



Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023

No. 10, 2023

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

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No. 10, 2023

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

[Assented to 21 March 2023]

The Parliament of Australia enacts:

1 Short title

This Act is the *Therapeutic Goods Amendment (2022 Measures No. 1) Act 2023*.

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 March 2023
2. Schedule 1	A single day to be fixed by Proclamation. However, if the provisions do not commence within the period of 24 months beginning on the day this Act receives the Royal Assent, they commence on the day after the end of that period.	21 March 2025
3. Schedule 2	The day after the end of the period of 3 months beginning on the day this Act receives the Royal Assent.	21 June 2023
4. Schedules 3 to 10	The day after this Act receives the Royal Assent.	22 March 2023
5. Schedule 11	The day after the end of the period of 6 months beginning on the day this Act receives the Royal Assent.	21 September 2023
6. Schedule 12	The day after this Act receives the Royal Assent.	22 March 2023

Note: This table relates only to the provisions of this Act as originally enacted.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Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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—Mandatory reporting of adverse events involving medical devices

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

healthcare facility means:

- (a) a public hospital; or
- (b) a private hospital; or
- (c) any other facility prescribed by regulations made for the purposes of this paragraph.

hospital has the meaning given by subsection 121-5(5) of the *Private Health Insurance Act 2007*.

private hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007* that the hospital is a private hospital.

public hospital means a hospital in respect of which there is in force a statement under subsection 121-5(8) of the *Private Health Insurance Act 2007* that the hospital is a public hospital.

reportable medical device means a medical device of a kind prescribed by regulations made for the purposes of this definition.

2 Subsection 6(1)

After “other than”, insert “Part 4-8A or”.

3 At the end of subsection 6(1)

Add:

Note: Part 4-8A is about mandatory reporting, by healthcare facilities, of adverse events involving medical devices.

4 After Part 4-8

Insert:

Part 4-8A—Mandatory reporting of adverse events by healthcare facilities

Division 1—Preliminary

41JK Simplified outline of this Part

The chief executive officer (however described) of a healthcare facility is required to give a report to the Secretary about an adverse event involving a reportable medical device in certain circumstances.

Civil penalties apply to the chief executive officer of a healthcare facility for failing to give such a report to the Secretary.

41JL Purposes of this Part

The purposes of this Part are to facilitate the following:

- (a) monitoring and enforcing compliance with the requirements of this Chapter;
- (b) monitoring the safety and performance of medical devices;
- (c) any activities that are incidental to the above purposes.

Division 2—Mandatory reporting of adverse events

41JM Requirement to report adverse events involving reportable medical devices

Report to be given to the Secretary

- (1) The chief executive officer (however described) of a healthcare facility must give a report to the Secretary if subsection (2), (3) or (4) applies to the healthcare facility in relation to a reportable medical device and a person.
- (2) This subsection applies to a healthcare facility if:
 - (a) a reportable medical device is used in the facility; and

- (b) the use of the device has resulted in the death, or a serious deterioration in the health, of a person while the device is used in the facility.
- (3) This subsection applies to a healthcare facility if:
 - (a) a reportable medical device is not used in the facility because of the intervention of a person in the facility; and
 - (b) the use of the device, if the device were used, would result in, or would be likely to result in, the death, or a serious deterioration in the health, of a person.
- (4) This subsection applies to a healthcare facility if:
 - (a) a health practitioner provides treatment to a person in the facility for a serious deterioration in the health of the person; and
 - (b) the use of a reportable medical device has resulted in the serious deterioration in the health of the person.

Report requirements

- (5) The report must include the following information about the reportable medical device and the person:
 - (a) the name, or a description, of the reportable medical device;
 - (b) a description of the matters covered in subsection (2), (3) or (4);
 - (c) any other information prescribed by regulations made for the purposes of this paragraph.

Note: For the release of information included in, or relating to, a report, see section 61.

- (6) The report must be given to the Secretary:
 - (a) within the period prescribed by regulations made for the purposes of this subparagraph or such longer period as the Secretary allows in a particular case; and
 - (b) in the manner prescribed by regulations made for the purposes of this subparagraph.

Exception

- (7) Subsection (1) does not apply if the chief executive officer (however described) of the healthcare facility has reported the matters covered by subsection (2), (3) or (4) to:
- (a) the chief executive officer of the Australian Commission on Safety and Quality in Health Care; or
 - (b) the head (however described) of a Department of State of a State or Territory that has responsibility for matters relating to health; or
 - (c) any other person prescribed by regulations made for the purposes of this paragraph.

Civil penalty

- (8) A person contravenes this subsection if:
- (a) the person is required to give a report to the Secretary in accordance with this section; and
 - (b) the person fails to comply with the requirement.

Maximum civil penalty: 30 penalty units.

5 Application provision

Section 41JM of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to:

- (a) a reportable medical device that is used, on or after the commencement of this Schedule, in a healthcare facility; or
- (b) a reportable medical device that is not used in a healthcare facility because of the intervention, on or after that commencement, of a person in the facility; or
- (c) treatment provided, on or after that commencement, by a health practitioner to a person in a healthcare facility for a serious deterioration in the health of the person.

Schedule 2—Export only biologicals

Therapeutic Goods Act 1989

1 Subsection 3(1) (paragraph (a) of the definition of *biological number*)

After “32DB(2),”, insert “32DCB(2),”.

2 Subsection 3(1) (definition of *Class 1 biological*)

After “biological”, insert “, other than an export only biological,”.

3 Subsection 3(1)

Insert:

export only biological means a biological that is:

- (a) manufactured in Australia for export only; or
- (b) imported into Australia for export only.

4 Paragraph 9(1)(aa)

After “Class 1 biological”, insert “or an export only biological”.

5 Paragraph 9A(4)(ca)

After “32DB(2),”, insert “32DCB(2),”.

6 Section 32D

Repeal the section, substitute:

32D Simplified outline of this Division

A Class 1 biological can be included in the Register if a proper application is made and the applicant certifies various matters (see Subdivision B).

An export only biological can be included in the Register if a proper application is made, the applicant certifies various matters and, if steps in the manufacture of the biological have been carried

out outside Australia, the Secretary has certified (where appropriate) that the manufacturing and quality control procedures used in those steps are acceptable (see Subdivision BA).

A biological, other than a Class 1 biological or an export only biological, can be included in the Register if a proper application is made and the Secretary is satisfied the biological is suitable for inclusion following an evaluation of the biological (see Subdivision C).

7 After Subdivision B of Division 4 of Part 3-2A

Insert:

Subdivision BA—Export only biologicals

32DCA Application for inclusion in the Register

Application

- (1) A person may make an application to the Secretary to include an export only biological in the Register.
- (2) The application must:
 - (a) be made in accordance with a form that is approved, in writing, by the Secretary; and
 - (b) be accompanied by a statement made by the applicant certifying the matters mentioned in subsection (4); and
 - (c) be accompanied by the fee prescribed by regulations made for the purposes of this paragraph.
- (3) 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.

Certification of matters

- (4) The matters the applicant must certify are:
 - (a) that the biological is an export only biological; and

- (b) that the biological is safe for the purposes for which it is to be used; and
- (c) that the presentation of the biological is not unacceptable; and
- (d) that the biological conforms to every standard (if any) applicable to it; and
- (e) that the requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations are complied with in relation to the biological; and
- (f) that the biological complies with all prescribed quality or safety criteria that are applicable to it; and
- (g) that all the manufacturers of the biological are nominated as manufacturers in the application; and
- (h) if a step in the manufacture of the biological has been carried out in Australia—that the biological is exempt from the operation of Part 3-3 or that the step has been carried out by a person who:
 - (i) is the holder of a licence to carry out that step; or
 - (ii) is exempt from the operation of that Part in relation to that step; and
- (i) that the biological does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and
- (j) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3):
 - (i) if those prohibitions cover imports—that any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (ii) if those prohibitions cover exports—that any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
- (k) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions:
 - (i) if those prohibitions cover imports—that any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and

- (ii) if those prohibitions cover exports—that any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and
- (l) any other matter prescribed by regulations made for the purposes of this paragraph.

Manufacturing steps outside Australia

- (5) Subject to subsection (7), if one or more steps in the manufacture of the biological have been carried out outside Australia, the Secretary must certify, or refuse to certify, that the manufacturing and quality control procedures used in each such step are acceptable.

Note: See also subsections 32EA(5), (7A) and (7B) and section 32EB in relation to conditions and certifications for the manufacture of a biological outside Australia after the biological is included in the Register.

- (6) In deciding whether so to certify for the purposes of subsection (5), the matters that may be taken into account include:
- (a) whether the applicant has provided:
 - (i) if a step in the manufacture of the biological has been carried out in a country that is a member of the European Community or a member of EFTA—an EC/EFTA attestation of conformity in relation to the biological; or
 - (ii) if a step in the manufacture of the biological has been carried out in a country declared by the Minister under section 3B to be covered by a non-EC/EFTA MRA—a non-EC/EFTA attestation of conformity, for the non-EC/EFTA MRA, in relation to the biological; or
 - (iii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the biological is of an acceptable standard; and
 - (b) whether the applicant has agreed to provide, if the Secretary considers inspection of the manufacturing procedures used in the manufacture of the biological to be necessary:
 - (i) funds for the carrying out of that inspection by, or on behalf of, the Secretary; and

- (ii) evidence that the manufacturer has agreed to such an inspection; and
 - (c) whether the applicant has complied with any requirements made by the Secretary under section 32JA in relation to the manufacture of the biological.
- (7) If:
 - (a) one or more steps in the manufacture of the biological have been carried out outside Australia; and
 - (b) had the biological been manufactured in Australia, it would have been exempt from the operation of Part 3-3 because of the operation of subsection 34(1);subsection (5) of this section does not apply in relation to those steps.

32DCB Inclusion of export only biological in the Register

Secretary must include biological in Register

- (1) The Secretary must include an export only biological in the Register in relation to a person if:
 - (a) an application is made under subsection 32DCA(1) for the biological to be included in the Register in relation to the person; and
 - (b) the application complies with subsection 32DCA(2); and
 - (c) if one or more steps in the manufacture of the biological have been carried out outside Australia and the Secretary is required to make a decision under subsection 32DCA(5)—the Secretary has certified, under that subsection, that the manufacturing and quality control procedures used in each such step are acceptable.

Biological number

- (2) If the Secretary includes the biological in the Register, the Secretary must assign a unique number to the biological. The number assigned may be any combination of numbers and either or both of letters and symbols.

Note: The number assigned is the biological number of the biological.

Certificate

- (3) As soon as practicable after the biological has been included in the Register, the Secretary must give to the applicant a certificate of the inclusion of the biological in the Register.
- (4) The certificate must:
 - (a) specify the biological number of the biological; and
 - (b) specify the day on which the inclusion of the biological in the Register commences.

Duration of inclusion in the Register

- (5) The biological remains included in the Register in relation to the person until the Secretary cancels the entry of the biological from the Register under this Part.

Note: The biological is taken not to be included in the Register while it is suspended: see section 32FD.

32DCC Refusal to include export only biological in the Register

If:

- (a) a person makes an application under subsection 32DCA(1) to include an export only biological in the Register; and
 - (b) the Secretary refuses the application;
- the Secretary must, as soon as practicable after the refusal, give the person notice of the refusal and of the reasons for the refusal.

8 Subdivision C of Division 4 of Part 3-2A (heading)

Repeal the heading, substitute:

Subdivision C—Biologicals other than Class 1 biologicals or export only biologicals**9 Section 32DD**

After “Class 1 biological”, insert “or an export only biological”.

10 Subsection 32EA(7)

Omit “the evaluation”, substitute “any evaluation”.

11 After subsection 32EA(7)

Insert:

(7A) Paragraph (5)(b) does not apply in relation to a step that:

- (a) is the subject of a certification in force under subsection 32DCA(5); or
- (b) was not required to be the subject of a decision under that subsection because of subsection 32DCA(7).

(7B) Paragraph (7A)(a) ceases to apply in relation to that step if either or both of the following occur:

- (a) that step begins to be carried out at premises that are different from the premises in respect of which that certification was given;
- (b) that step begins to be carried out by a manufacturer that is different from the manufacturer in respect of which that certification was given.

12 After subsection 32GA(1)

Insert:

(1AA) Paragraph (1)(k) does not apply to export only biologicals.

13 Paragraph 32GB(1)(b)

After “32DA(3)”, insert “or 32DCA(4)”.

Schedule 3—Decisions to give information gathering notices are not reviewable decisions

Therapeutic Goods Act 1989

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

Repeal the paragraph.

2 After subsection 60(1)

Insert:

- (1AA) A decision under a provision of this Act to give a notice to a person requiring the person to give information, or give or produce documents, to the Secretary is not an initial decision for the purposes of this section.

3 Application provision

The amendments made by this Schedule apply in relation to a notice given on or after the commencement of this item.

Schedule 4—Extension of time to pay amount under infringement notice

Therapeutic Goods Act 1989

1 Section 42YKB

Repeal the section, substitute:

42YKB Extension of time to pay amount—application by person

- (1) A person to whom an infringement notice has been given may apply to the Secretary for an extension of the period (the *current period*) for paying the amount stated in the notice.

Note: The current period for paying the amount may be the 28-day period referred to in paragraph 42YKA(1)(h) or an extended period under this section or section 42YKBA.
- (2) If the application is made before the end of the current period, the Secretary may, in writing, extend that period. The Secretary may do so before or after the end of that period.
- (3) For the purposes of this Part, if the Secretary extends the current period, the period within which the amount stated in the notice is to be paid is the extended period.
- (4) For the purposes of this Part, if the Secretary does not extend the current period, the period within which the amount stated in the notice is to be paid is the period that ends at the end of the later of the following days:
 - (a) the day that is the last day of the current period;
 - (b) the day that is 7 days after the day the person was given notice of the Secretary's decision not to extend.
- (5) The Secretary may give more than one extension under this section in relation to the infringement notice.

42YKBA Extension of time to pay amount—extension by Secretary on own initiative

- (1) If the Secretary gives a person an infringement notice, the Secretary may, on the Secretary's own initiative and in writing, extend the period for paying the amount stated in the notice. The Secretary may do so before or after the end of that period.

Note: The period for paying the amount may be the 28-day period referred to in paragraph 42YKA(1)(h) or an extended period under section 42YKB or this section.

- (2) For the purposes of this Part, if the Secretary extends that period, the period within which the amount stated in the notice is to be paid is the extended period.
- (3) The Secretary must give the person notice of the Secretary's decision.
- (4) The Secretary may give more than one extension under this section in relation to the infringement notice.

2 Subsection 42YKD(1)

Omit "referred to in paragraph 42YKA(1)(h)", substitute "within which the amount is to be paid".

3 Application provision

The amendments made by this Schedule apply in relation to the following:

- (a) an infringement notice given on or after the commencement of this item;
- (b) an infringement notice given before that commencement, where the period within which the amount stated in the notice is to be paid had not ended before that commencement.

Schedule 5—Information gathering powers

Therapeutic Goods Act 1989

1 Subsection 6(1)

After “This Act”, insert “(other than Part 6-1A)”.

2 After Part 6-1

Insert:

Part 6-1A—Information gathering powers

Division 1—Preliminary

45AA Simplified outline of this Part

The Secretary can gather information or documents that are relevant to a contravention or possible contravention of this Act or the regulations.

Division 2—Obtaining information or documents

45AB Secretary may require information or documents

- (1) The Secretary may, by written notice given to a person, require the person to give to the Secretary any information, or produce to the Secretary any documents, specified in the notice that are relevant to a contravention, or possible contravention, of a provision of this Act or the regulations.
- (2) The notice must specify a reasonable period within which the person must comply with the notice. The period must be at least 14 days starting on the day on which the notice is given.
- (3) The notice must set out the effect of the following:
 - (a) section 45AC (about failure to comply with notice);

-
- (b) section 45AD (about giving false or misleading information or documents);
 - (c) section 137.1 of the *Criminal Code* (about giving false or misleading information);
 - (d) section 137.2 of the *Criminal Code* (about producing false or misleading documents).
- (4) The notice may require the information to be given, or the documents to be produced, 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.

45AC Offences for failing to comply with notice

Fault-based offence

- (1) A person commits an offence if:
- (a) the person is given a notice under section 45AB; and
 - (b) the person fails to comply with the notice.

Penalty: 500 penalty units.

Strict liability offence

- (2) A person commits an offence of strict liability if:
- (a) the person is given a notice under section 45AB; and
 - (b) the person fails to comply with the notice.

Penalty: 100 penalty units.

Exception

- (3) Subsection (1) or (2) does not apply if the person has a reasonable excuse.

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

45AD Offences and civil penalty for giving false or misleading information or documents

Fault-based offence

- (1) A person commits an offence if:
- (a) the person is given a notice under section 45AB; and
 - (b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
 - (c) the information or document is false or misleading in a material particular.

Note: For the liability of an executive officer of a body corporate, see sections 54B and 54BA.

Penalty: Imprisonment for 12 months or 1,000 penalty units, or both.

Strict liability offence

- (2) A person commits an offence of strict liability if:
- (a) the person is given a notice under section 45AB; and
 - (b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
 - (c) the information or document is false or misleading in a material particular.

Penalty: 100 penalty units.

Civil penalty provision

- (3) A person contravenes this subsection if:
- (a) the person is given a notice under section 45AB; and
 - (b) the person gives information, or produces a document, in compliance or purported compliance with the notice; and
 - (c) the information or document is false or misleading in a material particular.

Maximum civil penalty:

- (a) for an individual—5,000 penalty units; and
- (b) for a body corporate—50,000 penalty units.

45AE Self-incrimination

- (1) An individual is not excused from giving information or producing a document under section 45AB on the ground that giving the information or producing the document might tend to incriminate the individual in relation to an offence.

Note: A body corporate is not entitled to claim the privilege against self-incrimination.

- (2) However:
- (a) the information given or document produced; and
 - (b) the giving of the information or the production of the document; and
 - (c) any information, document or thing obtained as a direct or indirect consequence of the giving of the information or the production of the document;
- are not admissible in evidence against the individual in criminal proceedings other than proceedings for an offence against:
- (d) subsection 45AC(1) or (2); or
 - (e) subsection 45AD(1) or (2); or
 - (f) section 137.1 or 137.2 of the *Criminal Code* in relation to giving the information or producing the document.

- (3) If, at general law, an individual would otherwise be able to claim the privilege against self-exposure to a penalty (other than a penalty for an offence) in relation to giving information or producing a document under section 45AB, the individual is not excused from giving the information or producing the document under that provision on that ground.

Note: A body corporate is not entitled to claim the privilege against self-exposure to a penalty.

Division 3—Inspecting, copying and retaining documents**45AF Secretary may inspect and copy documents**

The Secretary may inspect a document produced under section 45AB and make and retain copies of the whole or a part of the document.

45AG Secretary may retain documents

Retention of documents

- (1) The Secretary may take possession of a document produced under section 45AB and retain it for as long as is reasonably necessary.

Certified copy of documents

- (2) The person otherwise entitled to possession of a document produced under section 45AB is entitled to be supplied, as soon as practicable, with a copy certified by the Secretary to be a true copy.
- (3) The certified copy must be received in all courts and tribunals as evidence as if it were the original.
- (4) Until a certified copy is supplied, the Secretary must provide the person otherwise entitled to possession of the document, or a person authorised by that person, reasonable access to the document for the purposes of inspecting and making copies of the whole or a part of the document.

3 Section 54BA (after table item 47)

Insert:

47A Subsection 45AD(1)

4 Application provision

Part 6-1A of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to notices given under section 45AB of that Act on or after the commencement of this item, whether the contravention, or possible contravention, mentioned in that section occurs before, on or after that commencement.

Schedule 6—Retention of seized things

Therapeutic Goods Act 1989

1 Section 48H

Omit “90” (wherever occurring), substitute “120”.

2 Paragraph 48J(1)(a)

Omit “90”, substitute “120”.

3 Application provision

The amendments made by this Schedule apply in relation to things seized, under Part 6-2 of the *Therapeutic Goods Act 1989*, on or after the commencement of this item.

Schedule 7—Reducing regulatory burden for therapeutic goods advertisers

Therapeutic Goods Act 1989

1 Paragraph 42AA(1)(a)

Repeal the paragraph, substitute:

- (a) health practitioners; or
- (aa) persons who, under a law of a State or internal Territory, are registered or licensed to practice in any of the following health professions:
 - (i) chiropractic;
 - (ii) dental therapy, dental hygiene, dental prosthetics or oral health therapy;
 - (iii) osteopathy;
 - (iv) paramedicine; or

2 After subparagraph 42AA(1)(b)(ii)

Insert:

- (iii) purchasing therapeutic goods on behalf of a registered charity; or
- (iv) purchasing therapeutic goods on behalf of a government or government authority (including a foreign government or foreign government authority); or
- (v) purchasing officers, or practice managers, for a person mentioned in paragraph (a) or (aa) (other than a person in a retail pharmacy who, under a law of a State or internal Territory, is registered or licensed to practice in the health profession of pharmacy); or

3 Paragraph 42AA(1)(c)

Omit “, practitioners of traditional Chinese medicine or podiatrists”, substitute “or practitioners of traditional Chinese medicine”.

4 Subsection 42AA(4)

After “paragraph (1)(a)”, insert “, (aa)”.

5 Section 42B

Insert:

registered charity means an entity that is registered under the *Australian Charities and Not-for-profits Commission Act 2012* as the type of entity mentioned in column 1 of item 1 of the table in subsection 25-5(5) of that Act.

6 Application provision

The amendments made by this Schedule apply in relation to advertisements occurring on or after the commencement of this item.

Schedule 8—Use of restricted representations

Therapeutic Goods Act 1989

1 Subparagraph 42DI(1)(b)(i)

After “safety”, insert “or efficacy”.

2 Application provision

The amendment made by this Schedule applies in relation to approvals given on or after the commencement of this item.

Schedule 9—Approval of importation or supply of substitutable medicine

Therapeutic Goods Act 1989

1 Subparagraphs 19A(1)(c)(i), (1A)(e)(i) and (2)(c)(i)

Omit “of the Therapeutic Goods Regulations”, substitute “to the *Therapeutic Goods Regulations 1990*”.

2 After subsection 19A(2)

Insert:

- (2A) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods (the ***subject goods***) if the Secretary is satisfied:
- (a) that there are no registered goods that could act as a substitute for the subject goods; and
 - (b) either:
 - (i) that previously registered goods could act as a substitute for the subject goods; or
 - (ii) that therapeutic goods whose registration is suspended under section 29D could act as a substitute for the subject goods; and
 - (c) that the subject goods are registered or approved for general marketing in at least one foreign country specified by the Secretary in a determination under subsection (3); and
 - (d) that the subject goods are of a kind included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; and
 - (e) that the approval is necessary in the interests of public health.
- (2B) The Secretary may, by notice in writing, grant an approval to a person for the importation into Australia, or the supply in Australia, of specified therapeutic goods (the ***subject goods***) if the Secretary is satisfied:
- (a) that there are no registered goods that could act as a substitute for the subject goods; and

- (b) either:
 - (i) that previously registered goods could act as a substitute for the subject goods; or
 - (ii) that therapeutic goods whose registration is suspended under section 29D could act as a substitute for the subject goods; and
- (c) that all of the following apply:
 - (i) the subject goods are not registered or approved for general marketing in any of the foreign countries specified by the Secretary in a determination under subsection (3);
 - (ii) the subject goods are registered or approved for general marketing in at least one foreign country that is not specified by the Secretary in a determination under subsection (3);
 - (iii) the manufacturing and quality control procedures used in the manufacture of the subject goods are acceptable; and
- (d) that the subject goods are of a kind included in Schedule 10 to the *Therapeutic Goods Regulations 1990*; and
- (e) that the approval is necessary in the interests of public health.

3 Subsection 19A(3)

Repeal the subsection, substitute:

- (3) The Secretary may make written determinations specifying foreign countries for the purposes of this section.

4 Paragraph 19A(9)(a)

Omit “or paragraph (2)(a), (b), (ba), (c) or (d)”, substitute “paragraph (2)(a), (b), (ba), (c) or (d), paragraph (2A)(a), (b), (c), (d) or (e) or paragraph (2B)(a), (b), (c), (d) or (e)”.

5 Subsection 19A(11)

Omit “or (2)”, substitute “, (2), (2A) or (2B)”.

6 Subsection 31BA(1)

Omit “or (2)”, substitute “, (2), (2A) or (2B)”.

7 Paragraph 52G(3)(e)

Omit “or (2)”, substitute “, (2), (2A) or (2B)”.

8 Saving provision

A determination that was in force under subsection 19A(3) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continues in force (and may be dealt with) on and after that commencement as if it had been made under that subsection as substituted by this Schedule.

Schedule 10—Release of information

Therapeutic Goods Act 1989

1 At the end of section 61

Add:

- (13) The Secretary is not required to observe any requirements of the natural justice hearing rule in relation to:
 - (a) releasing information under subsection (5C) if:
 - (i) the release of the information is in the interests of public health or safety; or
 - (ii) the information relates to the safety of one or more therapeutic goods; or
 - (b) releasing information under any other provision of this section.
- (14) Subsection (13) is not to be taken to imply that the natural justice hearing rule applies in relation to any other exercise of power under this Act (including this section) or the regulations.
- (15) For the purposes of subparagraph (13)(a)(i), the release of information is not in the interests of public health or safety if the information:
 - (a) relates to the quality or efficacy of therapeutic goods; and
 - (b) does not relate to the safety of the therapeutic goods.

2 Application provision

The amendment made by this Schedule applies in relation to the release of information on or after the commencement of this item, whether the information started to be held, or was obtained, before, on or after that commencement.

Schedule 11—Reporting medicine shortages

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

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

2 Subsection 30EF(1)

After “any shortage of the medicine in Australia”, insert “at a particular time”.

3 Paragraph 30EF(1)(a)

After “critical impact”, insert “at that time”.

4 After paragraph 30EF(4)(a)

Insert:

(aa) specify the period of the shortage of the medicine in Australia; and

5 Paragraph 30EF(4)(b)

Omit “the”, substitute “any other”.

6 At the end of subsection 30EF(4)

Add:

Note: For *period* of a shortage of a medicine in Australia, see section 30EIA.

7 Subsection 30EF(7) (heading)

Repeal the heading, substitute:

Exceptions

8 At the end of section 30EF

Add:

- (8) A person is not subject to a requirement under subsection (1), in relation to a shortage (the **relevant shortage**) of a medicine in Australia at a particular time, if:
- (a) the person has complied with the requirement under subsection (1) in relation to a shortage (the **notified shortage**) of the same medicine at an earlier time; and
 - (b) the period of the shortage of the medicine in respect of the notified shortage (including any change to that period) is the same as the period of the shortage of the medicine in respect of the relevant shortage.

Example: There is a shortage of a medicine in Australia on 1 January 2024 because, at a time in the 6 months after that day, the supply of the medicine in Australia will not meet demand for the medicine (see section 30EI). The period of the shortage of the medicine will start on 1 March 2024 and end on 31 March 2024 (see section 30EIA).

The person in relation to whom the medicine is included in the Register has notified the Secretary of the shortage under this section.

On 1 February 2024 the period of the shortage of the medicine changes to a period that will start on 1 May 2024 and end on 31 May 2024.

The person must notify the change to the period of the shortage (see subsection 30EFA(1)). The person is not required to notify, under this section, of another shortage of the same medicine in respect of that same period starting on 1 May 2024 and ending on 31 May 2024.

9 After section 30EF

Insert:

30EFA Reporting changes to the period of a medicine shortage and resolution of a medicine shortage

Reporting changes to the period of a shortage

- (1) A person who has notified the period of a shortage of a medicine in Australia in accordance with section 30EF or this section must notify the Secretary of any change to that period. The person must do so:
- (a) if the shortage was first required to be notified in accordance with paragraph 30EF(1)(a)—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 change to that period; 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 change to that period.

Reporting the resolution of a shortage

- (2) A person who has notified the period of a shortage of a medicine in Australia in accordance with section 30EF or this section must notify the Secretary of any resolution of the shortage. The person must do so:
 - (a) if the shortage was first required to be notified in accordance with paragraph 30EF(1)(a)—as soon as possible, but no later than 2 working days, after the first day the person knows, or ought reasonably to have known, that the period of the shortage has ended; 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, that the period of the shortage has ended.

Notification requirements

- (3) A notification under subsection (1) or (2) must:
 - (a) be in accordance with a form that is approved, in writing, by the Secretary; and
 - (b) for a notification under subsection (1)—specify the period of the shortage of the medicine in Australia; and
 - (c) for a notification under subsection (2)—specify the day the period of the shortage of the medicine in Australia ended; and
 - (d) contain any other information required by that form.
- (4) 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

- (5) A person contravenes this subsection if:
- (a) the person is subject to a requirement under subsection (1) or (2); 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.

10 After section 30EI

Insert:

30EIA What is the period of a medicine shortage?

The *period* of a shortage of a medicine in Australia is the period:

- (a) starting on the day 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; and
- (b) ending on the day before the day the supply of that medicine in Australia will, or will be likely to, meet that demand.

11 Application provisions

- (1) The amendment of the *Therapeutic Goods Act 1989* made by item 4 of this Schedule applies in relation to a notification of a shortage of a medicine in Australia that is made on or after the commencement of this item.
- (2) The amendments of the *Therapeutic Goods Act 1989* made by items 8 and 9 of this Schedule apply in relation to a period of a shortage of a medicine in Australia that ends on or after the commencement of this item, whether the shortage was first notified before, on or after that commencement.

Schedule 12—Other amendments

Therapeutic Goods Act 1989

1 Subsection 3(1) (definition of *listable goods*)

Repeal the definition, substitute:

listable goods means therapeutic goods that are required under the regulations to be included in the part of the Register relating to listed goods.

2 Subsection 3(1) (paragraph (b) of the definition of *standard*)

After “subsection 3C(1)”, insert “in relation to the goods”.

3 Subsection 3(1) (paragraph (b) of the definition of *standard*)

After “subsection 3C(2)”, insert “in relation to the goods”.

4 Subsection 3(1) (paragraph (c) of the definition of *standard*)

After “subsection 3C(1)”, insert “in relation to the goods”.

5 Subsection 3(1) (paragraph (c) of the definition of *standard*)

After “subsection 3C(2)”, insert “in relation to the goods”.

6 Subsection 3(1) (paragraph (d) of the definition of *standard*)

After “subsection 3C(1)”, insert “in relation to the goods”.

7 Subsection 3(1) (paragraph (d) of the definition of *standard*)

After “subsection 3C(2)”, insert “in relation to the goods”.

8 Subsection 3C(1)

After “are exempt”, insert “in relation to specified therapeutic goods”.

9 At the end of subsection 3C(1) (before the note)

Add “The determination applies to those monographs as in force from time to time.”.

10 Subsection 3C(2)

After “are exempt”, insert “in relation to specified therapeutic goods”.

11 At the end of subsection 3C(2)

Add “The determination applies to those statements and monographs as in force from time to time.”.

12 At the end of section 3C

Add:

Incorporation of other instruments

- (3) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under subsection (1) or (2) 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 Subsection 7(3)

Repeal the subsection.

14 Subsections 9A(5) and (6)

Repeal the subsections.

15 At the end of section 26BF

Add:

- (6) Despite subsection 14(2) of the *Legislation Act 2003*, a determination 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.

16 After subsection 28(2A)

Insert:

- (2AA) Despite subsection 14(2) of the *Legislation Act 2003*, a determination under subsection (2) 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.

17 After paragraph 32BF(6)(c)

Insert:

- (ca) the person does not have the consent in writing of the Secretary; and

18 At the end of section 32BF

Add:

Decisions on whether to give consent

- (8) The Secretary must, as soon as practicable after making a decision to give a consent mentioned in subsection (6), cause particulars of the decision to be published on the Department's website.
- (9) The Secretary must, within 28 days after making a decision to refuse to give a consent mentioned in subsection (6), notify the applicant in writing of the decision and of the reasons for the decision.

19 Subsection 32CM(4)

Repeal the subsection, substitute:

- (4) An authority under subsection (1) may only be given to a medical practitioner:
 - (a) who is included in a class of medical practitioners prescribed by the regulations for the purposes of this paragraph; and
 - (b) who has the approval of an ethics committee to supply the specified biological.

Paragraph (b) does not apply in the circumstances (if any) prescribed by the regulations for the purposes of this subsection.

20 At the end of section 36

Add:

- (5) Despite subsection 14(2) of the *Legislation Act 2003*, the manufacturing principles 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.

21 At the end of subsection 41BD(2A)

Add “The notice takes effect on the day on which the notice is published in the Gazette or on the Department’s website or on such later day as is specified in the notice.”.

22 Subsection 41BD(3)

Omit “by order published in the Gazette or on the Department’s website”, substitute “by legislative instrument”.

23 Subsection 41BD(4)

Repeal the subsection.

24 Subparagraph 41FN(3)(a)(ii)

Omit “devices setting out the matters required by the regulations”, substitute “device”.

25 Subparagraph 41FN(3)(a)(ii)

Omit “within the period specified in the regulations”, substitute “within 20 working days”.

26 Paragraph 41FN(3)(b)

Repeal the paragraph, substitute:

- (b) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:
 - (i) has available sufficient information to substantiate that the conformity assessment procedures have been applied to the kind of medical device or that requirements, comparable to those procedures, have been applied to the kind of medical device to the satisfaction of an overseas regulator; or
 - (ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure

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- that such information can be obtained from the manufacturer within 20 working days; and
- (ba) at all times while the inclusion in the Register has effect, the person in relation to whom the kind of device is included in the Register:
- (i) has available information relating to changes to the kind of medical device, the product range or quality management system by the manufacturer of the kind of device; or
 - (ii) has procedures in place, including a written agreement with the manufacturer of the kind of device, to ensure that such information can be obtained from the manufacturer within 20 working days; and

27 Subsection 56A(4A)

After “19D(3) or (4)”, insert “or 32BF(6)”.

28 Subsections 57(10) to (11)

Repeal the subsections, substitute:

- (10) The power of the Minister under subsection 18A(1) may be delegated only to:
- (a) the Secretary; or
 - (b) an SES employee who holds, or performs the duties of, an SES Band 3 position in the Department; or
 - (c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.
- (10AA) The power of the Minister under subsection 30EK(1) may be delegated only to:
- (a) the Secretary; or
 - (b) an SES employee, or acting SES employee, in the Department; or
 - (c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.

- (10A) The power of the Minister under subsection 32CB(1) may be delegated only to:
- (a) the Secretary; or
 - (b) an SES employee who holds, or performs the duties of, an SES Band 3 position in the Department; or
 - (c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.
- (11) The power of the Minister under subsection 41GS(1) may be delegated only to:
- (a) the Secretary; or
 - (b) an SES employee who holds, or performs the duties of, an SES Band 3 position in the Department; or
 - (c) a person who is registered, in a State or internal Territory, as a medical practitioner and who holds, or performs the duties of, a position that is equivalent to, or higher than, an SES Band 2 position in the Department.

29 Subsection 60(1) (paragraph (da) of the definition of *initial decision*)

Repeal the paragraph.

30 After subsection 61(8C)

Insert:

- (9) Despite subsection 14(2) of the *Legislation Act 2003*, an instrument under subsection (5AB) or (5D) 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.

31 After paragraph 63(2)(g)

Insert:

- (ga) make provision for the reporting of matters relating to therapeutic goods; and

32 Application and saving provisions

- (1) The amendments of section 3C of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to determinations made on or after the commencement of this item.
- (2) Subsection 26BF(6) of the *Therapeutic Goods Act 1989*, as added by this Schedule, applies in relation to determinations made under subsection 26BF(1) of that Act on or after the commencement of this item.
- (3) Subsection 28(2AA) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to determinations made under subsection 28(2) of that Act on or after the commencement of this item.
- (4) Paragraph 32BF(6)(ca) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to supplies occurring on or after the commencement of this item.
- (5) The repeal and substitution of subsection 32CM(4) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to authorities given on or after the commencement of this item.
- (6) The repeal and substitution of subsection 32CM(4) of the *Therapeutic Goods Act 1989* made by this Schedule does not affect the continuity of regulations that were made for the purposes of paragraph 32CM(4)(a) or subsection 32CM(4) of that Act and were in force immediately before the commencement of this item.
- (7) Subsection 36(5) of the *Therapeutic Goods Act 1989*, as added by this Schedule, applies in relation to manufacturing principles determined on or after the commencement of this item.
- (8) The amendments of subsection 41BD(3) and section 60 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to declarations made on or after the commencement of this item.
- (9) A declaration that was in force under subsection 41BD(3) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item continues in force (and may be dealt with) on and after that commencement as if it had been made under that subsection as amended by this Schedule.

- (10) The repeal and substitution of subsections 57(10) to (11) of the *Therapeutic Goods Act 1989* made by this Schedule does not affect the validity of a delegation that was in force immediately before the commencement of this item.
- (11) Subsection 61(9) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to an instrument made under subsection 61(5AB) or (5D) of that Act on or after the commencement of this item.
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[Minister's second reading speech made in—
House of Representatives on 1 December 2022
Senate on 9 February 2023]

(128/22)
