Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017

I, General the Honourable Sir Peter Cosgrove AK MC (Ret'd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 30 November 2017

Peter Cosgrove
Governor-General

By His Excellency's Command

Greg Hunt
Minister for Health

OPC62585 - A

Contents

1 Name

This instrument is the *Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017*.

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.	2 December 2017
2. Schedule 1	1 January 2018.	1 January 2018
3. Schedule 2, Part 1	The day after this instrument is registered.	2 December 2017
4. Schedule 2, Part 2	Immediately after the commencement of Part 2 of Schedule 1 to the *Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017*.	4 December 2017
5. Schedule 3	1 January 2018.	1 January 2018
6. Schedule 4	The day after this instrument is registered.	2 December 2017

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

Therapeutic Goods (Medical Devices) Regulations 2002

1 After Division 4.1

Insert:

Division 4.1A—Conformity assessment (priority applicant) determinations

4.3A Application of Division

For the purposes of subsection 41ECA(1) of the Act, this Subdivision makes provision for and in relation to the making of conformity assessment (priority applicant) determinations.

4.3B Application for conformity assessment (priority applicant) determination

(1) A person may apply to the Secretary for a conformity assessment (priority applicant) determination in relation to a medical device.

(2) An application under subregulation (1) must:
  (a) be in writing; and
  (b) be in a form approved, in writing, by the Secretary; and
  (c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken not to have been made unless:
  (a) the application meets the requirements in subregulation (2); and
  (b) the fee prescribed in item 1.1A of Part 1 of Schedule 5 for making the application has been paid.

4.3C Making of conformity assessment (priority applicant) determination

(1) On receiving an application under subregulation 4.3B(1) for a conformity assessment (priority applicant) determination in relation to a medical device, the Secretary must:
  (a) consider the application; and
  (b) decide either:
    (i) to make the determination; or
    (ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the medical device (the ***new device***):
  (a) the intended purpose of the new device is the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;
  (b) either:

(i) no medical devices with that intended purpose are of a kind included in the Register; or

(ii) if one or more medical devices with that intended purpose are of a kind included in the Register (the ***existing devices***)—there is substantial evidence demonstrating that the safety or performance of the new device when used for that intended purpose provides a significant improvement compared to the existing devices;

(c) at least one of the following applies to the new device:

(i) the new device is a breakthrough technology and there is evidence that it offers a major clinical advantage over existing technology;

(ii) there is evidence that the new device offers a major clinical advantage over existing alternatives included in the Register;

(iii) the new device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

Information to be specified in determination

(3) The determination must specify:

(a) the person who, as a result of section 41ECA of the Act, is the priority applicant; and

(b) the medical device to which the determination relates; and

(c) the intended purpose of the medical device.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

4.3D Period during which conformity assessment (priority applicant) determination is in force

(1) A conformity assessment (priority applicant) determination in relation to a medical device:

(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 4.3C(4); and

(b) subject to subregulation (2) and regulation 4.3E, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an effective application under section 41EB of the Act for a conformity assessment certificate that covers the medical device before the end of the 6 month period beginning when the determination comes into force, the determination remains in force until:

(a) the priority applicant withdraws the application; or

(b) the application lapses in accordance with section 41EG of the Act; or

(c) the application is finally determined.

Note: See subsection 41EB(2) of the Act for when an application under section 41EB of the Act is effective.

4.3E Revocation of conformity assessment (priority applicant) determination

(1) The Secretary may revoke a conformity assessment (priority applicant) determination in relation to a medical device if:

(a) either:

(i) the priority applicant specified in the determination has not made an application under section 41EB of the Act for a conformity assessment certificate that covers the medical device; or

(ii) the priority applicant has made such an application, but the application is not effective; and

(b) the Secretary is satisfied that the criteria specified in subregulation 4.3C(2) are no longer satisfied in relation to the medical device.

Note: See subsection 41EB(2) of the Act for when an application under section 41EB of the Act is effective.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

2 Before regulation 5.2

Insert:

Subdivision A—Applications

3 After regulation 5.2

Insert:

Subdivision C—Auditing of applications

4 At the end of Division 5.1

Add:

Subdivision D—Miscellaneous—medical devices (priority applicant) determinations

5.4 Application of Subdivision

For the purposes of subsection 41FKA(1) of the Act, this Subdivision makes provision for and in relation to the making of medical devices (priority applicant) determinations.

5.4A Application for medical devices (priority applicant) determination

(1) A person may apply to the Secretary for a medical devices (priority applicant) determination in relation to a medical device.

(2) An application under subregulation (1) must:

(a) be in writing; and

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

(c) have with it written information in such detail as is reasonably necessary to allow the application to be properly considered.

(3) An application under subregulation (1) is taken not to have been made unless:

(a) the application meets the requirements in subregulation (2); and
(b) the fee prescribed in item 1.5A of Part 1 of Schedule 5 for making the application has been paid.

5.4B Making of medical devices (priority applicant) determination

(1) On receiving an application under subregulation 5.4A(1) for a medical devices (priority applicant) determination in relation to a medical device, the Secretary must:
(a) consider the application; and
(b) decide either:
(i) to make the determination; or
(ii) to refuse to make the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied, having regard to any matter that the Secretary considers relevant, that all of the following criteria are satisfied in relation to the medical device (the ***new device***):
(a) the intended purpose of the new device is the monitoring, treatment, prevention or diagnosis of a life-threatening or seriously debilitating condition;
(b) either:
(i) no medical devices with that intended purpose are of a kind included in the Register; or
(ii) if one or more medical devices with that intended purpose are of a kind included in the Register (the ***existing devices***)—there is substantial evidence demonstrating that the safety or performance of the new device when used for that intended purpose provides a significant improvement compared to the existing devices;
(c) at least one of the following applies to the new device:
(i) the new device is a breakthrough technology and there is evidence that it offers a major clinical advantage over existing technology;
(ii) there is evidence that the new device offers a major clinical advantage over existing alternatives included in the Register;
(iii) the new device is an IVD medical device and its early availability in Australia will result in a major public health benefit.

Information to be specified in determination

(3) The determination must specify:
(a) the person who, as a result of section 41FKA of the Act, is the priority applicant; and
(b) the medical device to which the determination relates; and
(c) the intended purpose of the medical device.

Notification of decision

(4) As soon as practicable after making the decision, the Secretary must notify the applicant, in writing, of the decision.

(5) If the Secretary decides to refuse to make the determination, the notification must include the reasons for the decision.

5.4C Period during which medical devices (priority applicant) determination is in force

(1) A medical devices (priority applicant) determination in relation to a medical device:

(a) comes into force on the day on which the Secretary notifies the priority applicant in accordance with subregulation 5.4B(4); and

(b) subject to subregulation (2) and regulation 5.4D, remains in force for 6 months.

(2) If the priority applicant specified in the determination makes an effective application under section 41FC of the Act for that kind of medical device to be included in the Register before the end of the 6 month period beginning when the determination comes into force, the determination remains in force until:

(a) the priority applicant withdraws the application; or

(b) the application lapses in accordance with section 41FK of the Act; or

(c) the application is finally determined.

Note: See subsection 41FC(2) of the Act for when an application under section 41FC of the Act is effective.

5.4D Revocation of medical devices (priority applicant) determination

(1) The Secretary may revoke a medical devices (priority applicant) determination in relation to a medical device if:

(a) either:

(i) the priority applicant specified in the determination has not made an application under section 41FC of the Act for that kind of medical device to be included in the Register; or

(ii) the priority applicant has made such an application, but the application is not effective; and

(b) the Secretary is satisfied that the criteria specified in subregulation 5.4B(2) are no longer satisfied in relation to the medical device.

Note: See subsection 41FC(2) of the Act for when an application under section 41FC of the Act is effective.

(2) The revocation must be by written notice given by the Secretary to the priority applicant.

5 Subregulation 10.7(1) (paragraph (a) of the definition of *initial decision*)

Repeal the paragraph, substitute:

(a) subparagraph 4.3C(1)(b)(ii);

(aa) subregulation 4.3E(1);

(ab) subregulation 4.10(2);

(ac) subparagraph 5.4B(1)(b)(ii);

(ad) subregulation 5.4D(1);

6 After subregulation 10.7(3)

Insert:

(3A) Despite subregulation (3), only the following persons may make a request under that subregulation in relation to a conformity assessment (priority applicant) determination:

(a) if the initial decision was to refuse to make the determination—the person who applied for the determination;

(b) if the initial decision was to revoke the determination—the priority applicant specified in the determination.

(3B) Despite subregulation (3), only the following persons may make a request under that subregulation in relation to a medical devices (priority applicant) determination:

(a) if the initial decision was to refuse to make the determination—the person who applied for the determination;

(b) if the initial decision was to revoke the determination—the priority applicant specified in the determination.

7 Part 1 of Schedule 5 (after table item 1.1)

Insert:

1.1A	Application for conformity assessment (priority applicant) determination in relation to a medical device	Paragraph 41ECA(3)(d) of the Act	9,660

8 Part 1 of Schedule 5 (after table item 1.5)

Insert:

1.5A	Application for medical devices (priority applicant) determination in relation to a medical device	Paragraph 41FKA(3)(d) of the Act	9,660

9 Dictionary

Insert:

conformity assessment (priority applicant) determination has the meaning given by subsection 41ECA(2) of the Act.

10 Dictionary (definition of *intended purpose*)

Omit "kind of".

11 Dictionary

Insert:

medical devices (priority applicant) determination has the meaning given by subsection 41FKA(2) of the Act.

Schedule 2—Variation of entries in Register

Part 1—Prescription medicines

Therapeutic Goods Legislation Amendment (2017 Measures No. 1) Regulations 2017

1 Subsection 2(1) (table item 3, columns 2 and 3)

Omit "1 January 2018", substitute "4 December 2017".

Part 2—Registered complementary medicines, registered OTC medicines, prescription medicines and biologicals

Therapeutic Goods Regulations 1990

2 Regulation 2

Insert:

TGA notifications process guidance document means Version 2.0 of the document published by the Therapeutic Goods Administration entitled *Notifications process—requests to vary biologicals and registered medicines where quality, safety and efficacy are not affected* (as in force on 4 December 2017).

Note: The TGA notifications process guidance document could in 2017 be viewed on the Therapeutic Goods Administration's website (http://www.tga.gov.au).

Therapeutic Goods Administration means that part of the Department known as the Therapeutic Goods Administration.

3 Paragraph 10AAA(2)(b)

Omit "Version 1.0 of the document entitled *Notifications process—requests to vary registered medicines where quality, safety and efficacy are not affected* (as in force on the day this regulation commences)", substitute "the TGA notifications process guidance document".

4 Subregulation 10AAA(2) (note)

Repeal the note.

5 Subregulation 10AAA(2) (at the end of the table)

Add:

17	A change to the font, letter height or text size on a label for the medicine, other than a change on the main label for the medicine	LFT
18	Removal of a graphic from a label for the medicine, other than a graphic that relates to directions for: (a) use of the medicine; or (b) use of a measuring device; or (c) use of an applicator	RGN
19	A change to the location of a graphic on the panel of a label for the medicine if: (a) there is no change to the size, shape or colour of the graphic; and (b) the change does not involve reformatting text	LGM
20	If the medicine is in a solid dosage form, the addition of a new pack size that is within the pack size range for the medicine	PSN
21	If the medicine is in a liquid or semi-solid dosage form, the addition of a new pack size that is within the pack size range for the medicine	PLN
22	The deletion of a pack size for the medicine	PSD
23	If the medicine is sterile:	MSS

	(a) the addition of a manufacturer of the medicine for the performance of any of the following steps: (i) release for supply; (ii) secondary packaging; (iii) chemical, physical or microbial testing; or (b) the inclusion of the performance of any of the steps mentioned in paragraph (a) as an additional step in the manufacture of the medicine by a manufacturer of the medicine	
24	If a measuring device had previously been supplied with the medicine, the supply of the medicine without the measuring device, if: (a) other means of accurately measuring the dose are readily available; and (b) any graphical representation of the device (including associated wording) is removed from any label for the medicine; and (c) there are no changes to the directions for use of the medicine	KMO

6 Paragraph 10AAB(2)(b)

Omit "Version 1.0 of the document entitled *Notifications process—requests to vary registered medicines where quality, safety and efficacy are not affected* (as in force on the day this regulation commences)", substitute "the TGA notifications process guidance document".

7 Subregulation 10AAB(2) (note)

Repeal the note.

8 Subregulation 10AAB(2) (at the end of the table)

Add:

53	A change to a physicochemical test method used for testing an active pharmaceutical ingredient of the medicine	ASPC
54	A minor change to: (a) the manufacture of an active pharmaceutical ingredient of the medicine; or (b) a starting material for the synthesis of an active pharmaceutical ingredient of the medicine; or (c) an intermediate of an active pharmaceutical ingredient of the medicine; if the change does not affect any step taken to sterilise the ingredient or intermediate	AMMC
55	A change to a label for the medicine that deletes text from side or rear panels if: (a) the text is present elsewhere on the label for the medicine; and (b) repetition of the information on the panel is not required by an order in force under subsection 10(1) of the Act, or a condition imposed by or under section 28 of the Act, that applies to the medicine	LPDR
56	A change to a label for the medicine to include, remove or amend the name or address of the Australian sponsor or distributor of the medicine	LPCS
57	A change to a label for the medicine to include, remove or change the	LPCL

	sponsor's or distributor's logo or livery	
58	A change to a label for the medicine to remove graphics, pictures or diagrams, and any associated text, other than a pictogram of the medicine or its dosage form	LPDG
59	A change to a label for the medicine to include, remove or change a pictogram of the medicine or its dosage form	LPCP
60	A change to a label for the medicine to include: (a) simple instructions or information relating to the packaging of the medicine; or (b) information describing a change in appearance of the dosage form	LPIA
61	A change to a label for the medicine to include or remove text written on the outer protective pouches, or the overwraps, of the container or primary pack of the medicine	LPOP
62	A change to a label for the medicine as a consequence of: (a) a variation, under subsection 9D(3) of the Act, of the entry in the Register that relates to the medicine; or (b) a condition imposed, under subsection 28(3) of the Act, on the listing or registration of the medicine	LOCI
63	A change to a label for the medicine that removes phrases indicating novelty, such as "New formulation" or "New appearance"	LPRP
64	A change to a label for the medicine to include a QR code, if the link is: (a) to a website owned by the person in relation to whom the medicine is included in the Register; and (b) to information that is non-promotional	LPQR
65	A change to a label for the medicine to include information about a patient support program	LPPS

9 Paragraph 10AAC(2)(b)

Omit "Version 1.0 of the document entitled *Notifications process—requests to vary registered medicines where quality, safety and efficacy are not affected* (as in force on the day this regulation commences)", substitute "the TGA notifications process guidance document".

10 Subregulation 10AAC(2) (note)

Repeal the note.

11 Subregulation 10AAC(2) (at the end of the table)

Add:

11	A change to the specifications for testing a drug substance or excipient of the medicine if the change makes a limit associated with the testing more stringent	ISNL
12	A change to the specifications for a drug substance or excipient of the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the drug substance or excipient; or (b) an order in force under subsection 10(1) of the Act that applies to the drug substance or excipient	ISPT

13	A change to a method used for testing a drug substance or excipient of the medicine if: (a) the change is to adopt a method in a default standard; and (b) the test is not for viral safety	ISAM
14	A change to the specifications for testing the medicine to include a new test and any associated limits if the new test is part of a default standard	PSNT
15	A change to the specifications for the medicine made for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the medicine; or (b) an order in force under subsection 10(1) of the Act that applies to the medicine	PSPT
16	A minor change to a physicochemical test method used for testing the medicine	PMPL
17	The replacement of an in-house reference standard with another if the protocol and acceptance criteria for establishing a replacement in-house reference standard have been approved by the Therapeutic Goods Administration	IRSR
18	A change to a label for the medicine that deletes text from a side or rear panel if: (a) the text is present elsewhere on the label for the medicine; and (b) repetition of the information on the panel is not required by an order in force under subsection 10(1) of the Act, or a condition imposed by or under section 28 of the Act, that applies to the medicine	LPDR
19	A change to a label for the medicine to include, remove or amend the name or address of the Australian sponsor or distributor of the medicine	LPCS
20	A change to a label for the medicine to include, remove or change the sponsor's or distributor's logo or livery	LPCL
21	A change to a label for the medicine to remove graphics, pictures or diagrams, and any associated text, other than a pictogram of the medicine or its dosage form	LPDG
22	A change to a label for the medicine to include, remove or change a pictogram of the medicine or its dosage form	LPCP
23	A change to a label for the medicine to include: (a) simple instructions or information relating to the packaging of the medicine; or (b) information describing a change in appearance of the dosage form	LPIA
24	A change to a label for the medicine to include or remove text written on the outer protective pouches, or the overwraps, of the container or primary pack of the medicine	LPOP
25	A reduction in the shelf life of the drug substance of the medicine	ASRS
26	A reduction in the shelf life of the medicine	PSLD
27	The introduction of anti-tamper packaging if the packaging material is not in contact with the medicine	PPAT
28	Either or both of the following changes to the manufacture of the medicine: (a) removal of a temperature excursion;	PSET

	(b) reduction in the time spent out of refrigeration or freezer storage	
29	The addition of a storage condition for the medicine	PSAR
30	A change to the name or contact details of an albumin manufacturer or supplier, if the site or process has not changed	OAMS

12 After regulation 10AAC

Insert:

10AAD Variation of entries in Register—biologicals

Kinds of variations

(1) For the purposes of paragraph 9D(3AC)(b) of the Act, a variation:
  (a) of an entry in the Register that relates to a biological; and
  (b) that is listed in the table in subregulation (2);
is specified.

Conditions

(2) For the purposes of paragraph 9D(3AC)(c) of the Act, the following conditions are specified in relation to a variation of an entry in the Register that is listed in column 1 of an item in the following table:
  (a) the variation reflects a change that will be made to, or in relation to, the biological;
  (b) the other conditions set out in the TGA notifications process guidance document in relation to the code listed in column 2 of the item are satisfied.

Kinds of variations—biologicals

Item	Column 1 Variation	Column 2 Code
1	A change to the specifications of the biological for the purposes of ensuring that the specifications are consistent with: (a) a default standard that applies to the biological; or (b) an order in force under subsection 10(1) of the Act that applies to the biological	PT
2	A change to the donor selection criteria for the starting materials for the biological to make the criteria more stringent	DS
3	A change to an infectious disease test kit used to test the starting materials for the biological if the change does not decrease the kit's ability to detect an infectious disease	TK
4	A change to a critical material used in the manufacture of the biological if: (a) the critical parameters for the changed material are equivalent or of greater quality; and (b) the material is not of human or animal origin; and (c) the material is not an excipient; and (d) in the case of critical material that is a container for the biological—the change is not a change to the composition of the material	SM

Kinds of variations—biologicals		
Item	**Column 1** **Variation**	**Column 2** **Code**
5	The introduction of more stringent limits to an in-process control test applied during the manufacture of the biological	MI
6	The removal of a product if the biological is a Class 2 biological	BR
7	The addition of a site at which secondary packaging or storage of the biological is performed	MA
8	A change to the location of a site at which either or both of the following are performed in relation to the biological, or the addition of a site at which either or both of the following are performed in relation to the biological: (a) quality control testing; (b) infectious disease testing	MT
9	The cessation of the manufacture or a step in the manufacture of the biological at a manufacturing site	MR
10	The introduction of more stringent limits to a release test applied during the manufacture of the biological	BS
11	A reduction in the shelf life or shipping timeframe of the biological	BT
12	A change to the label or supporting documentation for the biological to: (a) change the name, address or other contact details of the sponsor, manufacturer or distributor; or (b) change the name of an active ingredient as a result of a change to the Australian Cell and Tissue Name for the ingredient	LC

Schedule 3—Evaluations in relation to prescription medicines

Therapeutic Goods Regulations 1990

1 Regulation 2

Insert:

generic product means a medicine that, in comparison to a registered medicine or a medicine that has been registered but is no longer a registered medicine (the ***comparison medicine***):

(a) has the same quantitative composition of therapeutically active substances, being substances of similar quality to those used in the comparison medicine; and

(b) has the same pharmaceutical form; and

(c) is bioequivalent; and

(d) has the same safety and efficacy properties.

2 Regulation 10AA

Omit "A kind", substitute "(1) A kind".

3 At the end of regulation 10AA

Add:

(2) A request that is made under subsection 9D(3) of the Act to vary information included in an entry in the Register that relates to a medicine that is a product of a kind specified in Part 1 of Schedule 10 to these Regulations is prescribed for the purposes of subparagraph 9D(7)(b)(ii) of the Act.

4 Division 1 of Part 3A (heading)

Repeal the heading, substitute:

Division 1—Preliminary

5 After regulation 16A

Insert:

Division 1A—Goods mentioned in Part 1 of Schedule 10

6 Regulations 16B to 16D

Repeal the regulations, substitute:

16C Applications for registration—notification of effectiveness and period for completing evaluations—general

Application of this regulation

(1) This regulation applies if the Secretary receives an application:

(a) made under section 23 of the Act for the registration of a medicine that is a product of a kind specified in Part 1 of Schedule 10 to these Regulations; and

(b) to which regulation 16G does not apply.

Giving notification of effectiveness of application

(2) The Secretary must, within 40 working days from the day of receipt of the application, send a notification in writing to the applicant that states whether the application is effective.

Period for completing evaluation in relation to application

(3) For the purposes of paragraph 63(2)(da) of the Act, if section 25 of the Act requires an evaluation in relation to the application, the evaluation must be completed within the period of:

(a) if the conditions mentioned in subregulations 16DA(1) and (2) are satisfied—120 working days; or

(b) if the conditions mentioned in subregulation 16DA(1) are satisfied, but a condition mentioned in subregulation 16DA(2) is not satisfied—175 working days; or

(c) otherwise—255 working days;

beginning on the day the Secretary sends the notification that states that the application is effective.

16D Applications for variations—notification of effectiveness and period for deciding applications—general

Application of this regulation

(1) This regulation applies if the Secretary receives an application:

(a) made under subsection 9D(3) of the Act to vary information included in an entry in the Register that relates to a medicine that is a product of a kind specified in Part 1 of Schedule 10 to these Regulations; and

(b) to which regulation 16F does not apply.

Giving notification of effectiveness of application

(2) The Secretary must, within 40 working days from the day of receipt of the application, send a notification in writing to the applicant that states whether the application is effective.

Period for completing evaluation in relation to application

(3) For the purposes of paragraph 63(2)(df) of the Act, if the application is effective, the application must be decided, and the applicant must be given notification of the decision, within the period of:

(a) if, in respect of the evaluation in relation to the application, the conditions mentioned in subregulations 16DA(1) and (2) are satisfied—120 working days; or

(b) if, in respect of the evaluation in relation to the application, the conditions mentioned in subregulation 16DA(1) are satisfied, but a condition mentioned in subregulation16DA(2) is not satisfied—175 working days; or

(c) otherwise—255 working days;

beginning on the day the Secretary sends the notification that states that the application is effective.

16DA Conditions for periods for regulations 16C and 16D

Conditions for 175 day period

(1) For the purposes of paragraphs 16C(3)(b) and 16D(3)(b), the conditions are the following:

(a) the evaluation relates to a medicine (the ***evaluation medicine***) that is the same as a medicine (an ***acceptable foreign approved medicine***) that has been approved by a competent regulatory authority, of a foreign country or foreign jurisdiction determined under subregulation (3), for general marketing in that country or jurisdiction;

(b) the approval for the acceptable foreign approved medicine:

(i) is in force; and

(ii) was given not more than 12 months before the date of the application in relation to the evaluation;

(c) the indications of the evaluation medicine are equivalent to the indications of the acceptable foreign approved medicine;

(d) the strength, dosage form, formulation and directions for use of the evaluation medicine are identical to those of the acceptable foreign approved medicine;

(e) the manufacturer and manufacturing process for the evaluation medicine are identical to those for the acceptable foreign approved medicine;

(f) an application for marketing approval for the evaluation medicine has not been delayed, deferred, rejected, refused or withdrawn in any country;

(g) if the evaluation medicine is a generic product in comparison to a registered medicine:

(i) the indications of the evaluation medicine are identical to the indications of the registered medicine; and

(ii) the reference product used by the competent regulatory authority mentioned in paragraph (a) to assess the bioequivalence of the acceptable foreign approved medicine (in assessing the application for the approval for the acceptable foreign approved medicine) is identical to the registered medicine;

(h) if the evaluation medicine is a biosimilar in relation to a registered medicine—the reference product used by the competent regulatory authority mentioned in paragraph (a) (in assessing the application for the approval for the acceptable foreign approved medicine) is identical to the registered medicine;

(i) the applicant in relation to the evaluation has given the Secretary the assessment, by the competent regulatory authority mentioned in paragraph (a), of the application for the approval for the acceptable foreign approved medicine;

(j) the assessment mentioned in paragraph (i):

(i) is complete and unredacted; and

(ii) is in English; and

(iii) includes comprehensive details of studies assessed in connection with the application for the approval for the acceptable foreign approved medicine; and

(iv) includes copies of any correspondence relating to the application for the approval for the acceptable foreign approved medicine between the competent regulatory authority and the applicant for the approval; and

(v) includes the competent regulatory authority's final decision; and

(vi) includes any certifications or authentications of reports relating to the approval; and

(vii) is not, wholly or in part, based on (including compiled by reference to or in reliance on) any other assessment or evaluation (however described).

Conditions for 120 day period

(2) For the purposes of paragraphs 16C(3)(a) and (b) and 16D(3)(a) and (b), the conditions are the following:

(a) the manufacturing site at which manufacturing steps other than labelling and release for supply are carried out for the evaluation medicine is identical to that for the acceptable foreign approved medicine;

(b) if the evaluation medicine is manufactured in Australia—there is evidence that the medicine has been manufactured in accordance with Part 3-3 of the Act;

(c) if a step in the manufacture of the evaluation medicine has been carried out outside Australia—there is evidence that the manufacturing and quality control procedures used in the manufacture of the medicine are acceptable;

(d) no additional information is required to complete the evaluation, other than:

(i) the label and product information for the evaluation medicine; and

(ii) the risk management plan (if any) for the evaluation medicine.

Determining foreign countries or foreign jurisdictions

(3) The Secretary may, in writing published on the Therapeutic Goods Administration website, determine a foreign country or a foreign jurisdiction for the purposes of this regulation.

7 Regulation 16E (heading)

Repeal the heading, substitute:

16E Applications for variations—effect of failure to decide applications within specified period

8 Regulation 16E

Omit "relevant time stated in paragraph 16D(3)(a) or (b)", substitute "period specified in subregulation 16D(3)".

9 Regulation 16F (heading)

Repeal the heading, substitute:

16F Applications for variations—shorter period for deciding applications

10 Regulation 16G (heading)

Repeal the heading, substitute:

16G Applications for registration—shorter period for completing evaluations

11 Subclause 1(1) of Schedule 9 (definition of *generic product*)

Repeal the definition.

12 Schedule 10 (note to Schedule heading)

Repeal the note, substitute:

Note: See regulations 16C, 16D, 16F, 16G and 45.

Schedule 4—Miscellaneous amendments

Part 1—Procedure for amending the current Poisons Standard

Therapeutic Goods Regulations 1990

1 Regulation 42ZCZI (definition of *second closing date*)

Omit "paragraph 42ZCZP(c)", substitute "paragraph 42ZCZP(1)(c)".

2 Regulation 42ZCZP

Omit "As soon", substitute "(1) As soon".

3 Paragraph 42ZCZP(c)

Repeal the paragraph, substitute:

(c) inviting interested persons to make submissions to the Secretary in relation to the interim decision by a date mentioned in the notice as the closing date for submissions (the ***second closing date***); and

4 At the end of regulation 42ZCZP

Add:

(2) The second closing date must be at least 10 business days after publication of the notice.

Part 2—Delegation under the Act

Therapeutic Goods (Medical Devices) Regulations 2002

5 Paragraph 10.6A(c)

Repeal the paragraph, substitute:

(c) Chief Medical Adviser, Health Products Regulation Group;

(d) each position classified as Medical Officer Class 5, Health Products Regulation Group.

Therapeutic Goods Regulations 1990

6 Paragraph 46A(2)(c)

Repeal the paragraph, substitute:

(c) Chief Medical Adviser, Health Products Regulation Group;

(d) each position classified as Medical Officer Class 5, Health Products Regulation Group.

Part 3—Supply of unapproved therapeutic goods

Therapeutic Goods (Medical Devices) Regulations 2002

7 Subparagraph 7.2(1)(b)(ii)

Repeal the subparagraph, substitute:

(ii) a statement in relation to the person is completed in accordance with subregulation (1A);

8 After subregulation 7.2(1)

Insert:

(1A) For the purposes of subparagraph (1)(b)(ii), a statement in relation to the use of an exempt device in or on a person who is a Category A patient must:

(a) be completed by:

(i) the medical practitioner by whom, or at whose direction, the device is used; or

(ii) by a health practitioner acting on behalf of that medical practitioner; and

(b) be in the form approved by the Secretary for the purposes of this paragraph; and

(c) include the following:

(i) the initial letters of the person's given name and surname, and the person's date of birth and sex;

(ii) the diagnosis of the person's condition;

(iii) the expected duration of the treatment;

(iv) a description of the exempt device;

(v) the supplier of the exempt device;

(vi) the number of units of the exempt device to be supplied;

(vii) the treating medical practitioner's name, practising address and other contact details; and

(d) include a statement to the effect that:

(i) the person is a Category A patient; and

(ii) the person, or the person's guardian, has given informed consent to the use of the device in or on the person.

(1B) An approval of a form referred to in paragraph (1A)(b) may require 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.

(1C) A person commits an offence of strict liability if the person:

(a) completes a statement referred to in subparagraph (1)(b)(ii); and

(b) does not send a copy of the statement to the Secretary within 28 days after the use of the exempt device to which the statement relates.

Penalty: 10 penalty units.

9 Regulation 8.2

Repeal the regulation.

10 In the appropriate position in Part 11

Insert:

Division 11.6—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017

11.32 Definitions

In this Division:

Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017*.

commencement day means the day on which Part 3 of Schedule 4 to the Amendment Regulations commences.

11.33 Application—statements in relation to exempt devices

The amendments of regulations 7.2 and 8.2 of these Regulations made by Part 3 of Schedule 4 to the Amendment Regulations apply in relation to the use of a medical device in or on a person on or after the commencement day.

Therapeutic Goods Regulations 1990

11 Subparagraph 12A(2)(a)(iii)

Repeal the subparagraph, substitute:

(iii) a statement in relation to the person, in the form approved by the Secretary for the purposes of this subparagraph, is completed by the medical practitioner by whom, or at whose direction, the medicine or biological is given to the person or by a health practitioner acting on behalf of that medical practitioner; and

12 After subregulation 12A(2)

Insert:

(2A) An approval of a form referred to in subparagraph (2)(a)(iii) may require 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.

13 Subregulation 12A(3)

Omit "signs a statement referred to in subparagraph (2)(a)(iii) in relation to a medicine or biological to be", substitute "completes a statement referred to in subparagraph (2)(a)(iii) in relation to a medicine or biological that is".

14 In the appropriate position in Part 9

Insert:

Division 6—Transitional provisions relating to the Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017

57 Definitions

In this Division:

Amendment Regulations means the *Therapeutic Goods Legislation Amendment (2017 Measures No. 2) Regulations 2017*.

commencement day means the day on which Part 3 of Schedule 4 to the Amendment Regulations commences.

58 Application—statements in relation to unapproved medicines and biologicals

The amendments of regulation 12A of these Regulations made by Part 3 of Schedule 4 to the Amendment Regulations apply in relation to a medicine or a biological given to a person on or after the commencement day.

59 Transitional—approval of form for statements

(1) This regulation applies to the approval of a form if:
  (a) the approval was made for the purposes of subparagraph 12A(2)(a)(iii) of these Regulations; and
  (b) the approval was in force immediately before the commencement day.

(2) The approval has effect, on and after the commencement day, as if it had been made for the purposes of subparagraph 12A(2)(a)(iii) of these Regulations as amended by the Amendment Regulations.

Part 4—Narcotic drugs

Therapeutic Goods Regulations 1990

15 Schedule 5 (table item 6)

Repeal the item, substitute:

6	medicines that are dispensed, or extemporaneously compounded, for a particular person for therapeutic application to that person, other than medicines that are used for gene therapy

16 Schedule 5A (table item 5, column 2, paragraph (a))

Repeal the paragraph, substitute:

(a) the goods are not:
(i) biologicals; or
(ii) goods referred to in item 3; and

17 Schedule 8 (table item 2, column 3, paragraph (a))

Repeal the paragraph, substitute:

(a) the goods are not biologicals; and