

2019-2020

The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

Presented and read a first time

**Therapeutic Goods Amendment (2020
Measures No. 1) Bill 2020**

No. , 2020

(Health)

A Bill for an Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

Contents

1	Short title.....	1
2	Commencement.....	1
3	Schedules.....	2
Schedule 1—Medical devices		3
Part 1—Medical device definitions		3
<i>Therapeutic Goods Act 1989</i>		3
Part 2—Basis of certification of conformity assessment procedures		5
<i>Therapeutic Goods Act 1989</i>		5
Part 3—Cancellation of entries of kinds of medical devices from the Register		6
<i>Therapeutic Goods Act 1989</i>		6
Part 4—Medical device standards and conformity assessment standards		7
<i>Therapeutic Goods Act 1989</i>		7
Schedule 2—Scientific advice about quality, safety and efficacy of medicine		8
<i>Therapeutic Goods Act 1989</i>		8
Schedule 3—Variations to approved clinical trials		11
<i>Therapeutic Goods Act 1989</i>		11
Schedule 4—Preliminary assessment of applications for variation of permissible ingredients determination		15
<i>Therapeutic Goods Act 1989</i>		15
Schedule 5—Approving supply of therapeutic goods under authorised prescriber scheme		20
<i>Therapeutic Goods Act 1989</i>		20
Schedule 6—Removal of offences for person claiming to be able to arrange supply of therapeutic goods		22
<i>Therapeutic Goods Act 1989</i>		22

Schedule 7—Conditions of registration or listing of therapeutic goods	23
<i>Therapeutic Goods Act 1989</i>	23
Schedule 8—Changes to provisionally registered medicine	24
<i>Therapeutic Goods Act 1989</i>	24
Schedule 9—Data protection for certain listed medicine	29
<i>Therapeutic Goods Act 1989</i>	29
Schedule 10—Other amendments	31
<i>Patents Act 1990</i>	31
<i>Therapeutic Goods Act 1989</i>	31

A Bill for an Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

The Parliament of Australia enacts:

1 Short title

This Act is the *Therapeutic Goods Amendment (2020 Measures No. 1) Act 2020*.

2 Commencement

- (1) Each provision of this Act 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 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	
2. Schedule 1, Part 1	The later of: (a) 25 August 2020; and (b) the 28th day after this Act receives the Royal Assent.	
3. Schedule 1, Parts 2 to 4	The day after this Act receives the Royal Assent.	
4. Schedules 2 to 4	The 28th day after this Act receives the Royal Assent.	
5. Schedules 5 to 10	The day after this Act receives the Royal Assent.	

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

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

3 Schedules

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

Schedule 1—Medical devices

Part 1—Medical device definitions

Therapeutic Goods Act 1989

1 Subsection 3(1) (definition of accessory)

After “enable”, insert “or assist”.

2 Paragraph 7B(1)(b)

Omit “or a system or procedure pack”.

3 Paragraph 41BD(1)(a)

After “appliance,”, insert “software, implant, reagent,”.

4 Subparagraph 41BD(1)(a)(i)

After “monitoring,”, insert “prediction, prognosis,”.

5 Subparagraph 41BD(1)(a)(iii)

Omit “physiological process”, substitute “physiological or pathological process or state”.

6 Subparagraph 41BD(1)(a)(iv)

After “control”, insert “or support”.

7 After subparagraph 41BD(1)(a)(iv)

Insert:

- (v) in vitro examination of a specimen derived from the human body for a specific medical purpose;

8 Paragraph 41BD(1)(aa)

After “appliance,”, insert “software, implant, reagent,”.

9 Paragraph 41BD(1)(ab)

After “appliance,”, insert “software, implant, reagent,”.

10 Paragraph 41BD(1)(ab)

After “appliances,”, insert “software, implants, reagents,”.

11 Paragraph 41BD(1)(b)

After “appliance,”, insert “software, implant, reagent,”.

12 After paragraph 41BD(1)(b)

Insert:

; or (c) a system or procedure pack.

13 Subsection 41BD(2)

After “appliance,”, insert “software, implant, reagent,”.

14 Subsection 41BD(2A)

After “appliance,”, insert “software, implant, reagent,”.

15 Subsection 41BD(2B)

After “appliances,”, insert “software, implants, reagents,”.

16 Subsection 41BD(3)

After “appliance,”, insert “software, implant, reagent,”.

17 Subsection 41BD(3)

After “appliances,”, insert “software, implants, reagents,”.

18 Section 41BF

Repeal the section, substitute:

41BF System or procedure packs

Two or more goods (including at least one medical device) are a *system or procedure pack* if:

- (a) all of the goods are to be interconnected or combined for use in a medical or surgical procedure; or
- (b) all of the goods are packaged together for use in a medical or surgical procedure.

Part 2—Basis of certification of conformity assessment procedures

Therapeutic Goods Act 1989

19 Section 41FDA

Before “When”, insert “(1)”.

20 At the end of section 41FDA

Add:

- (2) However, subsection (1) does not apply if devices of the kind in question are class I medical devices (within the meaning of regulations made for the purposes of this Chapter).

21 Application provision

The amendments made by this Part apply in relation to an application made under section 41FC of the *Therapeutic Goods Act 1989* on or after the commencement of this item.

Part 3—Cancellation of entries of kinds of medical devices from the Register

Therapeutic Goods Act 1989

22 After paragraph 41GL(c)

Insert:

(ca) the kind of medical device is covered by an exemption under paragraph 41HA(1)(b); or

23 Application provision

The amendment made by this Part applies in relation to a kind of medical device included in the Register before, on or after the commencement of this item.

Part 4—Medical device standards and conformity assessment standards

Therapeutic Goods Act 1989

24 At the end of section 41CB

Add:

- (3) Despite subsection 14(2) of the *Legislation Act 2003*, an order under subsection (1) of this section, or a variation of such an order, may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

25 At the end of section 41DC

Add:

- (4) Despite subsection 14(2) of the *Legislation Act 2003*, an order under subsection (1) of this section, or a variation of such an order, may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in an instrument or other writing as in force or existing from time to time.

Schedule 2—Scientific advice about quality, safety and efficacy of medicine

Therapeutic Goods Act 1989

1 After Division 1A of Part 3-2

Insert:

Division 1B—Scientific advice about aspects of quality, safety or efficacy of medicine

22G Scientific advice about aspects of quality, safety or efficacy of medicine

Requests about aspects of the quality of medicine

- (1) A person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the quality of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established.
- (2) Each request under subsection (1) must relate only to one aspect of the quality of the medicine.

Requests about aspects of the safety of medicine

- (3) A person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the safety of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established.
- (4) Each request under subsection (3) must relate only to one aspect of the safety of the medicine.

Requests about aspects of the efficacy of medicine

- (5) A person may request the Secretary for advice about whether, if the person were to make an application under section 23 for registration of a medicine, a prescribed aspect of the efficacy of the medicine, for the purposes identified by the person as purposes for which the medicine may be used, has been satisfactorily established.
- (6) Each request under subsection (5) must relate only to one aspect of the efficacy of the medicine.

Secretary must give advice

- (7) The Secretary must give advice in response to a request under this section that is made in accordance with this section.

How request is to be made

- (8) A request under this section:
 - (a) must be made in accordance with a form approved, in writing, by the Secretary; and
 - (b) must be accompanied by the fee prescribed by the regulations; and
 - (c) may be accompanied by any information or documents the person making the request considers appropriate.
- (9) An approval of a form may require or permit a request, information or a document to be given in accordance with specified software requirements:
 - (a) on a specified kind of data processing device; or
 - (b) by way of a specified kind of electronic transmission.

2 After subsection 25(2)

Insert:

- (2AA) If:
 - (a) the applicant is applying for the registration of a medicine; and
 - (b) the Secretary has given the applicant or any other person advice under section 22G in relation to the medicine;

the Secretary must have regard to the advice in evaluating the medicine under this section.

(2AB) Subsection (2AA) does not limit the matters the Secretary may take into account in evaluating the medicine under this section.

3 Before paragraph 60(1A)(aa)

Insert:

(aaa) the giving of advice under section 22G;

Schedule 3—Variations to approved clinical trials

Therapeutic Goods Act 1989

1 At the end of subsection 19(1)

Add:

Note: For variation of an approval for use of the kind referred to in paragraph (1)(b), see subsection (4B).

2 Subparagraph 19(2)(b)(i)

Repeal the subparagraph, substitute:

- (i) be in a form (if any) approved, in writing, by the Secretary; and

3 After subsection 19(4A)

Insert:

(4B) If:

- (a) the Secretary grants an approval to a person under subsection (1) for use of the kind referred to in paragraph (1)(b); and
- (b) the person requests the Secretary to do either or both of the following:
 - (i) vary the therapeutic goods specified in the approval;
 - (ii) vary the conditions imposed under subsection (1) on the approval; and
- (c) the request is in a form (if any) approved, in writing, by the Secretary; and
- (d) the request is accompanied by such information relating to the therapeutic goods as is required by the Secretary; and
- (e) the request is accompanied by the fee prescribed by the regulations;

the Secretary must, by notice in writing, vary or refuse to vary the approval. Any variation may be different than the variation requested and may involve imposing new conditions on the approval or varying or removing existing conditions.

- (4C) The Secretary must notify the person making the request under subsection (4B) of:
- (a) the Secretary's decision on the request; and
 - (b) for a decision to vary the approval in a way that is different than the variation requested or a decision to refuse to vary the approval—the reasons for the decision.
- (4D) A variation under subsection (4B) takes effect at the time the Secretary notifies the person under subsection (4C) of the variation.

4 At the end of subsection 32CK(1)

Add:

Note: For variation of an approval for use of the kind referred to in paragraph (1)(e), see subsection (9A).

5 Paragraph 32CK(4)(b)

Repeal the paragraph, substitute:

- (b) be in a form (if any) approved, in writing, by the Secretary; and

6 After subsection 32CK(9)

Insert:

Varying approval for use solely for experimental purposes in humans

- (9A) If:
- (a) the Secretary grants an approval to a person under subsection (1) for use of the kind referred to in paragraph (1)(e); and
 - (b) the person requests the Secretary to do either or both of the following:
 - (i) vary the biological specified in the approval;
 - (ii) vary the conditions imposed under subsection (6) on the approval; and
 - (c) the request is in a form (if any) approved, in writing, by the Secretary; and
 - (d) the request is accompanied by such information relating to the biological as is required by the Secretary; and

- (e) the request is accompanied by the fee prescribed by the regulations;
- the Secretary must, by notice in writing, vary or refuse to vary the approval. Any variation may be different than the variation requested and may involve imposing new conditions on the approval or varying or removing existing conditions.
- (9B) The Secretary must notify the person making the request under subsection (9A) of:
 - (a) the Secretary’s decision on the request; and
 - (b) for a decision to vary the approval in a way that is different than the variation requested or a decision to refuse to vary the approval—the reasons for the decision.
 - (9C) A variation under subsection (9A) takes effect at the time the Secretary notifies the person under subsection (9B) of the variation.

7 At the end of subsection 41HB(1)

Add:

Note: For variation of an approval for use of the kind referred to in paragraph (1)(e), see subsection (8).

8 Paragraph 41HB(5)(a)

Repeal the paragraph, substitute:

- (a) be in a form (if any) approved, in writing, by the Secretary; and

9 At the end of section 41HB

Add:

Varying approval for use solely for experimental purposes in humans

- (8) If:
 - (a) the Secretary grants an approval to a person under subsection (1) for use of the kind referred to in paragraph (1)(e); and
 - (b) the person requests the Secretary to do either or both of the following:

- (i) vary the medical device or kind of medical device specified in the approval;
 - (ii) vary the conditions imposed under subsection (2) on the approval; and
 - (c) the request is in a form (if any) approved, in writing, by the Secretary; and
 - (d) the request is accompanied by such information relating to the medical device or kind of medical device as is required by the Secretary; and
 - (e) the request is accompanied by the fee prescribed by the regulations;
- the Secretary must, by notice in writing, vary or refuse to vary the approval. Any variation may be different than the variation requested and may involve imposing new conditions on the approval or varying or removing existing conditions.
- (9) The Secretary must notify the person making the request under subsection (8) of:
 - (a) the Secretary's decision on the request; and
 - (b) for a decision to vary the approval in a way that is different than the variation requested or a decision to refuse to vary the approval—the reasons for the decision.
 - (10) A variation under subsection (8) takes effect at the time the Secretary notifies the person under subsection (9) of the variation.

10 Application provisions

- (1) Paragraph 19(4B)(a) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to an approval granted before, on or after the commencement of this item.
- (2) Paragraph 32CK(9A)(a) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to an approval granted before, on or after the commencement of this item.
- (3) Paragraph 41HB(8)(a) of the *Therapeutic Goods Act 1989*, as added by this Schedule, applies in relation to an approval granted before, on or after the commencement of this item.

Schedule 4—Preliminary assessment of applications for variation of permissible ingredients determination

Therapeutic Goods Act 1989

1 Subsection 3(1) (after paragraph (b) of the definition of *passed preliminary assessment*)

Insert:

- (ba) when used in relation to a section 26BD application—has the meaning given by subsection 26BD(4); and

2 After section 26BC

Insert:

26BD Requirements relating to an application for variation of a section 26BB determination

- (1) A person may make an application to the Secretary for a recommendation by the Secretary that the Minister vary a section 26BB determination.
- (2) If such an application is made, the Secretary must carry out an assessment of whether the requirements set out in subsection (3) have been met in relation to the application.
- (3) The requirements are as follows:
 - (a) the application must be made in accordance with a form approved, in writing, by the Secretary;
 - (b) the application must set out the recommendation sought;
 - (c) the prescribed application fee must be paid;
 - (d) the application must be delivered to an office of the Department specified in the form;
 - (e) the application must be accompanied by information that is:
 - (i) of a kind determined under subsection (8); and
 - (ii) in a form determined under subsection (9).

Passing preliminary assessment

- (4) An application **passes preliminary assessment** if the Secretary:
 - (a) has carried out an assessment, under subsection (2), in relation to the application; and
 - (b) is satisfied that the requirements set out in subsection (3) have been met in relation to the application.
- (5) If the application has passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.
- (6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of forms etc.

- (7) An approval of a form mentioned in paragraph (3)(a) may require or permit an application or information to be given in accordance with specified software requirements:
 - (a) on a specified kind of data processing device; or
 - (b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

- (8) The Secretary may, by legislative instrument, determine a kind of information for the purposes of subparagraph (3)(e)(i).
- (9) The Secretary may, by legislative instrument, determine a form of information for the purposes of subparagraph (3)(e)(ii).

26BDA Lapsing of application for variation of a section 26BB determination

If an application made under subsection 26BD(1) has passed preliminary assessment, the application lapses if:

- (a) the application contains information that is inaccurate or misleading in a material particular; or
- (b) information given to the Secretary by, or on behalf of, the applicant in connection with the application is inaccurate or misleading in a material particular.

3 Section 26BE (heading)

Repeal the heading, substitute:

**26BE Evaluation of whether to make recommendation for variation
of a section 26BB determination**

4 Subsections 26BE(1) to (2B)

Repeal the subsections.

5 Paragraph 26BE(3)(a)

Repeal the paragraph, substitute:

- (a) an application is made under subsection 26BD(1) for a recommendation by the Secretary that the Minister vary a section 26BB determination; and
- (aa) the application has passed preliminary assessment; and

6 Paragraph 26BE(3)(c)

Omit “subsection (2A)”, substitute “subsection (3A)”.

7 After subsection 26BE(3)

Insert:

- (3A) The Secretary may, by written notice given to a person who has made an application under subsection 26BD(1), require the person to:
 - (a) give the Secretary such further information in connection with the application as is specified in the notice; and
 - (b) do so within such reasonable period as is specified in the notice.

8 Subsection 26BE(5B) (heading)

Omit “*application*”, substitute “*evaluation*”.

9 Paragraph 26BE(5B)(a)

Repeal the paragraph, substitute:

- (a) an evaluation fee is prescribed for the purposes of paragraph (3)(b); and

10 Paragraph 26BE(5B)(c)

Omit “subsection (1)”, substitute “subsection 26BD(1)”.

11 Subsection 26BE(5B)

Omit “the application fee”, substitute “the evaluation fee”.

12 Paragraph 26BE(5C)(b)

Omit “subsection (1)”, substitute “subsection 26BD(1)”.

13 Subsection 26BE(9)

Repeal the subsection, substitute:

Information may be given electronically

- (9) A notice mentioned in subsection (3A) may require or permit information to be given in accordance with specified software requirements:
- (a) on a specified kind of data processing device; or
 - (b) by way of a specified kind of electronic transmission.

14 Paragraph 60(1A)(aa)

After “23B,”, insert “26BD,”.

15 Subsection 60(2B)

Omit “subsection 26BE(1)”, substitute “subsection 26BD(1)”.

16 Application, saving and transitional provisions

- (1) The amendments made by this Schedule apply in relation to an application made under subsection 26BD(1) of the *Therapeutic Goods Act 1989* on or after the commencement of this item.
- (2) Section 26BE and subsection 60(2B) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continue to apply on and after that commencement in relation to an application made under subsection 26BE(1) of that Act before that commencement.
- (3) An approved form that was in effect immediately before the commencement of this item for the purposes of paragraph 26BE(2)(a)

of the *Therapeutic Goods Act 1989* continues in force on and after that commencement as if it were an approved form in effect for the purposes of paragraph 26BD(3)(a) of that Act.

Schedule 5—Approving supply of therapeutic goods under authorised prescriber scheme

Therapeutic Goods Act 1989

1 Subsection 19(6)

Omit “exceptional”.

2 Subsection 32CM(4)

Omit “exceptional”.

3 Subsection 41HC(4)

Omit “exceptional”.

4 Application and transitional provisions

- (1) The amendment of subsection 19(6) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an authority given under subsection 19(5) of that Act on or after the commencement of this item.
 - (2) Regulations made for the purposes of subsection 19(6) of the *Therapeutic Goods Act 1989* that are in force immediately before the commencement of this item are taken, on and after that commencement, to have been made for the purposes of that subsection as amended by this Schedule.
 - (3) The amendment of subsection 32CM(4) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an authority given under subsection 32CM(1) of that Act on or after the commencement of this item.
 - (4) Regulations made for the purposes of subsection 32CM(4) of the *Therapeutic Goods Act 1989* that are in force immediately before the commencement of this item are taken, on and after that commencement, to have been made for the purposes of that subsection as amended by this Schedule.
 - (5) The amendment of subsection 41HC(4) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an authority given
-

under subsection 41HC(1) of that Act on or after the commencement of this item.

- (6) Regulations made for the purposes of subsection 41HC(4) of the *Therapeutic Goods Act 1989* that are in force immediately before the commencement of this item are taken, on and after that commencement, to have been made for the purposes of that subsection as amended by this Schedule.

Schedule 6—Removal of offences for person claiming to be able to arrange supply of therapeutic goods

Therapeutic Goods Act 1989

1 Subsection 22(6)

Repeal the subsection.

2 Subsection 32BJ(4)

Repeal the subsection.

3 Section 41MM

Repeal the section.

4 Saving provisions

- (1) Despite the repeal of subsection 22(6) of the *Therapeutic Goods Act 1989* made by this Schedule, that subsection, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to claims made before that commencement.
- (2) Despite the repeal of subsection 32BJ(4) of the *Therapeutic Goods Act 1989* made by this Schedule, that subsection, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to claims made before that commencement.
- (3) Despite the repeal of section 41MM of the *Therapeutic Goods Act 1989* made by this Schedule, that section, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to claims made before that commencement.

Schedule 7—Conditions of registration or listing of therapeutic goods

Therapeutic Goods Act 1989

1 Before paragraph 28(5)(aa)

Insert:

(aaa) if:

- (i) the person proposes to make a change to the information included in the entry in the Register that relates to the subject goods; and
- (ii) the information proposed to be changed is of a kind that relates to one or more of the matters referred to in paragraphs 25(1)(c) to (ja), 26(1)(c) to (n), 26A(2)(a) to (ja) or 26AB(2)(a) to (p) (as appropriate); and
- (iii) the Secretary would be required, under section 9D, to vary that entry, or to consider whether to vary that entry, in relation to the information proposed to be changed if the person made a request under that section for a variation of that entry;

make that request and not make the change unless the Secretary varies that entry in accordance with that request; and

2 Application provision

The amendment made by this Schedule applies on and after the commencement of this item in relation to therapeutic goods included in the Register before, on or after that commencement.

Schedule 8—Changes to provisionally registered medicine

Therapeutic Goods Act 1989

1 Section 23AA

Before “If”, insert “(1)”.

2 At the end of section 23AA

Add:

(2) If:

- (a) in accordance with subsection 29(2), a medicine (the *original medicine*) is provisionally registered because of an application by a person that, under subsection (1) of this section, is taken to be an application for provisional registration of the original medicine; and
- (b) another medicine (the *new medicine*) is taken, under subsection 16(1), to be separate and distinct from the original medicine; and
- (c) the person makes an application under section 23 for the registration of the new medicine; and
- (d) the person makes the application before the end of the provisional registration period for the original medicine under subsection 29(3) (including that period as extended under subsection 29(6)); and
- (e) the person specifies in the application that the person is seeking provisional registration of the new medicine; and
- (f) at the time the person makes the application, the active ingredients of the new medicine are the same as the active ingredients of the original medicine; and
- (g) at the time the person makes the application, the indications of the new medicine are the same as the indications of the original medicine;

then, for the purposes of this Act, the application is taken to be an application for provisional registration of the new medicine.

3 Subparagraph 25(1)(d)(iii)

Before “whether”, insert “if subsection 23AA(1) applies in relation to the application—”.

4 Subsection 29(3)

Repeal the subsection, substitute:

- (3) Subject to this section, the *provisional registration period*, for a medicine that is provisionally registered because of an application that, under subsection 23AA(1), is taken to be an application for provisional registration of the medicine, is the period of 2 years starting on the day the registration commences.

Note: Subsection 25AB(6) provides that registration commences on the day specified in the certificate of registration.

- (3A) Subject to this section, the *provisional registration period*, for a medicine (the *new medicine*) that is provisionally registered because of an application that, under subsection 23AA(2), is taken to be an application for provisional registration of the new medicine, is as follows:

- (a) if, in relation to the new medicine, the day (the *start day*) referred to in subsection 25AB(6) occurs in the period (the *original period*) referred to in subsection (3) of this section in relation to the original medicine concerned—the period starting on the start day and ending at the end of the original period;
- (b) if, in relation to the new medicine, the start day occurs in a period of extension of the original period that is granted under subsection (6)—the period starting on the start day and ending at the end of that extension period.

Note: Subsection 25AB(6) provides that registration commences on the day specified in the certificate of registration.

5 Paragraph 29(5)(c)

Repeal the paragraph, substitute:

- (c) be made:
- (i) if the medicine is provisionally registered because of an application that, under subsection 23AA(1), was taken to be an application for provisional registration of the

medicine—at least 6 months before the provisional registration of the medicine is due to end; or

- (ii) if the medicine is provisionally registered because of an application that, under subsection 23AA(2), was taken to be an application for provisional registration of the medicine—at least 1 month before the provisional registration of the medicine is due to end; and

6 Subsection 29(6)

Repeal the subsection, substitute:

(6) If:

- (a) a person makes an application under subsection (4) in accordance with this section; and
- (b) the medicine is provisionally registered because of an application that, under subsection 23AA(1), was taken to be an application for provisional registration of the medicine;

the Secretary must decide to grant, or to refuse to grant, an extension of the provisional registration period. In making that decision, the Secretary must have regard to:

- (c) whether the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years starting on the day the provisional registration commenced; and
- (d) such other matters (if any) as the Secretary considers relevant.

(6A) If:

- (a) a person makes an application under subsection (4) in accordance with this section; and
- (b) the medicine is provisionally registered because of an application that, under subsection 23AA(2), was taken to be an application for provisional registration of the medicine;

the Secretary must decide to grant, or to refuse to grant, an extension of the provisional registration period. In making that decision, the Secretary must have regard to such matters as the Secretary considers relevant.

7 Subsection 29(7)

Omit “after making the decision”, substitute “after making a decision under subsection (6) or (6A)”.

8 Subsection 29(8)

After “granted”, insert “in relation to a medicine”.

9 After subsection 29(8)

Insert:

- (8A) The Secretary must not, under subsection (6A), extend the provisional registration period applicable under subsection (3A) for the new medicine so that period would end more than 6 years after the provisional registration for the original medicine concerned commenced.

10 Paragraph 60(2D)(a)

After “subsection 29(6)”, insert “or (6A)”.

11 Application, saving and transitional provisions

- (1) Paragraph 23AA(2)(a) of the *Therapeutic Goods Act 1989*, as added by this Schedule, applies in relation to a medicine provisionally registered before, on or after the commencement of this item.
- (2) Paragraph 23AA(2)(d) of the *Therapeutic Goods Act 1989*, as added by this Schedule, applies in relation to an application made on or after the commencement of this item.
- (3) The amendment of subparagraph 25(1)(d)(iii) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an application for provisional registration of a medicine that is made on or after the commencement of this item.
- (4) Subsections 29(3) and (3A) of the *Therapeutic Goods Act 1989*, as substituted by this Schedule, apply in relation to an application for provisional registration of a medicine that is made on or after the commencement of this item.
- (5) The repeal and substitution of paragraph 29(5)(c) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an

application made under subsection 29(4) of that Act on or after the commencement of this item.

- (6) Subsections 29(6) and (6A) of the *Therapeutic Goods Act 1989*, as substituted by this Schedule, apply in relation to an application made under subsection 29(4) of that Act on or after the commencement of this item.
- (7) The repeal of subsection 29(6) of the *Therapeutic Goods Act 1989* made by this Schedule does not affect the validity of a decision made under that subsection before the commencement of this item.
- (8) If, before the commencement of this item, an application was taken, under section 23AA of the *Therapeutic Goods Act 1989*, to be an application for provisional registration of a medicine, then, on and after that commencement, the application is to be treated as if it was taken, under subsection 23AA(1) of that Act, to be an application for provisional registration of the medicine.

Schedule 9—Data protection for certain listed medicine

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

restricted information has the meaning given by section 26AF.

2 At the end of subsection 26AE(1)

Add:

Note: The Secretary must not use restricted information when evaluating the medicine for listing: see section 26AF.

3 After section 26AE

Insert:

26AF When the Secretary must not use restricted information in evaluating medicine for listing under section 26AE

- (1) If an application is made under section 23 for the listing of a medicine under section 26AE, then, in evaluating the medicine under section 26AE, the Secretary must not use information about other medicine that is restricted information.
- (2) Information is *restricted information* if:
 - (a) the information was given to the Secretary in relation to an application made under section 23 for the listing of a medicine (the *existing medicine*) under section 26AE; and
 - (b) the information is derived from a clinical trial in relation to an indication of the existing medicine, being an indication that is not covered by a determination under paragraph 26BF(1)(a); and
 - (c) the information is not available to the public; and
 - (d) at the time the application to list the existing medicine was made:

- (i) no other medicine with that indication was included in the Register; and
- (ii) no other medicine with that indication had been included in the Register at any time before that time; and
- (e) the existing medicine was listed under section 26AE on or after the commencement of this subsection; and
- (f) 5 years have not passed since the day that listing commenced; and
- (g) the person in relation to whom the existing medicine is listed has not given the Secretary permission in writing for the Secretary to use the information.

4 After subsection 30(4A)

Insert:

- (4B) The Secretary must, by notice in writing given to a person in relation to whom a medicine is listed under section 26AE, cancel the listing of the medicine if the Secretary becomes aware that restricted information was used when evaluating the medicine for listing.

5 Subsection 61(8)

Omit “section 25A”, substitute “sections 25A and 26AF”.

6 Application provisions

- (1) Subsection 26AF(1) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to an application made on or after the commencement of this item.
- (2) Subsection 30(4B) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to a medicine listed on or after the commencement of this item, where the application for the listing was made on or after that commencement.

Schedule 10—Other amendments

Patents Act 1990

1 Subparagraph 119A(1)(a)(ii)

Omit “, or therapeutic devices,”.

Therapeutic Goods Act 1989

2 Subsection 3(1)

Insert:

Australia-UK Mutual Recognition Agreement means the Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates And Markings between the Government of Australia and the Government of the United Kingdom of Great Britain and Northern Ireland, as in force from time to time.

Note: The Agreement could in 2020 be viewed in the Australian Treaties Library on the AustLII website (<http://www.austlii.edu.au>).

3 Subsection 3(1) (definition of *gazetted therapeutic devices group*)

Repeal the definition.

4 Subsection 3(1) (paragraph (b) of the definition of *grouped therapeutic goods*)

Repeal the paragraph.

5 Subsection 3(1) (note to the definition of *included in the Register*)

Repeal the note.

6 Subsection 3(1) (definition of *listable devices*)

Repeal the definition.

7 Subsection 3(1) (definition of *medicine*)

Repeal the definition, substitute:

medicine means therapeutic goods (other than biologicals) that are represented to achieve, or are likely to achieve, their principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human.

8 Subsection 3(1) (definition of *therapeutic device*)

Repeal the definition.

9 Paragraph 7B(2)(b)

Omit “or therapeutic devices”.

10 Section 9B

Repeal the section.

11 Chapter 3 (note to Chapter heading)

Repeal the note.

12 Section 10A

Repeal the section.

13 Section 15A

Repeal the section, substitute:

15A Part does not apply to a medical device

This Part does not apply to a medical device.

Note: Chapter 4 deals with medical devices.

14 Subsection 16(2)

Omit “or therapeutic devices”.

15 Subsection 16(3)

Repeal the subsection.

16 Subsection 16(4)

Omit “, (3)”.

17 Section 19 (heading)

Repeal the heading, substitute:

19 Approvals or authorities for certain uses

18 Section 19A (heading)

Repeal the heading, substitute:

19A Approvals where unavailability etc. of therapeutic goods

19 Paragraph 19D(3)(a)

Omit “(other than listed goods that are therapeutic devices)”.

20 Paragraph 19D(4)(a)

Omit “(other than listed goods that are therapeutic devices)”.

21 Section 21

Omit “(other than listable devices)”.

22 Section 23A

Before “The”, insert “(1)”.

23 At the end of section 23A

Add:

- (2) Without limiting subsection (1), a class of therapeutic goods may be specified by reference to one or more of the matters referred to in paragraphs 16(1)(a) to (g) or 16(1A)(a) to (d).

24 Transitional provision

An instrument in force immediately before the commencement of this item under section 23A of the *Therapeutic Goods Act 1989* continues in force on and after that commencement as if it were an instrument made under subsection 23A(1) of that Act.

25 Subsection 23C(2) (note)

Omit “26AA,”.

26 Subparagraphs 25(2)(a)(i) and (ia)

Omit “the goods are not therapeutic devices and”.

27 Subsection 25AB(1)

Repeal the subsection.

28 Subsection 25AB(2) (heading)

Repeal the heading.

29 Paragraph 25AB(2)(b)

Omit “and”.

30 Paragraph 25AB(2)(c)

Repeal the paragraph.

31 Paragraph 25A(2)(a)

Repeal the paragraph, substitute:

- (a) the information was given to the Secretary in relation to an application to register therapeutic goods (the *new goods*) consisting of, or containing, an active component; and

32 Section 25B

Repeal the section.

33 Paragraph 26(1)(aa)

Omit “if goods are not therapeutic devices—”.

34 Subsection 26(1)

Omit “and section 26AA”.

35 Paragraph 26(1)(g)

Omit “(not being therapeutic devices other than devices prescribed for the purposes of this paragraph)”.

36 Subparagraphs 26(2)(a)(i) and (ia)

Omit “the goods are not therapeutic devices and”.

37 Section 26AA

Repeal the section.

38 Section 32CM (heading)

Repeal the heading, substitute:

32CM Authorities for health practitioners

39 Section 33A

Repeal the section, substitute:

33A Part does not apply to a medical device

This Part does not apply to a medical device.

Note: Chapter 4 deals with medical devices.

40 Chapter 4 (note to Chapter heading)

Repeal the note.

41 Section 41BJ

Repeal the section.

42 Section 41HC (heading)

Repeal the heading, substitute:

41HC Authorities for health practitioners

43 Paragraph 46A(4)(b)

Omit “registration or listing of the therapeutic goods”, substitute “registration, listing or inclusion”.

44 Section 52EB

Repeal the section.

45 Subsection 60(1) (paragraph (a) of the definition of *initial decision*)

Omit “under the definition of *therapeutic devices* in subsection 3(1) or”.

46 Subsection 60(1) (paragraph (c) of the definition of *initial decision*)

After “goods)”, insert “, other than a decision under paragraph 26BE(4)(a), or a decision under subsection 26BJ(8), to make a recommendation”.

47 Application provision

The amendment made by item 46 applies in relation to a decision made on or after the commencement of this item.

48 Paragraph 60(2AB)(c)

Repeal the paragraph.

49 Subsection 61(1) (definition of *therapeutic goods information*)

Omit “or the EFTA Mutual Recognition Agreement”, substitute “, the EFTA Mutual Recognition Agreement or the Australia-UK Mutual Recognition Agreement”.