; and
- (b) manufactured from other medical devices that are included in the Register and are covered by item 3A, 3B, 3C, 3D or 3E of the table in Schedule 1 to the *Therapeutic Goods (Medical Devices—Specified Articles) Instrument 2020*, as that instrument is in force from time to time

Part 6—Patient-matched medical devices

Therapeutic Goods (Medical Devices) Regulations 2002

46 At the end of regulation 7.1

Add:

- (8) For a kind of medical device that is exempt under item 1.7 of the table in Part 1 of Schedule 4, the exemption, to the extent that it relates to a particular manufacturer of a patient-matched medical device, is subject to the condition that the exemption only has effect in relation to the first 5 patient-matched medical devices manufactured by the manufacturer in a financial year.

47 Part 1 of Schedule 4 (at the end of the table)

Add:

- 1.7 Patient-matched medical device

48 Part 2 of Schedule 4 (table item 2.14, column headed “Conditions”)

Omit “25 August 2021”, substitute “25 August 2022”.

Part 7—Surgical loan kits

Therapeutic Goods (Medical Devices) Regulations 2002

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

Add:

- 2.16 Medical device that is a surgical loan kit, where:
- (a) the kit is intended by its manufacturer to be supplied to hospitals in Australia; and
 - (b) the kit is intended by its manufacturer to be used in a surgical procedure; and
 - (c) the kit contains 2 or more reusable surgical instruments and the only other therapeutic goods (if any) in the kit are either or both of the following:
 - (i) one or more implantable medical devices;
 - (ii) one or more Class I medical devices; and
 - (d) each of the medical devices in the kit is included in the Register
- (a) The device must comply with the essential principles.
 - (b) The manufacturer of the device must apply the appropriate conformity assessment procedures (if any) at all times.
 - (c) The manufacturer of the device must, on request by the Secretary, provide the following information within 20 working days of receiving the request:
 - (i) whether the device complies with the essential principles;
 - (ii) whether the conformity assessment procedures (if any) have been applied to the device;
 - (iii) whether the device complies with every requirement (if any) relating to advertising applicable under Part 5-1 of the Act or the *Therapeutic Goods Regulations 1990*.
 - (d) The manufacturer of the device must, at all times, have available sufficient information to substantiate that the conformity assessment procedures (if any) have been applied to the device.
 - (e) The manufacturer of the device must allow an authorised person to do any of the following:
 - (i) enter, at any reasonable time, any premises at which the manufacturer manufactures the device;
 - (ii) inspect the premises and the device, and examine, take measurements of, conduct tests on or require tests to be conducted on the device or anything on those premises that relates to the device;
 - (iii) make any still or moving image or any recording of those premises or anything on those premises.
 - (f) If asked to do so by an authorised person, the manufacturer of the device must give to the person any documents relating to the device that the person requires and allow the person to copy the documents.
 - (g) The Secretary must not have directed that the supply of the device be stopped or should cease because the supply compromises public health and safety.
 - (h) The manufacturer or sponsor of the device must provide information of a kind mentioned in

subsection 41MP(2) or 41MPA(2) of the Act to the Secretary within the following periods:

- (i) if the information relates to an event or other occurrence that represents a serious threat to public health—48 hours after the manufacturer or sponsor becomes aware of the event or occurrence;
 - (ii) if the information relates to an event or other occurrence that led to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—10 days after the manufacturer or sponsor becomes aware of the event or occurrence;
 - (iii) if the information relates to an event or other occurrence a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the device, or another person—30 days after the manufacturer or sponsor becomes aware of the event or occurrence;
 - (iv) in any other case—60 days after the manufacturer or sponsor becomes aware of the information.
- (i) The person under whose name the device is or is to be supplied must keep records relating to the supply of the device by or on behalf of the person.
 - (j) The person under whose name the device is or is to be supplied must, on request by the Secretary, provide to the Secretary those records within 20 working days of receiving the request or a longer period agreed to by the Secretary.

Part 8—Nicotine vaping products

Therapeutic Goods (Medical Devices) Regulations 2002

50 Part 1 of Schedule 4 (table item 1.6, column headed “Kinds of medical devices”, subparagraph (a)(iii))

Before “the sponsor”, insert “the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or”.

51 Part 1 of Schedule 4 (table item 1.6, column headed “Kinds of medical devices”, subparagraph (b)(iii))

Before “the manufacturer”, insert “the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or”.

52 Part 1 of Schedule 4 (table item 1.6, column headed “Kinds of medical devices”, subparagraph (c)(iii))

Before “the intermediate supplier”, insert “the nicotine vaping product is covered by an item in the table in Schedule 5 or 5A to those regulations or”.

53 Part 1 of Schedule 4 (table item 1.6, column headed “Kinds of medical devices”, subparagraph (d)(iii))

After “the nicotine vaping product is”, insert “covered by an item in the table in Schedule 5 or 5A to those regulations or is”.

Therapeutic Goods Regulations 1990

54 Schedule 5 (after table item 5)

Insert:

- 5A a kit covered by subsection 7B(1) of the Act if:
- (a) the kit contains one or more nicotine vaping products; and
 - (b) the kit does not contain any other therapeutic goods

Part 9—Access to medicines in emergency situations

Therapeutic Goods Regulations 1990

55 Schedule 5A (after table item 1A)

Insert:

- 1B Therapeutic goods imported into Australia that are needed for dispensing as a medicine prescribed for persons who are seriously ill with a condition from which premature death is reasonably likely to occur in the absence of early treatment
- (a) the supply of the goods must be in accordance with such a prescription; and
 - (b) until the goods need to be so supplied, either or both of the following apply:
 - (i) the goods are kept in a warehouse or a properly secured area under the control of the sponsor;
 - (ii) the goods are kept at a hospital or other healthcare facility after being delivered to the hospital or facility by, or on behalf of, the sponsor; and
 - (c) the sponsor must:
 - (i) keep records relating to the source, and delivery, of the goods; and
 - (ii) if requested by the Secretary, give the records to the Secretary

Part 10—Consumer medicine information documents

Therapeutic Goods Regulations 1990

56 Subregulation 9A(1)

After “Schedule 10”, insert “and are included in the Register”.

57 Paragraph 9A(1A)(b)

Omit “are”.

58 After paragraph 9A(1A)(b)

Insert:

and (c) included in the Register;

59 Subregulation 72(2)

Repeal the subregulation, substitute:

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 registered good.

60 At the end of subregulation 72(3)

Add:

Note: Subregulations 9A(1) and (1A) cover supplies of therapeutic goods that are included in the Register.

61 Subregulation 72(5)

Repeal the subregulation, substitute:

- (5) 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 application medicines on and after 1 January 2026.

Note: Subregulations 9A(1) and (1A) cover supplies of therapeutic goods that are included in the Register.

Part 11—Other amendments

Therapeutic Goods (Medical Devices) Regulations 2002

62 Division 9.3 of Part 9 (heading)

Repeal the heading, substitute:

Division 9.3—Assessment fees and reductions or refunds of fees connected with applications for conformity assessment certificates

63 At the end of Division 9.3 of Part 9

Add:

9.8 Refund of fees—kinds of medical devices covered by former regulation 4.1

(1) If:

- (a) on or after 1 January 2019 and before the commencement of this regulation, a person made an application under section 41EB of the Act for a conformity assessment certificate in respect of a kind of medical device covered by regulation 4.1 (as in force immediately before 28 July 2021); and
- (b) on or after 1 January 2019 and before 1 December 2021, the person paid all or part of one or more of the following:
 - (i) the fee covered by item 1.1 of the table in Part 1 of Schedule 5 in connection with the application;
 - (ii) the fee covered by item 1.9, 1.9A, 1.10 or 1.10A of the table in Part 1 of Schedule 5 (to the extent that fee is in connection with the application);
 - (iii) the fee covered by item 1.11 or 1.12 of the table in Part 1 of Schedule 5 (to the extent that fee is in connection with the application);
 - (iv) the fee covered by clause 2.1 or 2.2 in Part 2 of Schedule 5 (to the extent that fee is in connection with the application); and
- (c) on or after 28 July 2021 and before 1 March 2022, the person, by notice in writing given to the Secretary, withdrew the application; and
- (d) the person withdrew the application before the Secretary had made a decision on the application; and
- (e) on or after 28 July 2021 and before 1 March 2022, the person requested the Secretary, in writing, for a refund of that fee; and
- (f) the request is accompanied by information that satisfies the requirements of subparagraphs 41FDB(2)(d)(i) and (ii) of the Act for that classification of medical device;

then, before the end of the applicable period, the Secretary must:

- (g) decide whether or not to refund any of that fee; and
- (h) if the Secretary decides to make a refund on behalf of the Commonwealth—decide the amount of that fee to be refunded.

- (2) In making a decision under paragraph (1)(g) or (h), the Secretary must take into account the extent of completion of the assessment or assessments, or of the testing, in connection with the application for the conformity assessment certificate, at the time the person withdrew the application.
- (3) Subregulation (2) does not limit the matters the Secretary may take into account.
- (4) For the purposes of this regulation, the *applicable period* is:
 - (a) if the person requested the refund on or after 28 July 2021 and before the commencement of this regulation—the period of 20 working days beginning on the day this regulation commences; or
 - (b) if the person requested the refund on or after the commencement of this regulation—the period of 20 working days beginning on the day the Secretary received the request.

64 Subregulation 10.7(1) (at the end of the definition of *initial decision*)

Add:

- ; (d) paragraph 9.8(1)(g) or (h).

65 Subregulation 11.29(2)

Omit “subregulation (3)”, substitute “subregulations (3) and (4A)”.

66 Subregulation 11.29(3)

Repeal the subregulation, substitute:

- (3) The amendment does not apply in relation to the pre-commencement entry before the day mentioned in subregulation (4) if:
 - (a) the person applies under the Act:
 - (i) on or after the inclusion day for the pre-commencement entry; and
 - (ii) on or after the commencement of Part 11 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*; and
 - (iii) before 1 December 2021;
 - to have a kind of medical device included in the Register; and
 - (b) that kind of medical device is surgical mesh (other than urogynaecological mesh).

67 After subregulation 11.29(4)

Insert:

- (4A) The amendment referred to in subregulation (2) does not apply in relation to the pre-commencement entry before the day applicable under subregulation (4B) if:
 - (a) the kind of medical device covered by that entry is surgical mesh (other than urogynaecological mesh); and
 - (b) the person has not made an application of the kind covered by subregulation (3) (as in force before or after the commencement of this subregulation) before 1 December 2021; and
 - (c) on or after 1 July 2020 and before 1 December 2021, the person made an application under section 41EB of the Act for a conformity assessment certificate in respect of a kind of medical device that is surgical mesh (other than urogynaecological mesh); and

- (d) the person has not withdrawn that application before 1 December 2021; and
 - (e) that application has not lapsed under section 41EG of the Act before 1 December 2021; and
 - (f) if the conformity assessment certificate was issued before 1 December 2021—the period of 6 months beginning on the day of the issue of the certificate has not ended before 1 December 2021.
- (4B) For the purposes of subregulation (4A), the day applicable under this subregulation is the later of 1 December 2021 and the day after the earliest of the following days:
- (a) the day the person withdraws the application mentioned in paragraph (4A)(c);
 - (b) the day that application lapses under section 41EG of the Act;
 - (c) in the case of a decision to refuse to issue the conformity assessment certificate and where there is no longer any possibility of a change in the outcome of that decision—the first day on which there is no longer that possibility;
 - (d) if the conformity assessment certificate was issued:
 - (i) if, at the end of the period of 6 months beginning on the day of the issue of the certificate, the person has not made an application under the Act to have the kind of medical device referred to in paragraph (4A)(c) included in the Register—the last day of that 6-month period; or
 - (ii) if, before the end of the period of 6 months beginning on the day of the issue of the certificate, the person has made an application under the Act to have the kind of medical device referred to in paragraph (4A)(c) included in the Register—the relevant day under subregulation (4C).
- (4C) For the purposes of subparagraph (4B)(d)(ii), the *relevant day* is:
- (a) the day the person withdraws the application mentioned in that subparagraph; or
 - (b) the day that application lapses under section 41FK of the Act; or
 - (c) the day on which that application is finally determined;
- whichever occurs first.

68 Subregulation 11.29(5)

Omit “The”, substitute “For the purposes of this regulation, an”.

69 Regulation 11.30

Repeal the regulation.

Therapeutic Goods Regulations 1990

70 After paragraph 3(3)(ba)

Insert:

- (baa) the *Therapeutic Goods Act 2019* (Qld);
- (bab) the *Therapeutic Goods Regulation 2021* (Qld);

71 Subregulation 12B(1B) (table item 1)

Repeal the item.

72 Subregulation 12B(1B) (after table item 4)

Insert:

4A	argipressin	injection	intravenous	to increase blood pressure in adults with vasodilatory shock who remain hypotensive despite fluids and catecholamines
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73 Subregulation 12B(1B) (after table item 26)

Insert:

26A	disulfiram	tablet	oral	deterrent to alcohol consumption
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74 Subregulation 12B(1B) (after table item 30)

Insert:

30A	famotidine	injection	intravenous	prevention and management of hypersensitivity reactions to chemotherapy
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75 Subregulation 12B(1B) (after table item 40)

Insert:

40A	iloprost	injection	intravenous infusion	(a) treatment of patients with severe disabling Raynaud's phenomenon; or (b) treatment of peripheral ischaemia
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76 Subregulation 12B(1B) (after table item 42)

Insert:

42AA	interferon alpha-2b	eye drops	ophthalmic	treatment of ocular surface squamous neoplasia
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77 Subregulation 12B(1B) (after table item 45)

Insert:

45A	lifitegrast	eye drops	topical	treatment of dry eye disease
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78 Subregulation 12B(1B) (after table item 46)

Insert:

46A	lutetium-177 (Lu 177) dotatate	injection	intravenous	treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs)
46B	lutetium-177 (Lu 177) Prostate Specific Membrane Antigen	injection	intravenous	treatment of metastatic castration-resistant prostate cancer

(PSMA)

79 Subregulation 12B(1B) (after table item 58)

Insert:

58A	nifedipine	immediate release tablet	oral	(a) treatment of preterm labour; or (b) treatment of pre-eclampsia
58B	nifedipine	capsule	oral	(a) treatment of preterm labour; or (b) treatment of pre-eclampsia

80 Subregulation 12B(1B) (after table item 63)

Insert:

63A	progesterone	injection	subcutaneous	treatment of progesterone deficiency
63B	progesterone in oil	injection	intramuscular	treatment of progesterone deficiency

81 Subregulation 12B(1B) (after table item 72)

Insert:

72A	Technetium-99m (99m Tc) prostate specific membrane antigen (PSMA)	injection	intravenous	prostate cancer imaging study
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82 After subregulation 12B(1B)

Insert:

- (1C) For the purposes of subsection 19(6) of the Act, paragraph 19(6)(aa) of the Act does not apply if the supply is of a medicine by the medical practitioner to a patient of that practitioner, where:
- (a) the circumstances specified in column 2 of an item in the following table exist in relation to the medicine; and
 - (b) the medicine is in the dosage form specified in column 3 of that item; and
 - (c) the medicine is to be administered by the route specified in column 4 of that item; and
 - (d) the supply is for the indication specified in column 5 of that item.

Specified therapeutic goods

Column 1	Column 2	Column 3	Column 4	Column 5
Item	Circumstances	Dosage form	Route of administration	Indication
1	(a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and (b) any cannabinoids, other than cannabidiol, in the	liquid	oral	(a) treatment of refractory chronic pain in adult patients; or (b) treatment of refractory anxiety in adult patients

Schedule 1 Amendments
Part 11 Other amendments

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Circumstances	Dosage form	Route of administration	Indication
	<p>medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and</p> <p>(c) the medicine contains no other active ingredients</p>			
2	<p>(a) cannabidiol comprises 98% or more of the total cannabinoid content of the medicine; and</p> <p>(b) any cannabinoids, other than cannabidiol, in the medicine are only those naturally found in cannabis and comprise 2% or less of the total cannabinoid content of the medicine; and</p> <p>(c) the medicine contains no other active ingredients</p>	capsule	oral	<p>(a) treatment of refractory chronic pain in adult patients; or</p> <p>(b) treatment of refractory anxiety in adult patients</p>
3	<p>(a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and</p> <p>(b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and</p> <p>(c) the medicine contains no other active ingredients</p>	liquid	oral	<p>(a) treatment of refractory chronic pain in adult patients; or</p> <p>(b) treatment of refractory anxiety in adult patients</p>
4	<p>(a) cannabidiol derived from cannabis comprises 60% or more and less than 98% of the total cannabinoid content of the medicine; and</p> <p>(b) other cannabinoids (including</p>	capsule	oral	<p>(a) treatment of refractory chronic pain in adult patients; or</p> <p>(b) treatment of refractory anxiety in adult patients</p>

Specified therapeutic goods				
Column 1	Column 2	Column 3	Column 4	Column 5
Item	Circumstances	Dosage form	Route of administration	Indication
	<p>tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and</p> <p>(c) the medicine contains no other active ingredients</p>			
5	<p>(a) cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; and</p> <p>(b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and</p> <p>(c) the medicine contains no other active ingredients</p>	liquid	oral	treatment of refractory chronic pain in adult patients
6	<p>(a) cannabidiol derived from cannabis comprises 40% or more and less than 60% of the total cannabinoid content of the medicine; and</p> <p>(b) other cannabinoids (including tetrahydrocannabinol) derived from cannabis comprise the remaining cannabinoid content of the medicine; and</p> <p>(c) the medicine contains no other active ingredients</p>	capsule	oral	treatment of refractory chronic pain in adult patients

Part 12—Application and transitional provisions

Therapeutic Goods (Medical Devices) Regulations 2002

83 Regulation 11.39 (column 1 of item 3 of the table in the definition of *transitional medical device*)

Omit “subclause 3.1(2A)”, substitute “clause 5.10”.

84 Regulation 11.39 (column 1 of item 4 of the table in the definition of *transitional medical device*)

Omit “subclause 3.1(4)”, substitute “clause 5.11”.

85 Subregulations 11.40(1), (2), (3) and (5)

After “amending regulations”, insert “, and the amendments made by Part 4 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*,”.

86 In the appropriate position in Part 11

Insert:

Division 11.13—Application, saving and transitional provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

11.59 System or procedure packs

Applications and entries other than a transitional kind of medical device

- (1) The amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply 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 November 2021;
 - (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) The amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to a transitional kind of medical device on and after 25 November 2025.

Exempt devices

- (3) The amendments made by Part 1 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, to the extent the amendments relate to a system or procedure pack covered by an item in Part 1 of Schedule 4, or by column 2 of an item in Part 2 of Schedule 4, to these Regulations, apply in relation to a system or procedure pack that is manufactured on or after 25 November 2025.

Definitions

- (4) In this regulation:

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 that was made before 25 November 2021 (whether the inclusion day for the entry of that kind of medical device occurred before, on or after that day).

11.60 Reports about adverse events or occurrences for medical devices

Subregulation 5.8A(1), as inserted by Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to information of a kind mentioned in subsection 41MP(2) or 41MPA(2) of the Act that is given to the Secretary on or after the commencement of that Part.

11.61 Patient implant cards and patient information leaflets

- (1) The amendments of Part 9 and of item 1.15 of the table in Part 1 of Schedule 5 made by Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to an application for consent that is made on or after the commencement of those amendments.
- (2) The amendments of clauses 13A.1 to 13A.4 of Schedule 1 made by Part 3 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to an implantable medical device, or an active implantable medical device, that is imported, supplied or exported on or after the commencement of that Part.
- (3) If:
 - (a) on or after 1 January 2021 and before the commencement of this regulation, a person made an application of a kind covered by paragraph (a) or (b) of item 1.15 of the table in Part 1 of Schedule 5 (as that item was in force before that commencement); and
 - (b) the application was made solely in relation to the application of either or both of clauses 13A.2 and 13A.3 of Schedule 1 (as those clauses were in force before that commencement); and
 - (c) on or after 1 January 2021 and before the commencement of this regulation, the person paid the fee applicable in relation to the application under item 1.15 of the table in Part 1 of Schedule 5 (as that item was in force before that commencement);

the Secretary must, on behalf of the Commonwealth, refund to the person the difference between the fee paid and the fee that would have been applicable in relation to the application under regulation 9.1AA if the application had been made on the day on which this regulation commences.

11.62 Medical devices assembled or adapted at point of care

Item 1.3B of the table in Part 1 of Schedule 4, as inserted by Part 5 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3)*

Regulations 2021, applies in relation to a medical device that is manufactured on or after the commencement of that item.

11.63 Patient-matched medical devices

Subregulation 7.1(8) and item 1.7 of Part 1 of Schedule 4, as added by Part 6 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, apply in relation to patient-matched medical devices manufactured on or after the commencement of that item in the following:

- (a) the financial year in which that item commences;
- (b) each later financial year.

11.64 Surgical loan kits

The amendment made by Part 7 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies on and after the commencement of that Part in relation to a surgical loan kit manufactured before, on or after that commencement.

11.65 Nicotine vaping products

- (1) The amendment of subparagraph (a)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack imported into Australia on or after the commencement of that amendment.
- (2) The amendment of subparagraph (b)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack manufactured on or after the commencement of that amendment.
- (3) The amendment of subparagraph (c)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack supplied on or after the commencement of that amendment, where that system or procedure pack was imported or manufactured on or after that commencement.
- (4) The amendment of subparagraph (d)(iii) of item 1.6 of the table in Part 1 of Schedule 4 made by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* applies in relation to a system or procedure pack supplied on or after the commencement of that amendment, where that system or procedure pack was imported or manufactured on or after that commencement.

11.66 Surgical mesh

Regulations 11.29 and 11.30, as in force immediately before the commencement of Part 11 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, continue to apply on and after that commencement in relation to an application referred to in paragraph 11.29(3)(a) (as so in force) that was made before that commencement.

Therapeutic Goods Regulations 1990

87 In the appropriate position in Part 9

Insert:

Division 16—Application provisions relating to the Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021

80 Nicotine vaping products

Item 5A of the table in Schedule 5, as inserted by Part 8 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to kits manufactured on or after the commencement of that Part.

81 Access to medicines in emergency situations

Item 1B of the table in Schedule 5A, as inserted by Part 9 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021*, applies in relation to therapeutic goods imported into Australia on or after the commencement of that Part.

82 Consumer medicine information documents

The amendments of regulation 9A (except the amendment of paragraph 9A(1A)(b)) made by Part 10 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to supplies of therapeutic goods on or after the commencement of that Part (whether the goods were included in the Register before, on or after that commencement).

83 Approving supply of therapeutic goods under authorised prescriber scheme

The amendments of regulation 12B made by Part 11 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2021 Measures No. 3) Regulations 2021* apply in relation to an authority given under subsection 19(5) of the Act on or after the commencement of that Part.