Therapeutic Goods Amendment (2018 Measures No. 1) Act 2018

No. 104, 2018

An Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

Note: An electronic version of this Act is available on the Federal Register of Legislation (https://www.legislation.gov.au/)

Contents

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An Act to amend the *Therapeutic Goods Act 1989*, and for related purposes

[*Assented to 21 September 2018*]

The Parliament of Australia enacts:

1 Short title

This Act is the *Therapeutic Goods Amendment (2018 Measures No. 1) Act 2018*.

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.	21 September 2018
2. Schedule 1	The later of: (a) 1 January 2019; and (b) the 28th day after this Act receives the Royal Assent.	1 January 2019 (paragraph (a) applies)
3. Schedule 2, Part 1	The day after this Act receives the Royal Assent.	22 September 2018
4. Schedule 2, Part 2	The 28th day after this Act receives the Royal Assent.	19 October 2018

Note: This table relates only to the provisions of this Act as originally enacted.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Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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—Reporting medicine shortages and discontinuation of supply of medicine

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

reportable medicine has the meaning given by section 30EH.

shortage of a medicine in Australia has the meaning given by section 30EI.

2 After Division 2A of Part 3-2

Insert:

Division 2B—Reporting medicine shortages and discontinuation of supply of medicine

30EF Reporting medicine shortages

(1) A person in relation to whom a reportable medicine is included in the Register must notify the Secretary of any shortage of the medicine in Australia. The person must do so:

(a) for a shortage that has a critical impact—as soon as possible, but no later than 2 working days, after the first day the person knows, or ought reasonably to have known, of the shortage; or

(b) in any other case—before the end of 10 working days beginning on the first day the person knows, or ought reasonably to have known, of the shortage.

Note: For ***reportable medicine***, see section 30EH. For ***shortage*** of a medicine in Australia, see section 30EI.

Critical impact

(2) The shortage of a medicine in Australia at a particular time has a ***critical impact*** if, at that time, the medicine is included in an instrument under section 30EJ.

(3) The shortage of a medicine in Australia at a particular time also has a ***critical impact*** if:

(a) either:

(i) at that time, there are no registered goods that could reasonably be used as a substitute for the medicine; or

(ii) at that time, there are other registered goods that could reasonably be used as a substitute for the medicine but the other registered goods are not likely to be available in sufficient quantities to meet the demand for the other registered goods that is likely to arise because of the shortage; and

(b) the shortage has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

Notification requirements

(4) A notification under subsection (1) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain the information required by that form.

(5) An approval of a form 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.

Civil penalty

(6) A person contravenes this subsection if:

(a) the person is subject to a requirement under subsection (1); and

(b) the person contravenes the requirement.

Maximum civil penalty:

(a) for an individual—100 penalty units; and
(b) for a body corporate—1,000 penalty units.

Exception

(7) Subsection (6) does not apply if:
(a) paragraph (1)(a) and subsection (3) apply in relation to the shortage but subsection (2) does not; and
(b) as a result of steps taken by the person, it was reasonable for the person to assume that paragraph (1)(b) applied in relation to the shortage; and
(c) the person complied with paragraph (1)(b) in relation to the shortage.

30EG Reporting discontinuation of supply of medicine

(1) A person in relation to whom a reportable medicine is included in the Register must notify the Secretary of any decision (the ***discontinuation decision***) of the person to permanently discontinue the supply of the medicine in Australia. The person must do so:
(a) if the discontinuation is likely to be of critical impact:
(i) at least 12 months before the discontinuation is proposed to occur; or
(ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made; or
(b) in any other case:
(i) at least 6 months before the discontinuation is proposed to occur; or
(ii) if the person is unable to comply with subparagraph (i)—as soon as practicable after the decision is made.

Note: For ***reportable medicine***, see section 30EH.

Critical impact

(2) The discontinuation of the supply of a medicine in Australia is likely to be of ***critical impact*** if, when the discontinuation decision is made, the medicine is included in an instrument under section 30EJ.

(3) The discontinuation of the supply of a medicine in Australia is also likely to be of ***critical impact*** if:

(a) either:

(i) when the discontinuation decision is made, there are no registered goods that could reasonably be used as a substitute for the medicine; or

(ii) when the discontinuation decision is made, there are other registered goods that could reasonably be used as a substitute for the medicine but the other registered goods are not likely to be available in sufficient quantities to meet the demand for the other registered goods that is likely to arise because of the discontinuation; and

(b) the discontinuation has the potential to have a life-threatening impact on, or a serious impact on the physical or mental health or functioning of, persons who take, or who may need to take, the medicine.

Notification requirements

(4) A notification under subsection (1) must:

(a) be in accordance with a form that is approved, in writing, by the Secretary; and

(b) contain the information required by that form.

(5) An approval of a form 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.

Civil penalty

(6) A person contravenes this subsection if:

(a) the person is subject to a requirement under subsection (1); and

(b) the person contravenes the requirement.

Maximum civil penalty:

(a) for an individual—100 penalty units; and

(b) for a body corporate—1,000 penalty units.

Exception

(7) Subsection (6) does not apply if:

(a) paragraph (1)(a) and subsection (3) apply in relation to the discontinuation but subsection (2) does not; and

(b) as a result of steps taken by the person, it was reasonable for the person to assume that paragraph (1)(b) applied in relation to the discontinuation; and

(c) the person complied with paragraph (1)(b) in relation to the discontinuation.

30EH What is a reportable medicine?

(1) For the purposes of this Act, registered goods are a ***reportable medicine*** if:

(a) the goods are medicine; and

(b) either:

(i) the medicine contains one or more substances included in Schedule 4 or 8 to the current Poisons Standard; or

(ii) the medicine is determined in an instrument under subsection (2).

(2) The Minister may, by legislative instrument, determine medicine for the purposes of subparagraph (1)(b)(ii).

(3) The Minister must not determine a medicine unless the Minister is satisfied of either or both of the following:

(a) the medicine is critical to the health of patients in Australia;

(b) the notification to the Secretary of any shortage of the medicine, or of any decision to permanently discontinue the supply of the medicine, in Australia would be in the interests of public health.

30EI When is there a medicine shortage?

For the purposes of this Act, there is a ***shortage*** of a medicine in Australia at a particular time if, at any time in the 6 months after that particular time, the supply of that medicine in Australia will not, or will not be likely to, meet the demand for the medicine for all of the patients in Australia who take, or who may need to take, the medicine.

30EJ Medicines Watch List

(1) The Minister may, by legislative instrument, determine medicine for the purposes of subsections 30EF(2) and 30EG(2).

(2) The Minister must not determine a medicine unless the Minister is satisfied that any shortage of the medicine, or any permanent discontinuation of the supply of the medicine, in Australia has the potential to result in:

(a) significant morbidity in patients in Australia; or

(b) the death of one or more patients in Australia.

3 After paragraph 31(1)(j)

Insert:

(ja) if the goods are a reportable medicine and the medicine is registered in relation to the person:

(i) whether or not there is a shortage of the medicine in Australia; or

(ii) if there is a shortage of the medicine in Australia—the shortage; or

(iii) any decision of the person to permanently discontinue the supply of the medicine in Australia;

4 Application provisions

(1) Section 30EF of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to a shortage of a medicine in Australia that arises on or after the commencement of this item, whether the medicine was included in the Register before, on or after that commencement.

(2) Section 30EG of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to a decision to permanently discontinue the supply of a medicine in Australia that is made on or after the commencement of this item, whether the medicine was included in the Register before, on or after that commencement.

Schedule 2—Other amendments

Part 1—Amendments commencing day after Royal Assent

Therapeutic Goods Act 1989

1 After subsection 9D(2C)

Insert:

(2D) Subsection (2C), to the extent that it relates to therapeutic goods that are registered, applies despite subsection 16(1).

2 At the end of section 10

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.

3 After subsection 19(7G)

Insert:

(7GA) Subsection (7F) does not apply in relation to a person and a requirement to notify a supply of therapeutic goods if a health practitioner, on behalf of the person, does the following:

(a) notifies the supply to the Secretary within 28 days after the supply;

(b) makes the notification in accordance with the requirements referred to in subsection (7D).

Note: A defendant bears an evidential burden in relation to the matter in subsection (7GA): see subsection 13.3(3) of the *Criminal Code*.

4 At the end of subsection 25AAA(3)

Add:

; (e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

5 After subsection 32CM(7G)

Insert:

(7GA) Subsection (7F) does not apply in relation to a person and a requirement to notify a supply of a biological if a health practitioner, on behalf of the person, does the following:

(a) notifies the supply to the Secretary within 28 days after the supply;

(b) makes the notification in accordance with the requirements referred to in subsection (7D).

Note: A defendant bears an evidential burden in relation to the matter in subsection (7GA): see subsection 13.3(3) of the *Criminal Code*.

6 At the end of subsection 32DEA(3)

Add:

; (e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

7 At the end of subsection 41ECA(3)

Add:

; (e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

8 At the end of subsection 41FKA(3)

Add:

; (e) empowering the Secretary to give the applicant a written notice requiring the applicant to give to the Secretary specified information or documents in connection with the

application within a specified period (which must be at least 10 working days after the notice is given to the applicant).

9 Subsection 41FN(1)

After "kind of device is included in the Register", insert "will".

10 After subsection 41HC(6F)

Insert:

(6FA) Subsection (6E) does not apply in relation to a person and a requirement to notify a supply of a medical device if a health practitioner, on behalf of the person, does the following:

(a) notifies the supply to the Secretary within 28 days after the supply;

(b) makes the notification in accordance with the requirements referred to in subsection (6C).

Note: A defendant bears an evidential burden in relation to the matter in subsection (6FA): see subsection 13.3(3) of the *Criminal Code*.

11 Section 42BAA

Before "The", insert "(1)".

12 At the end of section 42BAA

Add:

(2) Despite subsection 14(2) of the *Legislation Act 2003*, an instrument under subsection (1) of this section 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.

13 Application and transitional provisions

(1) The amendment of section 19 of the *Therapeutic Goods Act 1989* made by this Part applies in relation to the supply of therapeutic goods on or after the commencement of this item.

(2) The amendment of section 32CM of the *Therapeutic Goods Act 1989* made by this Part applies in relation to the supply of a biological on or after the commencement of this item.

(3) The amendment of section 41HC of the *Therapeutic Goods Act 1989* made by this Part applies in relation to the supply of a medical device on or after the commencement of this item.

(4) An instrument in force under section 42BAA of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continues in force on and after that commencement as if it were an instrument in force under subsection 42BAA(1) of that Act.

Part 2—Amendments commencing 28th day after Royal Assent

Therapeutic Goods Act 1989

14 Section 42DE

Repeal the section, substitute:

42DE Applications for approval of use of restricted representation

(1) An application for approval of the use of a restricted representation must be made to the Secretary in accordance with a form approved, in writing, by the Secretary.

(2) An approval of a form may require or permit an application 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.

15 Application provision

The repeal and substitution of section 42DE of the *Therapeutic Goods Act 1989* made by this Part applies in relation to applications made on or after the commencement of this item.

[*Minister's second reading speech made in—*
House of Representatives on 28 June 2018
Senate on 20 August 2018]

(143/18)