



Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021

No. 8, 2021

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

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No. 8, 2021

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

[Assented to 19 February 2021]

The Parliament of Australia enacts:

1 Short title

This Act is the *Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021*.

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.	19 February 2021
2. Schedules 1 to 4	The day after this Act receives the Royal Assent.	20 February 2021
3. Schedules 5 and 6	The day after the end of the period of 2 months beginning on the day this Act receives the Royal Assent.	19 April 2021
4. Schedules 7 to 10	The day after this Act receives the Royal Assent.	20 February 2021

Note: This table relates only to the provisions of this Act as originally enacted.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Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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

Therapeutic Goods Act 1989

1 At the end of subsection 4(1)

Add:

- ; (c) provide for a scheme allowing pharmacists to substitute certain medicine for other medicine if the Minister has declared there is a serious scarcity of the other medicine.

2 After Division 2B of Part 3-2

Insert:

Division 2C—Substitution of prescription medicine by pharmacists

30EK Minister may declare a serious scarcity of medicine

- (1) The Minister may, by legislative instrument:
 - (a) declare that there is a serious scarcity of specified medicine (the *scarce medicine*) across the whole or a specified part or parts of Australia; and
 - (b) specify the medicine (the *substitutable medicine*) that pharmacists are permitted to dispense in substitution for the scarce medicine and specify the circumstances in which that substitution is permitted.

Note 1: For specification by class, see subsection 13(3) of the *Legislation Act 2003*.

Note 2: For variation and revocation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

Pre-conditions to making instrument

- (2) The Minister may make an instrument under subsection (1) only if the Minister is satisfied:
 - (a) that either or both of the following apply:

- (i) the supply of the scarce medicine in Australia is not currently meeting the demand for that medicine for all of the patients in Australia who take that medicine;
 - (ii) there is an imminent risk that supply of the scarce medicine in Australia will not, or will not be likely to, meet the demand for that medicine for all of the patients in Australia who take, or who may need to take, that medicine; and
- (b) that there is a significant risk of adverse health consequences for patients in Australia if those patients are unable to take the scarce medicine; and
 - (c) of any other matters prescribed by the regulations for the purposes of this paragraph.

Kind of medicine that can be covered by instrument

- (3) The scarce medicine, and the substitutable medicine, must be medicine:
 - (a) that contains one or more substances included in Schedule 4 to the current Poisons Standard; and
 - (b) that does not contain any substances included in Schedule 8 to that standard.

Suitability of substitutable medicine

- (4) Without limiting paragraph (1)(b), the circumstances may relate to:
 - (a) the class of persons for whom the substitutable medicine is suitable; or
 - (b) the class of persons for whom the substitutable medicine is not suitable.

Period instrument in force

- (5) Unless sooner revoked, an instrument under subsection (1) remains in force for the period specified in the instrument.

Note: For variation, see subsection 33(3) of the *Acts Interpretation Act 1901*.

Definition

- (6) For the purposes of this section, a **pharmacist** is a person registered as a pharmacist under a law of a State or Territory providing for the registration of pharmacists.

30EL Substitution of prescription medicine by pharmacists

- (1) If:
- (a) an instrument is in force under subsection 30EK(1); and
 - (b) under a law of a State or Territory, a pharmacist is authorised to dispense medicine (the **scarce medicine**) covered by paragraph 30EK(1)(a) to a person;

then, despite any law of a State or Territory, the pharmacist may dispense medicine covered by paragraph 30EK(1)(b) to that person in substitution for the scarce medicine, provided that the substitution is in the circumstances specified in the instrument under subsection 30EK(1).

- (2) For the purposes of this section, a **pharmacist** is a person registered as a pharmacist under a law of a State or Territory providing for the registration of pharmacists.

3 After subsection 57(10)

Insert:

- (10AA) The power of the Minister under subsection 30EK(1) may be delegated only to the Secretary or to an SES employee, or acting SES employee, in the Department.

Schedule 2—Unique device identification system

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

personal information has the same meaning as in the *Privacy Act 1988*.

unique device identifier of a medical device means any combination of numbers, symbols and letters given to the device to enable identification of the device (whether or not that combination also allows identification of information relating to the device).

2 Section 41C

Omit “compliance with essential principles.”, substitute “compliance with essential principles. The regulations may make provision for and in relation to the Secretary causing a database of unique device identifiers of medical devices to be established and maintained.”.

3 At the end of section 41CA

Add:

- (3) Regulations made for the purposes of subsection (1) may include requirements in relation to the inclusion in the database referred to in section 41CE of the following:
 - (a) unique device identifiers of medical devices;
 - (b) information relating to those unique device identifiers, those medical devices or the import, export, manufacture or supply of those medical devices.
- (4) Subsection (3) has effect subject to subsection 41CE(2).
- (5) Subsection (3) does not limit subsection (1).

4 At the end of Part 4-2

Add:

Division 3—Database of unique device identifiers of medical devices

41CE Database of unique device identifiers of medical devices

- (1) The regulations may make provision for and in relation to the Secretary causing a database to be established and maintained, to be known as:
 - (a) the Australian Unique Device Identification Database; or
 - (b) if another name is prescribed by the regulations—that other name.

Note: The essential principles may include requirements in relation to the inclusion in the database of unique device identifiers of medical devices and related information: see subsection 41CA(3).

Personal information

- (2) The regulations must provide that the database must not include personal information, unless the personal information:
 - (a) is the name of a person in relation to whom a kind of medical device is included in the Register; or
 - (b) is about an authorised representative of the manufacturer of a kind of medical device; or
 - (c) is about an authorised representative of a person in relation to whom a kind of medical device is included in the Register.

Removal of information

- (3) The regulations may provide for the removal of information from the database.

Corrections to information

- (4) The regulations may provide for corrections to information in the database.

Making the database available

- (5) The regulations may provide for the whole or a part of the database to be made:
 - (a) available to specified persons, authorities or bodies; or

(b) publicly available.

- (6) However, the regulations must provide that personal information covered by paragraph (2)(b) or (c) must not be made publicly available.

No limit on subsection (1)

- (7) Subsections (2) to (6) do not limit subsection (1).

Database not a legislative instrument

- (8) The database is not a legislative instrument.

5 After paragraph 41GT(e)

Insert:

- (ea) compliance with the requirements referred to in subsection 41CA(3) (about unique device identifiers of medical devices);

Schedule 3—Protection from criminal responsibility

Therapeutic Goods Act 1989

1 After section 61A

Insert:

62 Protection from criminal responsibility

- (1) An APS employee in the Department who, for the purpose of finding out whether this Act or the regulations have been complied with, obtains, possesses or conveys, or facilitates the conveyance of, goods is not criminally responsible for an offence against a law of the Commonwealth, or a State law, relating to the obtaining, possession, conveyance or facilitation of the conveyance of the goods.
- (2) If an APS employee in the Department, in connection with finding out whether this Act or the regulations have been complied with, arranges for another person to convey goods, the other person is not criminally responsible for an offence against a law of the Commonwealth, or a State law, relating to:
 - (a) the possession of the goods by the other person, to the extent the possession is in connection with that conveyance of the goods; or
 - (b) that conveyance of the goods.

2 Application provision

Section 62 of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to the obtaining, possession, conveyance or facilitation of the conveyance of goods on or after the commencement of this item.

Schedule 4—International agreements

Therapeutic Goods Act 1989

1 After Chapter 2

Insert:

Chapter 2A—Prohibition on import, export, manufacture or supply of therapeutic goods—international agreements

9J Simplified outline of this Chapter

The regulations may prohibit imports into Australia, exports from Australia, the manufacture in Australia and supplies in Australia of therapeutic goods, or therapeutic goods containing a particular ingredient or component, to give effect to international agreements to which Australia is a party.

There is an offence and a civil penalty for contravening such a prohibition.

9K Prohibition on import, export, manufacture or supply of therapeutic goods—international agreements

Prohibition on therapeutic goods themselves

- (1) If therapeutic goods are the subject of an international agreement prescribed for the purposes of this subsection, the regulations may prohibit one or more of the following:
- (a) the import into Australia of the therapeutic goods;
 - (b) the export from Australia of the therapeutic goods;
 - (c) the manufacture in Australia of the therapeutic goods;
 - (d) the supply in Australia of the therapeutic goods.

-
- (2) Before regulations are made prescribing an international agreement for the purposes of subsection (1), the Minister must be satisfied that the agreement requires parties to the agreement to take steps to prohibit or restrict one or more of the import, export, manufacture and supply of certain goods.

Prohibition on therapeutic goods containing an ingredient or component

- (3) If an ingredient or component of therapeutic goods is the subject of an international agreement prescribed for the purposes of this subsection, the regulations may prohibit one or more of the following:
- (a) the import into Australia of all or specified therapeutic goods that contain that ingredient or component;
 - (b) the export from Australia of all or specified therapeutic goods that contain that ingredient or component;
 - (c) the manufacture in Australia of all or specified therapeutic goods that contain that ingredient or component;
 - (d) the supply in Australia of all or specified therapeutic goods that contain that ingredient or component.
- (4) Before regulations are made prescribing an international agreement for the purposes of subsection (3), the Minister must be satisfied that the agreement requires parties to the agreement to take steps to prohibit or restrict one or more of the import, export, manufacture and supply of goods containing that ingredient or component.

Nature of prohibition

- (5) A prohibition referred to in subsection (1) or (3) may be absolute or be subject to such conditions as are prescribed.

Procedural requirements for regulations containing prohibition

- (6) Regulations containing a prohibition referred to in subsection (1) or (3) must not be made unless:
- (a) the Minister causes to be published on the Department's website a notice setting out details of:
 - (i) the international agreement; and

- (ii) the Minister's satisfaction mentioned in subsection (2) or (4); and
 - (iii) the proposed prohibition; and
- (b) a period of 30 days has passed since the notice was published.

Commencement of regulations containing prohibition

- (7) Regulations containing a prohibition referred to in subsection (1) or (3) must not be expressed to commence on a day earlier than the day the international agreement enters into force for Australia.

Content of regulations containing prohibition

- (8) Without limiting subsection (5), regulations prescribing conditions referred to in that subsection may do one or more of the following:
- (a) make provision in relation to a matter by conferring on the Minister or Secretary a power to make a decision of an administrative character;
 - (b) refer to the Minister or Secretary being satisfied of one or more specified matters;
 - (c) make provision for and in relation to the Minister or Secretary delegating powers to an SES employee, or acting SES employee, in the Department.

9L Offence and civil penalty

Offence

- (1) A person commits an offence if:
- (a) the person:
 - (i) imports into Australia therapeutic goods; or
 - (ii) exports from Australia therapeutic goods; or
 - (iii) manufactures in Australia therapeutic goods; or
 - (iv) supplies in Australia therapeutic goods; and
 - (b) the import, export, manufacture or supply contravenes:
 - (i) an absolute prohibition in force for the purposes of subsection 9K(1) or (3); or

-
- (ii) one or more conditions of a prohibition in force for the purposes of subsection 9K(1) or (3).

Penalty: 300 penalty units.

Civil penalty

- (2) A person contravenes this subsection if:
 - (a) the person:
 - (i) imports into Australia therapeutic goods; or
 - (ii) exports from Australia therapeutic goods; or
 - (iii) manufactures in Australia therapeutic goods; or
 - (iv) supplies in Australia therapeutic goods; and
 - (b) the import, export, manufacture or supply contravenes:
 - (i) an absolute prohibition in force for the purposes of subsection 9K(1) or (3); or
 - (ii) one or more conditions of a prohibition in force for the purposes of subsection 9K(1) or (3).

Maximum civil penalty:

- (a) for an individual—300 penalty units; and
- (b) for a body corporate—3,000 penalty units.

9M Application of *Customs Act 1901*

If:

- (a) the importation or exportation of goods is an offence under subsection 9L(1) or a contravention of subsection 9L(2); and
- (b) the Secretary notifies the Comptroller-General of Customs in writing that the Secretary wishes the *Customs Act 1901* to apply to that importation or exportation;

the *Customs Act 1901* has effect as if the goods included in that importation or exportation were goods described as forfeited to the Crown under section 229 of that Act because they were:

- (c) prohibited imports within the meaning of that Act; or
- (d) prohibited exports within the meaning of that Act;

as the case requires.

9N Constitutional basis

- (1) This Chapter, and any other provision of this Act to the extent it relates to this Chapter, relies on the Commonwealth's legislative power under paragraph 51(xxix) of the Constitution to give effect to an international agreement prescribed for the purposes of subsection 9K(1) or (3).
- (2) This section does not limit section 6.

2 At the end of subsection 23B(2)

Add:

- ; (g) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the application must be accompanied by a statement from the applicant certifying that:
- (i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
- (h) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the application must be accompanied by a statement from the applicant certifying that:
- (i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and
 - (ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those conditions.

3 At the end of subsection 23C(2) (before the note)

Add:

- ; and (f) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the application is accompanied by a statement from the applicant certifying that:
 - (i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those prohibitions; and
- (g) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the application is accompanied by a statement from the applicant certifying that:
 - (i) if those prohibitions cover imports—any imports into Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and
 - (ii) if those prohibitions cover exports—any exports from Australia of the goods by, or on behalf of the applicant, will not contravene those conditions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the goods by, or on behalf of the applicant, will not contravene those conditions.

4 After paragraph 25(1)(h)

Insert:

- (i) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether, if the Secretary were to register the goods, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the goods would contravene those prohibitions; and

- (ia) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether, if the Secretary were to register the goods, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the goods would contravene those conditions; and

5 After paragraph 26(1)(k)

Insert:

- (l) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those prohibitions; or
- (la) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those conditions; or

6 After subsection 30(4B)

Insert:

- (4C) The Secretary must, by notice in writing given to a person in relation to whom therapeutic goods are included in the Register, cancel the registration or listing of the goods if the Secretary is satisfied that:
 - (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those prohibitions; or
 - (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—imports into Australia, exports from Australia or supplies in Australia of the goods would contravene one or more of those conditions.

7 Paragraph 30(5)(a)

Omit “or (1D)”, substitute “, (1D) or (4C)”.

8 Subsection 30EA(1) (after table item 4)

Insert:

- | | | |
|-----|--|--------------------------------|
| 4A. | The goods are supplied and the Secretary is satisfied that: | The person supplying the goods |
| | (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the supply contravenes one or more of those prohibitions; or | |
| | (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the supply contravenes one or more of those conditions | |

9 After paragraph 31(1)(ha)

Insert:

- (hb) if the goods are registered in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those prohibitions;
- (hc) if the goods are registered in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those conditions;

10 After paragraph 31(2)(ga)

Insert:

- (gb) if the goods are listed in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia or any exports from Australia of the goods contravene those prohibitions;
- (gc) if the goods are listed in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether any supplies in Australia, any imports into Australia

or any exports from Australia of the goods contravene those conditions;

11 At the end of subsection 32DA(3)

Add:

- ; and (g) 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—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—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
- (h) 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—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—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those conditions.

12 At the end of subsection 32DDA(2)

Add:

- ; (f) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the application must be accompanied by a statement from the applicant certifying that:
 - (i) if those prohibitions cover imports—any imports into Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and

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- (ii) if those prohibitions cover exports—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those prohibitions; and
- (g) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the application must be accompanied by a statement from the applicant certifying that:
- (i) if those prohibitions cover imports—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—any exports from Australia of the biological by, or on behalf of the applicant, will not contravene those conditions; and
 - (iii) if those prohibitions cover supplies—any supplies in Australia of the biological by, or on behalf of the applicant, will not contravene those conditions.

13 After paragraph 32DE(1)(f)

Insert:

- (fa) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether, if the Secretary were to include the biological in the Register, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the biological would contravene those prohibitions; and
- (fb) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether, if the Secretary were to include the biological in the Register, the Secretary is satisfied that imports into Australia, exports from Australia or supplies in Australia of the biological would contravene those conditions; and

14 After subsection 32GA(1)

Insert:

- (1A) The Secretary must, by written notice given to the person in relation to whom a biological is included in the Register, cancel the entry of the biological from the Register if the Secretary is satisfied that:
- (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia or supplies in Australia of the biological would contravene one or more of those prohibitions; or
 - (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—imports into Australia, exports from Australia or supplies in Australia of the biological would contravene one or more of those conditions.

15 Subsection 32GA(2)

After “subsection (1)”, insert “or (1A)”.

16 Subsection 32HA(1) (after table item 4)

Insert:

- 4A. It is supplied and the Secretary is satisfied that: The person supplying it
- (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the supply contravenes one or more of those prohibitions; or
 - (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the supply contravenes one or more of those conditions

17 After paragraph 32JA(1)(n)

Insert:

- (na) if the biological is included in the Register in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia or any exports from Australia of the biological contravene those prohibitions;

-
- (nb) if the biological is included in the Register in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether any supplies in Australia, any imports into Australia or any exports from Australia of the biological contravene those conditions;

18 At the end of subsection 37(1)

Add:

- ; and (h) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—be accompanied by a statement from the applicant certifying that the manufacture in Australia of the therapeutic goods or classes of therapeutic goods the subject of the application will not contravene those prohibitions; and
- (i) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—be accompanied by a statement from the applicant certifying that the manufacture in Australia of the therapeutic goods or classes of therapeutic goods the subject of the application will not contravene those conditions.

19 After paragraph 38(1)(f)

Insert:

- (fa) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the manufacture in Australia of the goods would contravene one or more of those prohibitions; or
- (fb) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the manufacture in Australia of the goods would contravene one or more of those conditions; or

20 After paragraph 41(1)(ga)

Insert:

- (gb) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the Secretary is satisfied that the manufacture in Australia of the goods to

which the licence relates would contravene one or more of those prohibitions; or

- (gc) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the Secretary is satisfied that the manufacture in Australia of the goods to which the licence relates would contravene one or more of those conditions; or

21 After paragraph 41FD(h)

Insert:

- (ha) 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—any imports into Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (ii) if those prohibitions cover exports—any exports from Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (iii) if those prohibitions cover manufacture—any manufacture in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and
 - (iv) if those prohibitions cover supplies—any supplies in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those prohibitions; and
- (hb) 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—any imports into Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and
 - (ii) if those prohibitions cover exports—any exports from Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and
 - (iii) if those prohibitions cover manufacture—any manufacture in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and

-
- (iv) if those prohibitions cover supplies—any supplies in Australia of devices of that kind by, or on behalf of the applicant, will not contravene those conditions; and

22 Section 41GK

Before “The”, insert “(1)”.

23 At the end of section 41GK

Add:

- (2) The Secretary must, by written notice given to the person in relation to whom a kind of medical device is included in the Register, cancel the entry of the kind of device from the Register if the Secretary is satisfied that:
 - (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—imports into Australia, exports from Australia, the manufacture in Australia or supplies in Australia of the kind of device would contravene one or more of those prohibitions; or
 - (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—imports into Australia, exports from Australia, the manufacture in Australia or supplies in Australia of the kind of device would contravene one or more of those conditions.

24 After paragraph 41JA(1)(i)

Insert:

- (iaa) if the kind of medical device is included in the Register in relation to the person and there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—whether any supplies in Australia, any imports into Australia, any exports from Australia or any manufacture in Australia of medical devices of that kind contravene those prohibitions;
- (iab) if the kind of medical device is included in the Register in relation to the person and there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—whether any supplies in Australia, any imports into Australia, any exports from Australia or any

manufacture in Australia of medical devices of that kind
contravene those conditions;

25 Subsection 41KA(1) (after table item 4)

Insert:

- 4A. It is supplied and the Secretary is satisfied that: The person supplying the kind of medical device
- (a) if there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3)—the supply contravenes one or more of those prohibitions; or
 - (b) if there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions—the supply contravenes one or more of those conditions

26 Before section 53

Insert:

52G Exemptions, approvals and authorities to be consistent with prohibitions under Chapter 2A

- (1) If there are one or more absolute prohibitions in force for the purposes of subsection 9K(1) or (3), a thing referred to in subsection (3) of this section must not be made or given in relation to therapeutic goods the subject of those prohibitions.
- (2) If there are one or more prohibitions in force for the purposes of subsection 9K(1) or (3) that are subject to conditions (the **first conditions**), a thing referred to in subsection (3) of this section must not be made or given in relation to therapeutic goods the subject of those prohibitions unless the thing is made or given subject to conditions that are consistent with the first conditions.
- (3) The things are the following:
 - (a) an exemption under subsection 18(1) or 18A(1);
 - (b) an approval under subsection 19(1);
 - (c) an authority under subsection 19(5);
 - (d) an authorisation under subsection 19(7A);
 - (e) an approval under subsection 19A(1), (1A) or (2);

- (f) an exemption under section 32CA or 32CB;
- (g) an approval under subsection 32CK(1);
- (h) an authority under subsection 32CM(1);
- (i) an authorisation under subsection 32CM(7A);
- (j) an approval under subsection 32CO(1), (1A) or (2);
- (k) an exemption under section 41GS or 41HA;
- (l) an approval under subsection 41HB(1);
- (m) an authority under subsection 41HC(1);
- (n) an authorisation under subsection 41HC(6);
- (o) an approval under subsection 41HD(1), (1A) or (2);
- (p) a variation of a thing mentioned in any of the above paragraphs.

27 Application provisions—registration or listing of therapeutic goods

- (1) The amendments of sections 23B, 23C, 25 and 26 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to an application made under section 23 of that Act on or after the commencement of this item.
- (2) The amendments of sections 30 and 31 of the *Therapeutic Goods Act 1989* made by this Schedule apply on and after the commencement of this item in relation to therapeutic goods included in the Register before, on or after that commencement.
- (3) The amendment of section 30EA of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to the supply of goods on or after the commencement of this item.

28 Application provisions—biologicals

- (1) The amendment of section 32DA of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an application made under subsection 32DA(1) of that Act on or after the commencement of this item.
- (2) The amendments of section 32DDA and 32DE of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to an application made under section 32DD of that Act on or after the commencement of this item.

- (3) The amendments of sections 32GA and 32JA of the *Therapeutic Goods Act 1989* made by this Schedule apply on and after the commencement of this item in relation to a biological included in the Register before, on or after that commencement.
- (4) The amendment of section 32HA of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to the supply of a biological on or after the commencement of this item.

29 Application provisions—manufacturing of therapeutic goods

- (1) The amendments of sections 37 and 38 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to an application for a licence made on or after the commencement of this item.
- (2) The amendment of section 41 of the *Therapeutic Goods Act 1989* made by this Schedule applies on and after the commencement of this item in relation to a licence granted before, on or after that commencement.

30 Application provisions—medical devices

- (1) The amendment of section 41FD of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to an application made under section 41FC of that Act on or after the commencement of this item.
- (2) The amendments of sections 41GK and 41JA of the *Therapeutic Goods Act 1989* made by this Schedule apply on and after the commencement of this item in relation to a kind of medical device included in the Register before, on or after that commencement.
- (3) The amendment of section 41KA of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to the supply of a kind of medical device on or after the commencement of this item.

Schedule 5—Restricted information

Therapeutic Goods Act 1989

1 Paragraphs 26AF(2)(b), (c) and (d)

Repeal the paragraphs, substitute:

- (b) the information is derived from a clinical trial in relation to an indication of the existing medicine, where:
 - (i) the trial number of that trial is specified in the application for the listing of the existing medicine; and
 - (ii) the Secretary is satisfied that the trial number of that trial is set out in a registry prescribed by the regulations for the purposes of this subparagraph; and
- (c) that indication is either:
 - (i) a use of the existing medicine in preventing, curing or alleviating a disease, ailment, defect or injury in persons, other than a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; or
 - (ii) a use of the existing medicine in connection with alleviating a disease, ailment, defect or injury in persons, being a form of the disease, ailment, defect or injury that, under the Therapeutic Goods Advertising Code, is a serious form; and
- (d) at the time (the *relevant time*) the application for the listing of the existing medicine was made:
 - (i) that indication was not covered by a determination under paragraph 26BF(1)(a); and
 - (ii) no other medicine with that indication, and with the same active ingredients as the existing medicine, was included in the Register under section 26AE; and
- (da) no other medicine with that indication, and with the same active ingredients as the existing medicine, had been included in the Register under section 26AE at any time before the relevant time; and

2 After paragraph 26AF(2)(e)

Insert:

- (ea) the Secretary relied on the information in deciding to list the existing medicine; and
- (eb) at all times during the period:
 - (i) beginning on the day the application for the listing of the existing medicine was made; and
 - (ii) ending at the end of the day before the day that the existing medicine was included in the Register;the information (except information set out in a registry prescribed for the purposes of subparagraph (b)(ii)) was not available to the public; and

3 At the end of section 26AF

Add:

- (3) A registry prescribed for the purposes of subparagraph (2)(b)(ii):
 - (a) may be a registry established within or outside Australia; and
 - (b) must be a registry that is accessible by the public.

4 Application provision

The amendments made by this Schedule apply in relation to an application referred to in paragraph 26AF(2)(a) of the *Therapeutic Goods Act 1989* that is made on or after the commencement of this item.

Schedule 6—Variation of permissible ingredients determination

Therapeutic Goods Act 1989

1 At the end of section 26BDA

Add:

; or (c) the evaluation fee prescribed for the purposes of paragraph 26BE(3)(b) has not been paid before the end of the period worked out in accordance with the regulations.

2 Paragraph 26BE(5B)(b)

Omit “recommendations under this section”, substitute “a decision under paragraph (4)(a) or (b)”.

3 Paragraph 26BE(5B)(c)

Omit “a recommendation”, substitute “a decision under paragraph (4)(a) or (b)”.

4 Paragraph 26BE(5C)(a)

Omit “recommendations under this section”, substitute “a decision under paragraph (4)(a) or (b)”.

5 Paragraph 26BE(5C)(b)

Omit “a recommendation”, substitute “a decision under paragraph (4)(a) or (b)”.

6 Subsection 26BE(5D)

Omit “the recommendation”, substitute “a decision under paragraph (4)(a) or (b)”.

7 Paragraph 63(2)(daaa)

Omit “evaluations under section 26BE in relation to recommendations to vary a section 26BB determination are to be completed”, substitute “a decision under paragraph 26BE(4)(a) or (b), in relation to an application under subsection 26BD(1), must be made”.

8 Application provision

The amendments made by this Schedule apply in relation to an application under subsection 26BD(1) of the *Therapeutic Goods Act 1989* that is made on or after the commencement of this item.

Schedule 7—Delegation

Therapeutic Goods Act 1989

1 After subsection 57(5)

Insert:

- (5A) The powers of the Secretary under subsection 19(5) may be delegated only to a person referred to in paragraph (1)(a) or (c) of this section who is registered, or eligible for registration, in a State or internal Territory as a medical or dental practitioner or as a pharmacist.

2 Subsection 57(6)

Omit “19(5)”.

3 Saving provision

The amendments made by this Schedule do not affect the validity of an instrument in force under subsection 57(1) of the *Therapeutic Goods Act 1989* immediately before the commencement of this item.

Schedule 8—Retention of material on withdrawal of application

Therapeutic Goods Act 1989

1 After paragraph 53(b)

Insert:

- (baa) a recommendation by the Secretary that the Minister vary a section 26BB determination; or
- (bab) a recommendation by the Secretary that the Minister vary a determination under section 26BF; or

2 Application provision

The amendment made by this Schedule applies in relation to an application that is withdrawn on or after the commencement of this item.

Schedule 9—Consents to importations or supplies of therapeutic goods

Therapeutic Goods Act 1989

1 After paragraph 19D(3)(b)

Insert:

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

2 After paragraph 19D(4)(b)

Insert:

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

3 At the end of section 19D

Add:

Decisions on whether to give consent

- (6) The Secretary must, as soon as practicable after making a decision to give a consent mentioned in subsection (3) or (4), cause particulars of the decision to be published on the Department's website.
- (7) The Secretary must, within 28 days after making a decision to refuse to give a consent mentioned in subsection (3) or (4), notify the applicant in writing of the decision and of the reasons for the decision.

4 After subsection 56A(4)

Insert:

- (4A) In proceedings for the contravention of subsection 19D(3) or (4) (civil penalty provisions), a certificate by the Secretary, to the effect that the Secretary did not consent to the importation or supply that is the subject of the proceedings, is prima facie evidence of the matters specified in the certificate.

5 Application provisions

- (1) The amendment of subsection 19D(3) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to importations that occur on or after the commencement of this item.
- (2) The amendment of subsection 19D(4) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to supplies that occur on or after the commencement of this item.

Schedule 10—Other amendments

Therapeutic Goods Act 1989

1 Subsection 7(1)

Omit “particular goods or”.

2 Subsection 7(1)

Omit “Secretary may, by order published in the *Gazette* or on the Department’s website, declare that the goods, or the goods”, substitute “Secretary may, by legislative instrument, make an order declaring that the classes of goods, or the classes of goods”.

3 Subsection 7(1A)

Omit “particular goods or”.

4 Paragraph 7(4)(a)

Omit “particular goods or”.

5 Section 41HB (heading)

Repeal the heading, substitute:

41HB Approvals for special and experimental uses

6 Section 52EC

Repeal the section, substitute:

52F Incorporation of current Poisons Standard

- (1) Despite subsection 14(2) of the *Legislation Act 2003*, a legislative instrument, or a notifiable instrument, under this Act may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in the current Poisons Standard as in force or existing from time to time.
- (2) Despite subsection 46AA(2) of the *Acts Interpretation Act 1901*, an instrument under this Act (other than a legislative instrument or a

notifiable instrument) may make provision in relation to a matter by applying, adopting or incorporating, with or without modification, any matter contained in the current Poisons Standard as in force or existing from time to time.

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

Repeal the paragraph, substitute:

- (a) refusing to make, or refusing to vary or repeal, a declaration under section 7 upon an application made under subsection 7(2); or

8 Subsection 60(1) (after paragraph (d) of the definition of *initial decision*)

Insert:

- (da) under subsection 41BD(3); or

9 Saving provisions

- (1) The amendments made by this Schedule do not affect the validity of an order in force under section 7 of the *Therapeutic Goods Act 1989* immediately before the commencement of this item.
- (2) Section 60 of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to a decision made under subsection 7(1) of that Act before that commencement.

[Minister's second reading speech made in—
House of Representatives on 9 December 2020
Senate on 3 February 2021]

(178/20)
