2016-2017

The Parliament of the
Commonwealth of Australia

HOUSE OF REPRESENTATIVES

EXPOSURE DRAFT

Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017

No. , 2017

(Health)

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

Contents

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

The Parliament of Australia enacts:

1 Short title

This Act is the *Therapeutic Goods Amendment (2017 Measures No. 1) Act 2017*.

2 Commencement

(1) Each provision of this Act specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. Sections 1 to 3 and anything in this Act not elsewhere covered by this table	The day this Act receives the Royal Assent.	
2. Schedules 1 and 2	The later of: (a) 1 January 2018; and (b) the day after this Act receives the Royal Assent.	
3. Schedule 3	Immediately after the commencement of the provisions covered by table item 2.	
4. Schedules 4 and 5	The later of: (a) 1 January 2018; and (b) the day after this Act receives the Royal Assent.	
5. Schedule 6,	Immediately after the commencement of the	

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
Part 1	provisions covered by table item 4.	
6. Schedule 6, Part 2	The later of: (a) 1 July 2018; and (b) the day after this Act receives the Royal Assent.	
7. Schedule 7	Immediately after the commencement of the provisions covered by table item 4.	
8. Schedule 8	The later of: (a) 1 January 2018; and (b) the day after this Act receives the Royal Assent.	
9. Schedule 9	Immediately after the commencement of the provisions covered by table item 5.	

Note: This table relates only to the provisions of this Act as originally enacted.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Legislation that is specified in a Schedule to this Act is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Act has effect according to its terms.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

Therapeutic Goods Act 1989

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

Repeal the definition, substitute:

registered goods means:

(a) therapeutic goods included in the part of the Register for goods known as registered goods; or

(b) therapeutic goods included in the part of the Register for goods known as provisionally registered goods.

Note: Subsection (8) provides that a reference in this Act to therapeutic goods that are registered, or to the registration of therapeutic goods, includes a reference to a medicine that is provisionally registered under section 29.

2 At the end of section 3

Add:

(8) To avoid doubt:

(a) a reference in this Act to therapeutic goods that are registered includes a reference to a medicine that is provisionally registered; and

(b) a reference in this Act to the registration of therapeutic goods includes a reference to the provisional registration of a medicine.

Note: Subsection 29(2) deals with the provisional registration of a medicine.

3 After paragraph 6AAE(6)(a)

Insert:

(aa) in the part of the Register for goods known as provisionally registered goods; or

4 Subsection 9A(3)

Omit “4 parts”, substitute “5 parts”.

5 After paragraph 9A(3)(a)

Insert:

(aa) a part for goods to be known as provisionally registered goods; and

6 After subsection 9D(1)

Insert:

(1A) If:

(a) a medicine is included in the part of the Register for goods known as provisionally registered goods; and

(b) it appears to the Secretary that the quality, safety or efficacy of the medicine is unacceptable in relation to a class of persons;

the Secretary may, on the Secretary's own initiative, vary the entry in the Register in relation to the medicine:

(c) to reduce the class of persons for whom the medicine is suitable or to change the directions for use; or

(d) to add a warning, or precaution, that does not include any comparison of the medicine with any other medicine by reference to quality, safety or efficacy.

Note: The Secretary may also vary the product information relating to the medicine: see subsection 25AA(4).

(1B) If:

(a) a medicine is included in the part of the Register for goods known as provisionally registered goods; and

(b) the Secretary makes a decision under subsection 29(9) to extend the provisional registration period for the medicine;

the Secretary may, on the Secretary's own initiative, vary the entry in the Register in relation to the medicine to reduce the class of persons for whom the medicine is suitable or to change the directions for use.

Note: The Secretary may also vary the product information relating to the medicine: see subsection 25AA(4).

(1C) If the Secretary proposes to make a variation under subsection (1A) or (1B), the Secretary must:

(a) give the person in relation to whom the medicine is registered written notice of the proposed variation and of the reasons for the proposed variation; and

(b) give the person a reasonable opportunity to make a submission to the Secretary in relation to the proposed variation; and

(c) if the person makes a submission in accordance with paragraph (b)—take the submission into account before making a decision whether or not to make the variation.

(1D) Subsections (1A) and (1B) apply despite subsection 16(1).

7 After Division 1 of Part 3-2

Insert:

Division 1A—Provisional determinations for medicine

22C Applications for provisional determination

(1) A person may make an application to the Secretary for a provisional determination relating to a medicine of a kind prescribed by the regulations for the purposes of this subsection.

Note: If the Secretary makes the determination, the person applies under section 23 for registration of the medicine and that application passes preliminary assessment, then a different kind of evaluation of the medicine will occur under section 25.

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

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

(b) be accompanied by the prescribed application fee; and

(c) contain the information that the form requires, and any further information, statement or document the Secretary requires, whether in the form or otherwise; and

(d) satisfy any other requirement prescribed by the regulations for the purposes of this paragraph.

(3) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or
(b) by way of a specified kind of electronic transmission.

22D Provisional determinations

(1) If a person makes an application, in accordance with subsection 22C(2), for a provisional determination relating to a medicine, the Secretary must decide to make, or to refuse to make, the determination.

Criteria

(2) The Secretary may make the determination if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of this subsection are met in relation to the medicine.

Content of determination

(3) The determination must specify:
(a) the person to whom the determination relates; and
(b) the medicine to which the determination relates; and
(c) the indication of the medicine to which the determination relates; and
(d) each active ingredient of the medicine to which the determination relates.

The determination may specify any other matters that the Secretary considers appropriate.

Notice of decision

(4) As soon as practicable after making the decision, the Secretary must:
(a) give the person written notice of the decision; and
(b) if the Secretary refuses to make the determination—set out the reasons for the refusal in the notice.

22E Period during which provisional determination is in force

(1) A provisional determination under section 22D relating to a medicine:

(a) comes into force on the day on which the Secretary gives the person notice under subsection 22D(4); and

(b) subject to this section and section 22F, remains in force for the initial period.

Note: For revocation of the determination, see section 22F.

(2) The ***initial period*** is 6 months or another period prescribed by the regulations for the purposes of this subsection.

Extensions

(3) The person may make an application to the Secretary to extend the initial period.

(4) The application must:

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

(b) be made at least 28 days before the determination would otherwise cease to be in force; and

(c) be accompanied by the prescribed application fee.

(5) On receiving the application, the Secretary must decide to extend, or to refuse to extend, the initial period.

(6) The Secretary may extend the initial period by 6 months, or another period prescribed by the regulations for the purposes of this subsection, if the Secretary:

(a) is still satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are met in relation to the medicine; and

(b) is satisfied that, if the Secretary were to make the extension, the person would make an application under section 23 for provisional registration of the medicine before the end of the extended period.

(7) As soon as practicable after making the decision, the Secretary must:

(a) give the person written notice of the decision; and

(b) if the Secretary refuses to extend the initial period—set out the reasons for the refusal in the notice.

(8) Only one extension may be given.

Effect of application under section 23

(9) If the person to whom the provisional determination relates makes an application under section 23 for provisional registration of the medicine before the end of the initial period (or that period as extended), the determination remains in force until:

(a) the person withdraws the application; or

(b) the application lapses in accordance with subsection 24(2); or

(c) the person gives the Secretary written notice under subsection 24E(2) that the person wishes to treat the application as having been refused; or

(d) the application is finally determined.

(10) For the purposes of paragraph (9)(d), an application is ***finally determined*** when the application, and any applications for review or appeals arising out of it, have been finally determined or otherwise disposed of.

22F Revocation of provisional determination

Revocation on Secretary's own initiative

(1) The Secretary may revoke a provisional determination under section 22D relating to a person and a medicine if the Secretary is satisfied that the criteria prescribed by the regulations for the purposes of subsection 22D(2) are no longer met in relation to the medicine.

Revocation on request

(2) The Secretary must revoke a provisional determination under section 22D relating to a person and a medicine if the person requests the Secretary, in writing, to do so.

Notice of revocation

(3) As soon as practicable after making a revocation under this section, the Secretary must:

(a) give the person written notice of the revocation; and

(b) for a revocation under subsection (1)—set out the reasons for the revocation in the notice.

Day revocation takes effect

(4) A revocation under this section takes effect on the day on which the Secretary gives the person notice of the revocation.

8 After section 23

Insert:

23AA Applications for provisional registration of medicine

If:

(a) a person makes an application under section 23 for the registration of a medicine; and

(b) a provisional determination under section 22D relating to the person, the medicine and the indication to which the application relates is in force when the application is made;

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

9 Paragraph 25(1)(d)

Repeal the paragraph, substitute:

(c) unless the application is one referred to in paragraph (d)—whether the quality, safety and efficacy of the goods for the purposes for which they are to be used have been satisfactorily established; and

(d) for an application for provisional registration of a medicine:

(i) whether, based on preliminary clinical data, the safety and efficacy of the medicine for the purposes for which it is to be used have been satisfactorily established; and

(ii) whether the quality of the medicine for the purposes for which it is to be used has been satisfactorily established; and

(iii) whether, if the Secretary were to register the medicine, the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years that would start on the day that registration would commence; and

10 After paragraph 28(2A)(a)

Insert:

(aa) the provisional registration of medicine; and

11 Section 29

Omit "Where", substitute "(1) Subject to this section, if".

12 At the end of section 29

Add:

Provisionally registered medicine

(2) If:

(a) a person makes an application for provisional registration of a medicine; and

(b) in relation to that application, the Secretary decides under subsection 25(3) to register the medicine; and

(c) the medicine is included in the Register in relation to the person;

then:

(d) the medicine is provisionally registered; and

(e) the medicine remains included in the Register for the provisional registration period, unless the medicine's registration is cancelled under this Part earlier.

Note: The medicine is taken not to be included in the Register while its registration is suspended: see section 29G.

(3) Subject to this section, the ***provisional registration period*** is the 2 years starting on the day the registration commences.

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

Extension of provisional registration upon application

(4) The person in relation to whom the medicine is provisionally registered may make an application to the Secretary to extend the provisional registration period.

(5) The application must:

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

(b) contain the information that the form requires, and any further information, statement or document the Secretary requires, whether in the form or otherwise; and

(c) be made at least 6 months before the provisional registration of the medicine is due to end; and

(d) be accompanied by the prescribed application fee.

(6) On receiving the application, the Secretary must decide to grant, or to refuse to grant, an extension of the provisional registration period. In making that decision, the Secretary must have regard to:

(a) whether the Secretary is satisfied with the applicant's plan to submit comprehensive clinical data on the safety and efficacy of the medicine before the end of the 6 years starting on the day the provisional registration commenced; and

(b) such other matters (if any) as the Secretary considers relevant.

(7) As soon as practicable after making the decision, the Secretary must:

(a) give the applicant written notice of the decision; and

(b) if the Secretary decides to extend the provisional registration period—specify in the notice the period of the extension (which must not exceed 2 years and may be less than the period sought by the applicant); and

(c) if the Secretary refuses to extend the provisional registration period—set out the reasons for the refusal in the notice.

Note: At the time of granting an extension, the Secretary may impose new conditions on the provisional registration or vary the existing conditions: see subsection 28(3).

(8) No more than 2 extensions may be granted on applications under subsection (4).

Note: Under subsection (9) the Secretary may extend the provisional registration period on his or her own initiative.

Effect on provisional registration of later section 23 application

(9) If:

(a) before the provisional registration period ends, the person in relation to whom the medicine is provisionally registered makes an application under section 23 for registration of the medicine; and

(b) the application is for the medicine to be included in the part of the Register for goods known as registered goods;

then the Secretary may, in connection with the application, end or extend the provisional registration period as the Secretary considers appropriate.

Note: At the time of granting an extension, the Secretary may impose new conditions on the provisional registration or vary the existing conditions: see subsection 28(3).

(10) In ending or extending, under subsection (9), the provisional registration period:

(a) the Secretary must have regard to any matters prescribed by the regulations for the purposes of this paragraph; and

(b) the Secretary must ensure the provisional registration period continues while the Secretary is considering the application, unless the medicine's registration is cancelled under this Part; and

(c) the Secretary must not extend the provisional registration period so it would end more than 6 years after the provisional registration commenced, unless the extension is for the purposes of paragraph (b).

13 After paragraph 56A(1)(d)

Insert:

(da) particular therapeutic goods were or were not included in the Register as provisionally registered goods; or

14 Subsection 60(2)

Omit "A person whose", substitute "Subject to this section, a person whose".

15 After subsection 60(2A)

Insert:

(2AA) If the Secretary or a delegate of the Secretary makes a decision under subsection 9D(1A) or (1B) to vary an entry in the Register in relation to a medicine, a person is not entitled to request the Minister to reconsider the decision unless the person is the person in relation to whom the medicine is registered.

(2AB) If the Secretary or a delegate of the Secretary:

(a) makes a decision under section 22D in relation to an application under section 22C; or

(b) makes a decision under section 22E in relation to an application under subsection 22E(3); or

(c) makes a decision under section 23B in relation to an application for provisional registration of a medicine; or

(d) makes a decision under subsection 25(3) in relation to an application for provisional registration of a medicine;

a person is not entitled to request the Minister to reconsider the decision unless the person made the application.

(2AC) If the Secretary or a delegate of the Secretary makes a decision under section 22F to revoke a provisional determination under section 22D, a person is not entitled to request the Minister to reconsider the decision unless the person made the application for that provisional determination.

16 Subsection 60(2B)

After "the Secretary", insert "or a delegate of the Secretary".

17 Before subsection 60(3)

Insert:

(2D) If the Secretary or a delegate of the Secretary:

(a) makes a decision under subsection 29(6) in relation to an application under subsection 29(4); or

(b) makes a decision under subsection 29(9) to end, or extend, the provisional registration period for a medicine;

a person is not entitled to request the Minister to reconsider the decision unless the person is the person in relation to whom the medicine is provisionally registered.

Schedule 2—Indications and ingredients for listed medicines

Part 1—Amendments

Therapeutic Goods Act 1989

1 After paragraph 26A(2)(fb)

Insert:

(fba) if the medicine's label contains one or more indications—each indication:

(i) is covered by a determination under paragraph 26BF(1)(a); and

(ii) is proposed to be accepted in relation to the inclusion of the medicine in the Register; and

2 After paragraph 26A(2)(fc)

Insert:

(fd) each indication proposed to be accepted in relation to the inclusion of the medicine in the Register is covered by a determination under paragraph 26BF(1)(a); and

(fe) if a determination under paragraph 26BF(1)(b) specifies requirements in relation to an indication proposed to be accepted in relation to the inclusion of the medicine in the Register—none of the requirements have been contravened; and

3 Paragraph 26A(2)(j)

Repeal the paragraph, substitute:

(j) both:

(i) the applicant holds information or evidence to support any claim (other than a claim that is an indication) proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and

4 After paragraph 26A(2)(j)

Insert:

(ja) both:

(i) the applicant holds information or evidence to support each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(ii) the information or evidence complies with any requirements specified in a determination under subsection (2B); and

5 After subsection 26A(2A)

Insert:

(2B) The Minister may, by legislative instrument, specify requirements for the purposes of subparagraph (2)(j)(ii) or (2)(ja)(ii).

6 After subsection 26BB(2)

Insert:

(2A) The requirements referred to in paragraph (1)(b) may relate to a particular ingredient being contained in particular medicine only in the circumstances specified in the determination in relation to the ingredient.

7 Subsection 26BB(4)

Omit "and (3)", substitute ", (2A) and (3)".

8 Before subsection 26BE(1)

Insert:

Making an application for recommendation

9 After subsection 26BE(2)

Insert:

Further information about application for recommendation

(2A) The Secretary may, by written notice given to a person who has made an application under subsection (1), require the person to:

(a) give the Secretary such further information in connection with the application as is specified in the notice; and

(b) do so within such reasonable period as is specified in the notice.

Lapsing of application for recommendation

(2B) An application made under subsection (1) lapses if:

(a) the Secretary requires further information to be given in relation to the application within a period specified in a notice under subsection (2A); and

(b) the information is not given within that period.

10 After paragraph 26BE(3)(b)

Insert:

; and (c) if further information is required to be given under subsection (2A) within a specified period—the information is given within that period;

11 After subsection 26BE(5)

Insert:

(5A) If the Secretary refuses to make the recommendation, the Secretary must:

(a) notify the applicant in writing of his or her decision; and

(b) state in the notice the reasons for the decision.

Partial refund of application fee in certain circumstances

(5B) If:

(a) an application fee is prescribed for the purposes of paragraph (2)(d); and

(b) regulations made for the purposes of paragraph 63(2)(daaa) prescribe a period within which recommendations under this section must be made; and

(c) the Secretary makes a recommendation in relation to an application under subsection (1), but not within that period;

then 25% of the application fee must be refunded to the applicant.

Deemed refusal of applications in certain circumstances

(5C) If:

(a) regulations made for the purposes of paragraph 63(2)(daaa) prescribe a period within which recommendations under this section must be made; and

(b) at the end of that period, the Secretary has not made a recommendation in relation to an application under subsection (1);

the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(5D) A notice under subsection (5C) may be given at any time before the recommendation in relation to the application is made.

(5E) If a notice has been given under subsection (5C), this Act (except subsection 60(5)) has effect as if:

(a) the Secretary had decided not to make a recommendation under this section; and

(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and

(c) the Minister's decision had been made on the day on which notice was given to the Secretary under subsection (5C).

12 Subsection 26BE(8)

Repeal the subsection.

13 Subsection 26BE(9)

Omit "subsection (8)", substitute "subsection (2A)".

14 After section 26BE

Insert:

26BF Permissible indications

(1) The Minister may, by legislative instrument, make a determination in relation to either or both of the following:

(a) indications;

(b) requirements in relation to indications.

Note: See paragraphs 26A(2)(fba), (fd) and (fe) (which deal with matters that a person seeking the listing of a medicine under section 26A must certify).

(2) In deciding whether to make a determination under subsection (1) in relation to a particular indication, the Minister may have regard to whether the indication is a therapeutic use that relates to one or more of the following:

(a) maintaining health;

(b) enhancing health;

(c) preventing a dietary deficiency;

(d) a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury.

(3) Subsection (2) does not limit the matters to which the Minister may have regard in deciding whether to make a determination under subsection (1) in relation to a particular indication.

(4) Without limiting paragraph (1)(b), the requirements may relate to:

(a) the use of particular indications in specified circumstances; or

(b) the use of particular indications if certain specified conditions are met.

(5) A determination under paragraph (1)(b) may make different provision for different classes of medicines.

26BG Limitations on determination under section 26BF

(1) The Minister may, by legislative instrument, make a determination specifying indications that must not be covered by a determination under paragraph 26BF(1)(a).

(2) The determination may specify an indication either generally or in relation to specified circumstances.

(3) The Minister may, by legislative instrument, vary or revoke a determination under subsection (1).

26BH Variation of determination under section 26BF—Minister's initiative

The Minister may, on his or her own initiative and by legislative instrument, vary a determination under section 26BF.

26BJ Variation of determination under section 26BF—application by person

Application for recommendation to vary section 26BF determination

(1) A person may apply to the Secretary for a recommendation that the Minister vary a determination under section 26BF.

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

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

(b) set out the recommendation sought; and

(c) be delivered to an office of the Department specified in the form; and

(d) be accompanied by the prescribed application fee (if any).

Limits on kinds of applications that can be made

(3) A person cannot make an application under subsection (1) for a recommendation the effect of which would be for the determination to cover any of the following:

(a) an indication specified in a determination under section 26BG;

(b) an indication that is or contains a restricted representation (within the meaning of Part 5-1);

(c) unless subsection (4) applies—an indication that is or contains a prohibited representation (within the meaning of Part 5-1);

(d) unless subsection (5) applies—an indication that refers to preventing, curing or alleviating a disease, ailment, defect or injury.

(4) For the purposes of paragraph (3)(c), this subsection applies if:

(a) the indication is a therapeutic use that relates to sun protection; and

(b) the prohibited representation relates to the prevention of skin cancer; and

(c) the use of the prohibited representation is permitted under section 42DK.

(5) For the purposes of paragraph (3)(d), this subsection applies if the indication refers to:

(a) the prevention of a dietary deficiency; or

(b) the prevention of skin cancer or sun damage.

Further information about application for recommendation

(6) The Secretary may, by written notice given to a person who has made an application under subsection (1), require the person to:

(a) give the Secretary such further information in connection with the application as is specified in the notice; and

(b) do so within such reasonable time as is specified in the notice.

Lapsing of application for recommendation

(7) An application made under subsection (1) lapses if:

(a) the Secretary requires further information to be given in relation to the application within a time specified in a notice under subsection (6); and

(b) the information is not given within that time.

Decision on application for recommendation

(8) If:

(a) an application is made under subsection (1); and

(b) any applicable prescribed application fee has been paid; and

(c) if further information is required to be given under subsection (6) within a specified time—the information is given within that time;

the Secretary must decide whether to make the recommendation or refuse to make the recommendation.

(9) In deciding whether to make the recommendation, the Secretary may have regard to whether the indication to which the application relates is a therapeutic use that relates to one or more of the following:

(a) maintaining health;

(b) enhancing health;

(c) preventing a dietary deficiency;

(d) a disease, ailment, defect or injury, other than a serious form of the disease, ailment, defect or injury;

(e) sun protection.

(10) If the Secretary refuses to make the recommendation, the Secretary must:

(a) notify the applicant in writing of his or her decision; and

(b) state in the notice the reasons for the decision.

Minister may vary section 26BF determination

(11) If the Secretary makes a recommendation under subsection (8), the Minister must:

(a) by legislative instrument, vary the determination under subsection 26BF(1); or

(b) refuse to vary the determination.

(12) In deciding whether to vary a determination under subsection 26BF(1) to include an indication not already covered by the determination, the Minister may have regard to:

(a) the recommendation made under subsection (8) of this section; and

(b) whether the indication is a therapeutic use that relates to one or more of the matters in paragraphs (9)(a) to (e) of this section.

(13) Subsection (12) does not limit the matters to which the Minister may have regard in deciding whether to vary the determination.

Applications or information may be given electronically

(14) An approval of a form mentioned in paragraph (2)(a), or a notice mentioned in subsection (6), may require or permit an application

or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

15 Subsections 28(6) and (7)

Repeal the subsections, substitute:

(6) If in, or in connection with, an application for the listing of therapeutic goods, a claim (other than a claim that is an indication) is made by the applicant in relation to the goods, the listing of the goods is subject to the following conditions:

(a) a condition that the sponsor of the goods had, at the time when the claim was made, information or evidence that supported the claim and complied with the requirements (if any) specified in a determination made under subsection 26A(2B);

(b) a condition that the sponsor retains the information or evidence at all times while the goods remain listed;

(c) a condition that, at any time while the goods remain listed, the sponsor will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

16 At the end of section 28

Add:

(7) If:

(a) a medicine is listed under section 26A; and

(b) an indication is accepted in relation to the inclusion of the medicine in the Register;

the listing of the medicine is subject to the following conditions:

(c) a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed, information or evidence that supports the indication and complies with the requirements (if any) specified in a determination under subsection 26A(2B);

(d) a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

17 Paragraph 30(1)(e)

Omit "(e)", substitute "(e), (fba), (fd), (fe)".

18 Paragraph 30(2)(ba)

After "(j)", insert ", (ja)".

19 After subsection 60(2B)

Insert:

(2C) If the Secretary or a delegate of the Secretary decides, under subsection 26BJ(8), to refuse to make a recommendation, a person is not entitled to request the Minister to reconsider the decision unless the person made an application under subsection 26BJ(1) for the recommendation.

20 Before paragraph 63(2)(daa)

Insert:

(daaa) provide for the periods within which evaluations under section 26BE in relation to recommendations to vary a section 26BB determination are to be completed; and

Part 2—Application and transitional provisions

21 Definitions

In this Part:

Act means the *Therapeutic Goods Act 1989*.

transition period means the period of 3 years beginning on the day this Schedule commences.

22 Application of amendments

(1) The amendments of section 26A of the Act made by this Schedule apply in relation to applications for the listing of medicines made after the commencement of this Schedule.

(2) The amendments of section 26BE of the Act made by this Schedule apply in relation to applications for a recommendation to vary a determination made after the commencement of this Schedule.

(3) Subsection 26BF(2) of the Act, as inserted by this Schedule, applies to determinations made under section 26BF of that Act other than the first determination so made.

(4) The amendments of section 28 of the Act made by this Schedule apply in relation to medicines listed under section 26A of the Act after the commencement of this Schedule.

(5) The amendments of section 30 of the Act made by this Schedule apply in relation to medicines included in the Register after the commencement of this Schedule.

23 Transitional provisions

Scope of transitional provisions

(1) This item applies in relation to a medicine that is listed in relation to a person under section 26A of the Act immediately before the commencement of this Schedule.

(2) This item also applies in relation to a medicine if:

(a) a person has made an application under section 23 of the Act for the listing of the medicine before the commencement of this Schedule; and

(b) the application has not been finally determined before that commencement; and

(c) after that commencement, the Secretary lists the medicine in relation to the person under section 26A of the Act.

(3) This item also applies in relation to a medicine if the medicine:

(a) was listed under section 26 of the Act before 11 June 1996; and

(b) is, immediately before the commencement of this Schedule, listed goods; and

(c) is not subject to a condition that it must not be supplied in Australia; and

(d) is, is intended to be, or has been supplied in Australia.

Reapplying for listing of certain medicines to include permissible indications

(4) The person may, during the transition period, apply again in accordance with section 23 of the Act for the listing of the medicine in relation to the person under section 26A or 26AE of the Act.

Cancellation of listing if further application not made and listing not otherwise cancelled during transition period

(5) Subitem (6) applies if, during the transition period, one of the following events does not occur in relation to the medicine:

(a) the medicine is listed in relation to the person under section 26A of the Act;

(b) the medicine is listed in relation to the person under section 26AE of the Act;

(c) the listing of the medicine is cancelled;

(d) an application for the listing of the medicine in relation to the person under section 26AE of the Act that complies with section 23C of the Act has been made, but not yet decided.

(6) The listing of the medicine is cancelled, and the medicine ceases to be listed, by force of this subitem immediately after the end of the transition period.

(7) If:

(a) during the transition period, an application for the listing of the medicine in relation to the person under section 26AE of the Act has been made; and

(b) after the transition period, the application lapses;

the listing of the medicine is cancelled, and the medicine ceases to be listed, by force of this subitem immediately after the application lapses.

(8) Paragraph 26A(1)(e) of the Act does not apply to an application for the listing of a medicine under section 26A of the Act if the medicine had its listing cancelled only because of the operation of subitem (6) or (7).

(9) Paragraph 26AB(1)(g) of the Act does not apply to an application for the listing of a medicine under section 26AE of the Act if the medicine had its listing cancelled only because of the operation of subitem (6) or (7).

Cancellation of listing under section 26A if application under section 26AE made but not decided during transition period

(10) Subitem (11) applies if an application for the listing of the medicine in relation to the person under section 26AE of the Act that complies with section 23C of the Act has been made, but not yet decided, during the transition period.

(11) The listing of the medicine under section 26A of the Act is cancelled, and the medicine ceases to be listed under that section, by force of this subitem at the same time as the Secretary makes a decision under subsection 26AE(3) of the Act in relation to the medicine.

Schedule 3—New pathway for listed medicines

Therapeutic Goods Act 1989

1 Paragraphs 21A(1)(b) and (4)(b)

After "subsection 26A(2)", insert "or 26AB(2)".

2 Subsection 21B(1)

After "subsection 26A(2)", insert "or 26AB(2)".

3 At the end of paragraph 26(1)(ba)

Add "or 26AE".

4 After section 26A

Insert:

26AB Application for listing of certain medicines following efficacy evaluation

(1) If:

(a) an application is made under section 23 for the listing of medicine in relation to a person; and

(b) the application passes preliminary assessment; and

(c) the requirements of subsections (2), (3), (4) and (6) have been complied with; and

(d) the medicine is not a medicine which may be listed under section 26A; and

(e) the medicine is not export only medicine; and

(f) the medicine is not one that has previously had its registration or listing cancelled;

the Secretary must evaluate the medicine for listing under section 26AE.

(2) The applicant must certify that:

(a) the medicine is eligible for listing; and

(b) the medicine is safe for the purposes for which it is to be used; and

(c) the presentation of the medicine is not unacceptable; and

(d) the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a); and

(e) if a determination under paragraph 26BB(1)(b) specifies requirements in relation to ingredients being contained in the medicine—none of the requirements have been contravened; and

(f) the medicine conforms to every standard (if any) applicable to the medicine; and

(g) both of the following are complied with in relation to the medicine:

(i) the applicable provisions of the Therapeutic Goods Advertising Code;

(ii) the other requirements (if any) relating to advertising applicable under Part 5-1 or under the regulations; and

(h) if the medicine has been manufactured in Australia—each step in the manufacture of the medicine has been carried out by a person who is the holder of a licence to carry out that step; and

(i) the medicine complies with all prescribed quality or safety criteria that are applicable to the medicine; and

(j) the medicine's specifications comply with any requirements that are prescribed by the regulations for the purposes of this paragraph and that are applicable to the medicine; and

(k) the medicine's label:

(i) complies with any requirements that are prescribed by the regulations for the purposes of this subparagraph and that are applicable to the medicine; and

(ii) does not make a claim that is inconsistent with any claim made by the applicant in relation to the medicine in, or in connection with, the application; and

(l) the applicant holds information or evidence showing the medicine's specifications will be maintained under the conditions set out on the medicine's label until the medicine's expiry date; and

(m) the applicant has available sufficient information to substantiate each claim and each indication proposed to be accepted in relation to the inclusion of the medicine in the Register; and

(n) the medicine does not contain substances that are prohibited imports for the purposes of the *Customs Act 1901*; and

(o) all the manufacturers of the medicine are nominated as manufacturers in the application; and

(p) the applicant has, with manufacturers of the medicine who are manufacturers of the prescribed kind, written agreements containing such matters as are prescribed; and

(q) the information included in or with the application is complete and correct.

(3) The applicant must also certify any other matters prescribed by the regulations for the purposes of this subsection.

(4) Subject to subsection (9), if a step in the manufacture of the medicine has been carried out outside Australia, the Secretary must have certified, prior to the application being made, that the manufacturing and quality control procedures used in each such step are acceptable.

(5) In deciding whether to certify for the purposes of subsection (4), the matters that may be taken into account include:

(a) whether the applicant has provided:

(i) if a step in the manufacture of the medicine 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 medicine; or

(ii) if a step in the manufacture of the medicine 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 medicine; or

(iii) in any other case—an acceptable form of evidence from a relevant overseas authority establishing that the manufacture of the medicine 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 medicine to be necessary:

(i) funds for the carrying out of that inspection by the Department; 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 31 in relation to the manufacture or preparation of the medicine.

(6) If the medicine includes any ingredient of animal origin, the Secretary must have certified, prior to the application being made, that he or she is satisfied of the safety of the ingredient.

(7) If a medicine is exempt from the operation of Part 3-3 or a person is exempt from the operation of that Part in relation to the manufacture of the medicine, subsection (2) has effect, in relation to the medicine, as if paragraph (2)(h) were omitted.

(8) If a person (the ***manufacturer***) is exempt from the operation of Part 3-3 in relation to a step in the manufacture of a medicine, subsection (2) has effect, in relation to the medicine, as if the reference in paragraph (2)(h) to a person who is the holder of a licence were a reference to the manufacturer to the extent that Part 3-3 applies to the manufacturer in relation to the manufacture of the medicine.

(9) If:

(a) a medicine was made outside Australia; and

(b) had the medicine been made in Australia, it would have been exempt from the operation of Part 3-3;

subsection (4) does not apply in relation to the medicine.

26AC Evaluation fees for listing of medicine under section 26AE

(1) This section applies if:

(a) an application is made under section 23 in relation to a medicine for listing under section 26AE; and

(b) the application has passed preliminary assessment.

(2) A fee (the ***evaluation fee***) specified in or determined in accordance with the regulations is payable by the applicant in respect of the evaluation of a medicine for listing under section 26AE.

(3) The Secretary must notify each applicant of the amount of the evaluation fee.

(4) The evaluation fee payable by an applicant:

(a) is due and payable on the day on which the applicant is notified of the amount of the evaluation fee; and

(b) may be recovered by the Commonwealth as a debt due to the Commonwealth.

(5) If:

(a) an application is made under section 23 in relation to a medicine for listing under section 26AE; and

(b) the applicant has paid the whole of the evaluation fee; and

(c) regulations made for the purposes of paragraph 63(2)(daaaa) prescribe a period within which evaluations under section 26AE in relation to the medicine must be completed; and

(d) the evaluation is completed, but not within that period;

then 25% of the evaluation fee must be refunded to the applicant.

(6) For the purposes of paragraph (5)(d), the evaluation is taken to be completed when the applicant is notified of the Secretary's decision under subsection 26AE(3) in relation to the medicine.

26AD Lapsing and deemed refusal of applications for listing of medicine under section 26AE

Lapsing of applications

(1) An application for the listing of a medicine under section 26AE lapses if:

(a) any part of the evaluation fee referred to in section 26AC remains unpaid at the end of 28 days after the day on which the amount became due and payable; or

(b) the application contains information that is inaccurate or misleading in a material particular; or

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

Deemed refusal of applications

(2) If:

(a) regulations made for the purposes of paragraph 63(2)(daaaa) prescribe a period within which evaluations under section 26AE in relation to the medicine must be completed; and

(b) at the end of that period, the evaluation has not been completed;

the applicant may give the Secretary written notice that the applicant wishes to treat the application as having been refused.

(3) A notice under subsection (2) may be given at any time before the evaluation is completed.

(4) If a notice has been given, this Act (except subsection 60(5)) has effect as if:

(a) the Secretary had decided not to list the medicine which is the subject of the application; and

(b) the Minister had made a decision under subsection 60(3) confirming the decision of the Secretary; and

(c) the Minister's decision had been made on the day on which notice was given to the Secretary under subsection (2).

26AE Evaluation and listing of certain medicines

Evaluation

(1) If:

(a) an application is made under section 23 for the listing of a medicine in relation to a person under this section; and

(b) the application has passed preliminary assessment;

the Secretary must evaluate the medicine having regard to:

(c) whether the efficacy of the medicine for the purposes for which it is to be used has been satisfactorily established; and

(d) such other matters (if any) as the Secretary considers relevant.

(2) If a period in relation to which an evaluation under this section must be completed has been prescribed under paragraph 63(2)(daaaa), the evaluation must be completed within that period.

Secretary must decide whether to list medicine

(3) After an evaluation under this section of goods has been completed, the Secretary must decide:

(a) to list the medicine; or

(b) not to list the medicine.

Decision to list

(4) If the Secretary decides under subsection (3) to list the medicine, the Secretary must, in accordance with subsection (5), notify the applicant in writing of the decision within 28 days of making the decision.

(5) The notice must:

(a) set out the decision under subsection (3) to list the medicine in relation to the person; and

(b) inform the applicant that the medicine will not be included in the Register unless and until the applicant gives the Secretary:

(i) the certificate required under subsection 26B(1); or

(ii) a notice (in accordance with a form approved, in writing, by the Secretary) that a certificate under that subsection is not required in relation to the application.

(6) If the applicant gives the Secretary the certificate referred to in subparagraph (5)(b)(i) or the notice referred to in subparagraph (5)(b)(ii), the Secretary must:

(a) include the medicine in the Register; and

(b) give the applicant a certificate of listing.

(7) To avoid doubt, if the applicant gives the Secretary the certificate referred to in subparagraph (5)(b)(i) or the notice referred to in

subparagraph (5)(b)(ii), the Secretary must include the medicine in the Register under paragraph (3)(a) without inquiring into the correctness of the certificate or the notice.

Date listing commences

(8) The listing of the medicine commences on the day specified for the purpose in the certificate.

Refusal to list medicine

(9) If:

(a) an application is made for the listing of medicine in relation to a person; and

(b) the Secretary decides under subsection (3) not to list the medicine;

the Secretary must notify the applicant in writing of the decision, and the reasons for the decision, within 28 days of making the decision.

5 Section 26BA

Omit "or 26A(1)", substitute ", 26A(1) or 26AE(5)".

6 Subsection 26BB(1) (note)

After "section 26A", insert "or 26AB".

7 Subsection 28(5B)

After "26A", insert "or 26AE".

8 Paragraph 28(5B)(b)

After "26A(3)", insert ", 26AB(4)".

9 At the end of section 28

Add:

(8) If:

(a) a medicine is listed under section 26AE; and

(b) an indication is accepted in relation to the inclusion of the medicine in the Register;

the listing of the medicine is subject to the following conditions:

(c) a condition that the person in relation to whom the medicine is listed has, at all times while the medicine remains listed, information or evidence that supports the indication;

(d) a condition that, at any time while the medicine remains listed, the person will, if asked to do so by the Secretary, give the information or evidence to the Secretary.

10 Subsection 28A(1)

After "section 26A", insert "or 26AE".

11 Subsection 28A(3)

Repeal the subsection, substitute:

(3) In deciding whether to give the certification:

(a) subsection 26A(4) applies in a way corresponding to the way in which it applies for the purposes of subsection 26A(3); and

(b) subsection 26AB(5) applies in a way corresponding to the way in which it applies for the purposes of subsection 26AB(4).

12 Paragraph 29D(1)(b)

After "(e)", insert ", (ea)".

13 Paragraph 29D(1)(b)

After "(1C)", insert ", (1D)".

14 After paragraph 30(1)(e)

Insert:

(ea) in the case of a medicine listed under section 26AE, it appears to the Secretary that any of the certifications under paragraph 26AB(2)(a), (d), (e), (h) or (n) are incorrect or (if applicable) the requirements under subsection 26AB(4) or (6) are not fulfilled; or

15 Subsection 30(1A)

After "section 26A", insert "or 26AE".

16 After subsection 30(1C)

Insert:

(1D) The Secretary may, by notice in writing given to a person in relation to whom a medicine is listed under section 26AE, cancel the listing of the medicine if:

(a) the Secretary, under section 31, gives to the person a notice requiring the person to give to the Secretary information or documents relating to the medicine; and

(b) the notice is given for the purposes of ascertaining whether any of the certifications by the person under subsection 26AB(2) or (3) in relation to the medicine are incorrect; and

(c) the person fails to comply with the notice within 20 working days after the notice is given.

17 After paragraph 30(2)(ba)

Insert:

(bab) in the case of a medicine listed under section 26AE, it appears to the Secretary that any of the certifications under paragraph 26AB(2)(b), (c), (f), (g), (i), (j), (k), (l), (m), (o), (p) or (q) or subsection 26AB(3) are incorrect; or

18 Paragraph 30(5)(a)

Omit "or (1C)", substitute ", (1C) or (1D)".

19 Paragraph 31(2)(fa)

Omit "are medicine", substitute "are listed under section 26A".

20 After paragraph 31(2)(fa)

Insert:

(fab) if the goods are or were listed under section 26AE—any of the matters covered by a certification by the person under subsection 26AB(2) or (3) in relation to the medicine;

(fac) if the goods are or were listed under section 26AE—the efficacy of the goods in relation to the purposes for which they are to be used;

21 After paragraph 63(2)(da)

Insert:

(daaaa) provide for the periods within which evaluations under section 26AE in relation to specified medicines or specified classes of medicines are to be completed; and

Schedule 4—Preliminary assessment of applications

Part 1—Therapeutic goods

Therapeutic Goods Act 1989

1 Subparagraph 19A(1)(b)(ii)

Omit "that complies with section 23 has been made under that section for registration of the goods", substitute "under section 23 has been made for registration of the goods and the application has passed preliminary assessment".

2 Paragraph 19A(2)(b)

Omit "that complies with section 23 has been made under that section", substitute "under section 23 has been made".

3 After paragraph 19A(2)(b)

Insert:

(ba) the application has passed preliminary assessment; and

4 Paragraph 19A(9)(a)

After "(2)(a), (b),", insert "(ba),".

5 Section 23

Repeal the section, substitute:

23 Applications generally

A person may make an application to the Secretary for registration or listing of therapeutic goods.

6 Before section 24

Insert:

23A Classes of therapeutic goods

The Secretary may, by notifiable instrument, specify different classes of therapeutic goods for the purposes of section 23B.

23B Requirements relating to applications for registration of therapeutic goods and listing of medicines under section 26AE

(1) If an application is made under section 23 for:

(a) registration of therapeutic goods (including an application for provisional registration of a medicine); or

(b) the listing of a medicine under section 26AE;

the Secretary must carry out an assessment of whether the requirements set out in subsection (2) have been met in relation to the application.

(2) The requirements are as follows:

(a) the application must be made:

(i) in accordance with the form approved, in writing, by the Secretary for that class of therapeutic goods; or

(ii) in such other manner as is approved, in writing, by the Secretary for that class of therapeutic goods;

(b) the prescribed application fee for that class of therapeutic goods must be paid;

(c) the application must be delivered to an office of the Department specified by the Secretary;

(d) the application must be accompanied by information that is:

(i) of a kind determined under subsection (9) for that class of therapeutic goods; and

(ii) in a form determined under subsection (10) for that class of therapeutic goods;

(e) if the application is for the registration of restricted medicine—the application must be accompanied by product information, in relation to the medicine, that is in the form approved under section 7D in relation to the medicine;

(f) if the Secretary so requires—the applicant must:

(i) deliver to the Department a reasonable number of samples of the goods; and

(ii) do so in a manner approved, in writing, by the Secretary.

Passing preliminary assessment

(3) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (1), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (2) have been met in relation to the application.

(4) If the application has passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

(5) Subsection (4) does not apply if the period within which the Secretary must, under section 25, evaluate the goods to which the application relates is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of forms etc.

(7) For the purposes of paragraph (2)(a), the Secretary may approve different forms and different manners for making applications for different classes of therapeutic goods that are specified under section 23A.

(8) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(9) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of

subparagraph (2)(d)(i) to a class of therapeutic goods that is specified under section 23A.

(10) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to a class of therapeutic goods that is specified under section 23A.

23C Requirements relating to applications for listing of therapeutic goods under section 26 or 26A

(1) This section applies if an application is made under section 23 for listing of therapeutic goods under section 26 or 26A.

(2) The application complies with this section if:

(a) the application is made in accordance with a form approved, in writing, by the Secretary or in such other manner as is approved, in writing, by the Secretary for the purposes of this paragraph; and

(b) the application is delivered to an office of the Department specified by the Secretary; and

(c) the prescribed application fee has been paid; and

(d) the applicant has delivered to the office to which the application was made such information, in a form approved, in writing, by the Secretary, as will allow the determination of the application; and

(e) if the Secretary so requires—the applicant has delivered to the office to which the application was made a reasonable number of samples of the goods.

Note: To be listed, an application must comply with this section: see sections 26, 26AA, 26A and 26AB.

(3) The Secretary may, by legislative instrument, determine forms of information for the purposes of the application of paragraph (2)(d).

(4) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

7 Subsection 24(1)

Repeal the subsection, substitute:

(1) This section applies if:

(a) an application is made for the registration of therapeutic goods under section 23; and

(b) the goods are goods that are required to be registered; and

(c) the application has passed preliminary assessment.

(1A) A fee specified in, or determined in accordance with, the regulations is payable by the applicant in respect of the evaluation of the goods for registration, and the Secretary must notify each such applicant of the amount of the evaluation fee.

8 Subsection 25(1)

Omit "If an application is made for the registration of therapeutic goods in relation to a person in accordance with section 23, the Secretary must evaluate the goods for registration having regard to:", substitute:

If:

(a) an application is made for the registration of therapeutic goods in relation to a person under section 23; and

(b) the application has passed preliminary assessment;

the Secretary must evaluate the goods for registration having regard to:

9 Paragraph 25AB(1)(a)

Omit "in accordance with", substitute "under".

10 After paragraph 25AB(1)(a)

Insert:

(aa) the application has passed preliminary assessment; and

11 Paragraph 25AB(2)(a)

Omit "in accordance with", substitute "under".

12 After paragraph 25AB(2)(a)

Insert:

(aa) the application has passed preliminary assessment; and

13 Paragraph 25AC(a)

Omit "in accordance with", substitute "under".

14 After paragraph 25AC(a)

Insert:

(aa) the application has passed preliminary assessment; and

15 Paragraph 25B(1)(a)

Omit "in accordance with", substitute "under".

16 After paragraph 25B(1)(a)

Insert:

(aa) the application has passed preliminary assessment; and

17 Paragraph 26(1)(a)

Omit "in accordance with", substitute "under".

18 After paragraph 26(1)(a)

Insert:

(aaa) the application complies with section 23C; and

19 After paragraph 26(1AA)(b)

Insert:

(ba) the application complies with section 23C; and

20 Paragraph 26(1A)(a)

Omit "in accordance with", substitute "under".

21 After paragraph 26(1A)(a)

Insert:

(aa) the application complies with section 23C; and

22 Paragraph 26AA(1)(a)

Omit "in accordance with", substitute "under".

23 After paragraph 26AA(1)(a)

Insert:

(aa) the application complies with section 23C; and

24 Paragraph 26A(1)(a)

Omit "in accordance with", substitute "under".

25 After paragraph 26A(1)(a)

Insert:

(aa) the application complies with section 23C; and

26 After paragraph 26A(1A)(a)

Insert:

(aa) the application complies with section 23C; and

27 Subsection 30C(1)

Repeal the subsection, substitute:

(1) This section applies to an application for listing or registration of a therapeutic good under section 23 if:

(a) the therapeutic good is, or contains, a GM product or a genetically modified organism; and

(b) if the application is for registration—the application has passed preliminary assessment; and

(c) if the application is for the listing of a medicine under section 26AE—the application has passed preliminary assessment.

28 Paragraph 31(1B)(a)

Omit "23(1)(a)", substitute "23B(2)(a)".

29 After paragraph 31(1B)(a)

Insert:

(aa) the application has passed preliminary assessment; and

30 Application and transitional provisions

(1) The amendments made by this Part apply in relation to applications for registration or listing of therapeutic goods made after the commencement of this subitem.

(2) If regulations:

(a) were made for the purposes of subsection 24(1) of the *Therapeutic Goods Act 1989*; and

(b) were in force immediately before the commencement of this subitem;

the regulations have effect, after the commencement of this subitem, as if they had been made under subsection 24(1A) of the *Therapeutic Goods Act 1989* as inserted by this Part.

Part 2—Biologicals

Therapeutic Goods Act 1989

31 Section 32AA (note 2)

Omit "section 32DD", substitute "section 32DDA".

32 Paragraph 32CO(1)(d)

Omit "either", substitute "any of the following conditions is satisfied".

33 Subparagraph 32CO(1)(d)(i)

Omit "or" (second occurring).

34 Subparagraph 32CO(1)(d)(ii)

Omit "or 32DD".

35 Subparagraph 32CO(1)(d)(ii)

Omit "and".

36 After subparagraph 32CO(1)(d)(ii)

Insert:

(iii) an application under section 32DD has been made for inclusion of the biological in the Register, and the application has passed preliminary assessment; and

37 Paragraph 32CO(2)(d)

Repeal the paragraph, substitute:

(d) either:

(i) an application that complies with section 32DA has been made for inclusion of the biological in the Register; or

(ii) an application under section 32DD has been made for inclusion of the biological in the Register, and the application has passed preliminary assessment; and

38 Subsection 32DD(1)

Omit "(1)".

39 Subsections 32DD(2), (3) and (4)

Repeal the subsections.

40 After section 32DD

Insert:

32DDA Preliminary assessment of applications

(1) If an application is made under section 32DD for the inclusion of a biological in the Register, the Secretary must carry out an assessment of whether the requirements set out in subsection (2) of this section have been met in relation to the application.

(2) The requirements are as follows:

(a) the application must be made:

(i) in accordance with the form approved, in writing, by the Secretary for that class of biological; or

(ii) in such other manner as is approved, in writing, by the Secretary for that class of biological;

(b) the prescribed application fee for that class of biological must be paid;

(c) the application must be delivered to an office of the Department specified by the Secretary;

(d) the application must be accompanied by information that is:

(i) of a kind determined under subsection (9) for that class of biological; and

(ii) in a form determined under subsection (10) for that class of biological;

(e) if the Secretary so requires—the applicant must:

(i) deliver to the Department a reasonable number of samples of the biological; and

(ii) do so in a manner approved, in writing, by the Secretary.

Passing preliminary assessment

(3) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (1), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (2) have been met in relation to the application.

(4) If the application has passed preliminary assessment, the Secretary must give a written notice to the applicant stating that the application has passed preliminary assessment.

(5) Subsection (4) does not apply if the period within which the Secretary must, under section 32DE, evaluate the biological to which the application relates is prescribed by reference to the prescribed period within which the Secretary is required to consider an application under subsection 9D(3) to vary an entry in the Register.

(6) If the application has not passed preliminary assessment, the Secretary must, by written notice given to the applicant, refuse the application.

Approval of different forms etc.

(7) For the purposes of paragraph (2)(a), the Secretary may approve different forms and manners for making applications for different classes of biologicals that are prescribed by the regulations for the purposes of section 32AA.

(8) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(9) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

(10) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to a class of biological that is prescribed by the regulations for the purposes of section 32AA.

41 Subsection 32DE(1)

Omit "in accordance with", substitute "under".

42 Subsection 32DE(1)

After "a person,", insert "and the application has passed preliminary assessment,".

43 Paragraph 32DF(1)(a)

Omit "in accordance with", substitute "under".

44 After paragraph 32DF(1)(a)

Insert:

(aa) the application has passed preliminary assessment; and

45 Paragraph 32DG(a)

Omit "subsection 32DD(1)", substitute "section 32DD".

46 After paragraph 32DG(a)

Insert:

(aa) the application has passed preliminary assessment; and

47 Subsection 32DH(1)

Omit "subsection 32DD(1)", substitute "section 32DD".

48 Subsection 32DI(1)

Omit "in accordance with" (first occurring), substitute "under".

49 Subsection 32DI(1)

After "in the Register" (first occurring), insert ", and the application has passed preliminary assessment".

50 Application provisions

The amendments made by this Part apply in relation to applications for inclusion of a biological in the Register made after the commencement of this item.

Part 3—Medical devices

Therapeutic Goods Act 1989

51 Section 41E (note)

Repeal the note, substitute:

Note: A conformity assessment certificate may be required for an application to include a kind of medical device in the Register to pass preliminary assessment: see paragraph 41FDB(2)(e).

52 Division 3 of Part 4-4 (note to Division heading)

Repeal the note.

53 Division 4 of Part 4-4 (note to Division heading)

Repeal the note.

54 Section 41FA

Omit "automatically once a proper", substitute "once an".

55 Section 41FA

After "required certification", insert "and the application passes preliminary assessment".

56 Section 41FA (note 1)

Repeal the note, substitute:

Note 1: In some cases, an application relating to a kind of medical device will not pass preliminary assessment unless that kind of device is covered by a conformity assessment certificate under Part 4-4: see paragraph 41FDB(2)(e).

57 Section 41FB

Repeal the section.

58 Section 41FC

Repeal the section, substitute:

41FC Making an application

(1) A person may make an application to the Secretary for a kind of medical device to be included in the Register.

(2) An application must not contain information that is false or misleading in a material particular.

Note: A person might also commit an offence, or contravene a civil penalty provision, if the person makes a statement in an application that is false or misleading in a material particular: see sections 41FE and 41FEA.

59 Before section 41FE

Insert:

41FDB Preliminary assessment of applications

(1) If an application is made under section 41FC for a kind of medical device to be included in the Register in relation to a person, the Secretary must carry out an assessment of whether the requirements set out in subsection (2) have been met in relation to the application.

(2) The requirements are as follows:

(a) the application must be made:

(i) in accordance with the form approved, in writing, by the Secretary for that classification of medical device; or

(ii) in such other manner as is approved, in writing, by the Secretary for that classification of medical device;

(b) the prescribed application fee for that classification of medical device must be paid;

(c) the application must be delivered to an office of the Department specified by the Secretary;

(d) the application must be accompanied by information that is:

(i) of a kind determined under subsection (7) for that classification of medical device; and

(ii) in a form determined under subsection (8) for that classification of medical device;

(e) if regulations made for the purposes of section 41EA require the manufacturer of the kind of device to have a conformity

assessment certificate relating to the kind of medical device before an application under section 41FC can be made—such a certificate is in force;

(f) the applicant has certified the matters in section 41FD.

Passing preliminary assessment

(3) An application ***passes preliminary assessment*** if the Secretary:

(a) has carried out an assessment, under subsection (1), in relation to the application; and

(b) is satisfied that the requirements set out in subsection (2) have been met in relation to the application.

(4) If the application has not passed preliminary assessment, the Secretary must refuse the application.

Note: The Secretary is required to give notice of the refusal: see section 41FG.

Approval of forms etc.

(5) For the purposes of paragraph (2)(a), the Secretary may approve different forms and different manners for making applications for different medical device classifications.

(6) An approval of a form may require or permit an application or information to be given in accordance with specified software requirements:

(a) on a specified kind of data processing device; or

(b) by way of a specified kind of electronic transmission.

Determination of kinds and forms of information

(7) The Secretary may, by legislative instrument, determine a kind of information for the purposes of the application of subparagraph (2)(d)(i) to medical devices of a particular classification.

(8) The Secretary may, by legislative instrument, determine a form of information for the purposes of the application of subparagraph (2)(d)(ii) to medical devices of a particular classification.

60 Paragraphs 41FF(1)(a) and (b)

Repeal the paragraphs, substitute:

(a) an application for a kind of medical device to be included in the Register in relation to a person has passed preliminary assessment; and

(b) the application has not been selected for audit under section 41FH;

61 Subsection 41FF(1)

Omit ", unless the application has been selected under section 41FH for audit".

62 Subsection 41FF(2)

Omit "must give to the applicant", substitute "must make available to the applicant".

63 Section 41FG

Repeal the section, substitute:

41FG Notification of unsuccessful applications

(1) This section applies if an application under subsection 41FC(1) for a kind of medical device to be included in the Register:

(a) is refused under subsection 41FDB(5); or

(b) is refused under subsection 41FF(1A).

(2) The Secretary must notify the applicant in writing, of the refusal within 20 working days after the application has been received and the prescribed application fee has been paid.

64 Before subsection 41FH(1)

Insert:

(1A) This section applies to applications that have passed preliminary assessment.

65 Subparagraph 41FH(2)(a)(ii)

After "information", insert "or documents".

66 At the end of paragraph 41FH(3)(a)

Add "and the prescribed application fee has been paid".

67 At the end of subsection 41FM(1)

Add "or 41FJ".

68 Subparagraph 41HD(1)(d)(ii)

After "includes the medical device", insert "and the application has passed preliminary assessment".

69 Paragraph 41HD(2)(d)

After "includes the medical device", insert "and the application has passed preliminary assessment".

70 Application and transitional provisions

(1) The amendments made by this Part apply in relation to applications for inclusion of a kind of medical device in the Register made after the commencement of this item.

(2) If, immediately before the commencement of this item, a form or manner for making an application had been approved under paragraph 41FC(1)(a) of the *Therapeutic Goods Act 1989*, then, immediately after the commencement of this item, the form or manner is taken to have been approved for the purposes of paragraph 41FDB(2)(a) of that Act, as inserted by this Part.

(3) If, immediately before the commencement of this item, an application fee had been prescribed for the purposes of paragraph 41FC(2)(b) of the *Therapeutic Goods Act 1989*, then, immediately after the commencement of this item, the fee is taken to have been prescribed for the purposes of paragraph 41FDB(2)(b) of that Act, as inserted by this Part.

Part 4—Consequential amendments

Therapeutic Goods Act 1989

71 Subsection 3(1)

Insert:

passed preliminary assessment:

(a) when used in relation to a section 23 application for registration—has the meaning given by subsection 23B(3); and

(b) when used in relation to a section 23 application for listing under section 26AE—has the meaning given by subsection 23B(3); and

(c) when used in relation to a section 32DD application—has the meaning given by subsection 32DDA(3); and

(d) when used in relation to a section 41FC application—has the meaning given by subsection 41FDB(3).

72 Before paragraph 60(1A)(a)

Insert:

(aa) a preliminary assessment under section 23B, 32DDA or 41FDB;

Schedule 5—Conformity assessment procedures and certificates

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

Australian conformity assessment body certificate means a certificate that is issued by an Australian conformity assessment body and that is of a kind mentioned in section 41FIA.

conformity assessment document means:

(a) a conformity assessment certificate; or

(b) an Australian conformity assessment body certificate; or

(c) an overseas regulator conformity assessment document.

overseas regulator has the meaning given by section 41BIB.

overseas regulator conformity assessment document means a certificate or other document that is issued by an overseas regulator after that regulator has applied requirements comparable to the conformity assessment procedures to a medical device.

2 Subsection 3(6)

Omit "or an annual licensing charge", substitute ", an annual licensing charge or an annual conformity assessment body determination charge".

3 At the end of paragraph 41BA(b)

Add "or requirements comparable to conformity assessment procedures".

4 After paragraph 41BB(a)

Insert:

(aa) making conformity assessment body determinations; and

5 At the end of Division 2 of Part 4-1

Add:

41BIA Meaning of non-application of overseas requirements comparable to conformity assessment procedures

(1) A requirement that is comparable to a conformity assessment procedure is taken, for the purposes of this Chapter, not to have been applied to a medical device by an overseas regulator if:

(a) there has been a contravention of the requirement; and

(b) the contravention relates, wholly or partly, to that device or its manufacture.

(2) However, for the purposes of this Chapter (other than Part 4-11), subsection (1) does not apply if:

(a) the quality management system applied in the manufacture of the medical device complies with one or more conformity assessment standards that apply to it; and

(b) the contravention is only in respect of a part or parts of the requirement to which that conformity assessment standard, or one or more of those conformity assessment standards, relate.

41BIB Overseas regulators

(1) An ***overseas regulator*** is a body determined in an instrument under subsection (2).

(2) The Secretary may, by notifiable instrument, determine a body for the purposes of subsection (1). The Secretary must be satisfied that the body:

(a) is established outside Australia; and

(b) is responsible for applying, outside Australia, requirements to medical devices, being requirements that are comparable to the conformity assessment procedures.

(3) Without limiting subsection (2), the Secretary may determine a body by reference to a designation, recognition, approval or authorisation (however described) of the body by one or more countries.

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

6 Subparagraphs 41EC(3)(a)(viii) and (ix)

Omit "certificate", substitute "document".

7 At the end of section 41EE

Add:

(3) A conformity assessment certificate must contain any other information prescribed by the regulations for the purposes of this subsection.

8 At the end of subsection 41EF(1)

Add "The certificate must specify the period for which it is to be in force (which must be no longer than 5 years).".

9 Paragraph 41EF(2)(b)

Omit "(if any) specified in the certificate", substitute "specified in the certificate, or if the Secretary extends that period, until the end of that extended period".

10 At the end of section 41EF

Add:

Extensions

(3) The Secretary may, in writing and on his or her own initiative, extend the period for which a conformity assessment certificate is in force.

(4) An extension must be no longer than 12 months.

(5) Only one extension may be given.

(6) The Secretary:

(a) must give notice of an extension to the manufacturer in relation to whom the certificate was issued; and

(b) may give notice of an extension to the applicant for the certificate (if the applicant is not the manufacturer).

11 Subparagraphs 41ET(1)(e)(viii) and (ix)

Omit "certificate", substitute "document".

12 Subparagraphs 41EWA(4)(b)(i) and (ii)

Omit "kinds of".

13 After subsection 41EWA(4)

Insert:

(4A) If under the regulations the Secretary makes a conformity assessment body determination, the Secretary must assign a unique identification number to the body.

(4B) The Secretary must publish a list of the Australian conformity assessment bodies on the Department's website.

(4C) The Secretary may also publish on the Department's website any information relating to Australian conformity assessment bodies and either to conformity assessment body determinations or to certification-related activities of Australian conformity assessment bodies.

14 At the end of subsection 41EWA(5)

Add:

Note: See subsections 41MN(10) to (12) and 41MNA(3) for offences and a civil penalty for a breach of the conditions.

15 After subsection 41EWA(6)

Insert:

(6A) The regulations may make provision for and in relation to the effect on an Australian conformity assessment body certificate of the Australian conformity assessment body ceasing to carry on certification-related activities.

(6B) Without limiting subsection (6A), regulations made for the purposes of that subsection may make provision in relation to a matter by conferring on the Secretary a power to make a decision of an administrative character.

16 Subsection 41EWA(7)

After "revoke", insert ", suspend".

17 After subsection 41EWA(7)

Insert:

(7A) If under the regulations the Secretary suspends a conformity assessment body determination, the conditions referred to in subsection (5) continue during the suspension.

18 At the end of Part 4-4A

Add:

41EWB Content of Australian conformity assessment body certificates

(1) An Australian conformity assessment body certificate that is issued to a manufacturer of medical devices must specify whether it covers:

(a) all medical devices manufactured by the manufacturer; or

(b) only specified medical devices manufactured by the manufacturer.

(2) An Australian conformity assessment body certificate must contain any other information prescribed by the regulations for the purposes of this subsection.

(3) An Australian conformity assessment body certificate may be subject to conditions specified in the certificate.

41EWC Duration of Australian conformity assessment body certificates

(1) An Australian conformity assessment body certificate commences on the day specified for the purpose in the certificate. The certificate must specify the period for which it is to be in force (which must be no longer than 5 years).

(2) An Australian conformity assessment body certificate has effect at all times:

(a) unless the certificate is suspended by the Australian conformity assessment body; or

(b) until the end of the period specified in the certificate, or if the Australian conformity assessment body extends that period, until the end of that extended period; or

(c) until the certificate is revoked by the Australian conformity assessment body.

Extensions

(3) An Australian conformity assessment body that has issued an Australian conformity assessment body certificate may, in writing and on its own initiative, extend the period for which the certificate is in force.

(4) An extension must be no longer than 12 months.

(5) Only one extension may be given.

(6) The Australian conformity assessment body must give notice of an extension to the person to whom the certificate was issued.

41EWD Record-keeping

(1) If an Australian corporation:

(a) is an Australian conformity assessment body; and

(b) is required by a condition referred to in subsection 41EWA(5) to keep records relating to certification-related activities carried on by the corporation;

the Australian corporation must keep the records at all times while the corporation is an Australian conformity assessment body.

(2) If the Australian corporation ceases to be an Australian conformity assessment body, the corporation must keep the records referred to in subsection (1) for 15 years after that cessation.

Offences

(3) An Australian corporation commits an offence if:

(a) the corporation is subject to a requirement under this section; and

(b) the corporation contravenes the requirement.

Penalty: 1,200 penalty units.

(4) An Australian corporation commits an offence if:

(a) the corporation is subject to a requirement under this section; and

(b) the corporation contravenes the requirement.

Penalty: 300 penalty units.

(5) An offence against subsection (4) is an offence of strict liability.

19 Section 41F

After "of devices", insert "or requirements, comparable to those procedures, have been applied to the kinds of devices by an overseas regulator".

20 Paragraph 41FD(f)

Repeal the paragraph, substitute:

(f) either:

(i) appropriate conformity assessment procedures have been applied to devices of that kind; or

(ii) requirements, comparable to the conformity assessment procedures, have been applied to devices of that kind by an overseas regulator; and

21 Subparagraph 41FD(g)(i)

Omit "those conformity assessment procedures", substitute "the procedures referred to in subparagraph (f)(i) or the requirements referred to in subparagraph (f)(ii)".

22 Section 41FD (note)

Repeal the note, substitute:

Note: See section 41BH for when a medical device complies with the essential principles, section 41BI for when conformity assessment procedures are taken not to have been applied to a medical device and section 41BIA for when requirements comparable to those procedures are taken not to have been applied to a medical device.

23 After section 41FD

Insert:

41FDA Basis of certification of conformity assessment procedures

When certifying the matter referred to in paragraph 41FD(f), the applicant must also state that the certification of the matter is based:

(a) on a conformity assessment certificate that is in force; or

(b) on an Australian conformity assessment body certificate that is in force; or

(c) on an overseas regulator conformity assessment document that is in force.

24 Section 41FIA

Repeal the section, substitute:

41FIA Certificates issued by Australian conformity assessment bodies

(1) If:

(a) a section 41FC application is made for a kind of medical device to be included in the Register; and

(b) the application has been selected for audit; and

(c) a person has obtained a certificate issued by an Australian conformity assessment body to the effect that the body is satisfied that an appropriate conformity assessment procedure has been applied to devices of that kind; and

(d) the certificate was issued under a contract between the person and the body; and

(e) the certificate has been given to the Secretary; and

(f) if the conformity assessment body determination that relates to the body is limited as mentioned in paragraph 41EWA(4)(b)—the Secretary is satisfied that the certificate has been issued consistently with the determination;

the Secretary may have regard to the certificate in auditing the application.

(2) This section does not, by implication, limit the matters to which the Secretary may have regard.

25 Subparagraph 41FN(3)(b)(i)

After "device", insert "or that requirements, comparable to those procedures, have been applied to the kind of medical device by an overseas regulator".

26 Subparagraph 41FN(3)(e)(i)

After "procedures", insert "or requirements comparable to those procedures".

27 Section 41G

Omit "certificate", substitute "document".

28 Subdivision B of Division 1 of Part 4-6 (heading)

Repeal the heading, substitute:

Subdivision B—Suspension as a result of suspension of conformity assessment document

29 Section 41GF (heading)

Repeal the heading, substitute:

41GF Suspension where conformity assessment certificate suspended

30 After section 41GF

Insert:

41GFA Suspension where other certificates or documents are suspended

(1) The Secretary may, by written notice given to the person in relation to whom a kind of medical device is included in the Register, suspend the kind of device from the Register if:

(a) an Australian conformity assessment body certificate that applies to the kind of device is suspended by the Australian conformity assessment body; or

(b) an overseas regulator conformity assessment document that applies to the kind of device is suspended by the overseas regulator.

(2) However, before suspending the kind of device from the Register, the Secretary must:

(a) inform the person in writing that the Secretary proposes the suspension and set out the reasons for it; and

(b) give the person a reasonable opportunity to make submissions to the Secretary in relation to the proposed suspension.

(3) The Secretary is not to make a decision relating to the proposed suspension until the Secretary has had regard to any submissions the person makes under paragraph (2)(b).

(4) The Secretary must cause to be published on the Department's website, as soon as practicable after the suspension, a notice setting out particulars of the suspension.

31 Subsection 41GG(1)

Omit "The suspension", substitute "A suspension under section 41GF or 41GFA".

32 Subsection 41GH(1)

Omit "revoke the suspension", substitute "revoke a suspension under section 41GF".

33 After subsection 41GH(1)

Insert:

(1A) The Secretary may revoke a suspension under section 41GFA if:

(a) either:

(i) the suspension referred to in paragraph 41GFA(1)(a) or (b) ends; or

(ii) the person in relation to whom the kind of medical device is included in the Register provides the Secretary with another conformity assessment document that applies to the kind of device; and

(b) the Secretary is satisfied that there are no other grounds for suspending the kind of device from the Register.

34 Subsection 41GH(2)

Omit "revoking the suspension", substitute "making a revocation under subsection (1) or (1A)".

35 Paragraph 41GN(1)(f)

Omit "particular.", substitute "particular; or".

36 Paragraph 41GN(1)(f) (note)

Repeal the note.

37 At the end of subsection 41GN(1) (after the note)

Add:

(g) a conformity assessment document that applies to the kind of device expires; or

(h) either of the following applies:

(i) an Australian conformity assessment body certificate that applies to the kind of device is revoked by the Australian conformity assessment body;

(ii) an overseas regulator conformity assessment document that applies to the kind of device is revoked by the overseas regulator.

38 Section 41J

After "procedures", insert "or requirements comparable to those procedures".

39 Paragraphs 41JA(1)(b) and (ba)

After "certificate", insert ", or an Australian conformity assessment body certificate,".

40 Paragraph 41JA(1)(f)

After "devices", insert "or whether requirements, comparable to those procedures, have been applied to the devices by an overseas regulator".

41 After subsection 41JA(1D)

Insert:

(1E) The Secretary may, by written notice given to an Australian corporation that has been an Australian conformity assessment body require the corporation to give to the Secretary specified information, or specified documents, relating to:

(a) the certification-related activities carried on by the corporation while the corporation was an Australian conformity assessment body; or

(b) the conditions referred to in subsection 41EWA(5) that applied while the corporation was an Australian conformity assessment body.

42 Paragraph 41JB(3)(aa)

After "(da)", insert "or subsection 41JA(1E)".

43 Subsection 41KA(1) (table items 2 and 4)

After "applied to medical devices of that kind", insert "and that requirements, comparable to those procedures, have not been applied to medical devices of that kind by an overseas regulator".

44 Section 41M

After "devices", insert "or requirements, comparable to those procedures, have been applied to kinds of medical devices by an overseas regulator".

45 After subsection 41MG(2) (before the notes)

Insert:

(3) Sections 41ME, 41MEA and 41MF do not apply if requirements, comparable to the conformity assessment procedures, have been applied to the medical device by an overseas regulator.

46 Paragraph 41MH(a)

After "procedures", insert ", or the application of requirements comparable to those procedures by an overseas regulator,".

47 Paragraph 41MHA(b)

After "procedures", insert ", or the application of requirements comparable to those procedures by an overseas regulator,".

48 At the end of section 41MN

Add:

Offences relating to breaching a condition of a conformity assessment body determination

(10) An Australian corporation commits an offence if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5); and

(c) the act or omission has resulted in, will result in, or is likely to result in, harm or injury to any person.

Penalty: 20,000 penalty units.

(11) An Australian corporation commits an offence if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5).

Penalty: 5,000 penalty units.

(12) An Australian corporation commits an offence if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5).

Penalty: 500 penalty units.

(13) An offence against subsection (12) is an offence of strict liability.

49 At the end of section 41MNA

Add:

(3) An Australian corporation contravenes this subsection if:

(a) the corporation does an act or omits to do an act; and

(b) the act or omission breaches a condition referred to in subsection 41EWA(5).

Maximum civil penalty: 50,000 penalty units.

50 Paragraph 41MP(2)(d)

Omit "(other than one issued", substitute "or other document (other than a certificate or other document issued by the Secretary".

51 Subparagraph 41MP(2)(d)(ii)

Omit "particular device", substitute "device of that kind or the application of requirements, comparable to those procedures, to a device of that kind by an overseas regulator".

52 Paragraph 41MPA(2)(d)

Omit "(other than one issued", substitute "or other document (other than a certificate or other document issued by the Secretary".

53 Subparagraph 41MPA(2)(d)(ii)

Omit "particular device", substitute "device of that kind or the application of requirements, comparable to those procedures, to a device of that kind by an overseas regulator".

54 At the end of section 43

Add:

(3) An annual conformity assessment body determination charge is payable by the Australian corporation that is the subject of the conformity assessment body determination to which the charge relates.

55 After subsection 44(2)

Insert:

Annual conformity assessment body determination charge

(2A) An annual conformity assessment body determination charge for a financial year becomes payable:

(a) if the conformity assessment body determination was made in that financial year—on the 28th day after the determination came into force; and

(b) in any other case:

(i) on 1 October in that year; or

(ii) if the regulations specify another day for the purposes of this subparagraph—on that other day in that year.

This subsection is subject to subsection (3).

56 Subsection 44(3)

Omit "or (2)", substitute ", (2) or (2A)".

57 Section 44B

Omit "or an annual licensing charge", substitute ", an annual licensing charge or an annual conformity assessment body determination charge".

58 Paragraph 45(3)(a)

Omit "and annual licensing charge", substitute ", annual licensing charge and annual conformity assessment body determination charge".

59 At the end of subsection 46A(4)

Add:

; and (d) premises of a person who has been issued with, or who has applied for, an Australian conformity assessment body certificate.

60 Section 53A (after table item 31)

Insert:

31A	subsection 41MN(10)	subsection 41MN(11)

61 Subsection 54B(2)

Repeal the subsection, substitute:

(2) The maximum penalty for an offence against subsection (1) is:

(a) the maximum penalty that a court could impose in respect of an individual for the offence committed by the body corporate; or

(b) if the offence committed by the body corporate is an offence against subsection 41MN(10)—imprisonment for 5 years or 4,000 penalty units, or both.

62 Subsection 54B(4)

Repeal the subsection, substitute:

(4) The maximum civil penalty for a contravention of subsection (3) is:

(a) the maximum civil penalty that a court could impose in respect of an individual for the civil penalty provision contravened by the body corporate; or

(b) if the civil penalty provision contravened by the body corporate is subsection 41MNA(3)—5,000 penalty units.

63 Section 54BA (table item 40)

Repeal the item, substitute:

40	Subsection 41MN(1), (2) or (10)

64 After paragraph 56A(1)(l)

Insert:

(la) there was no conformity assessment body determination in force in respect of a particular Australian corporation; or

(lb) a conformity assessment body determination was in force in respect of a particular Australian corporation and the determination:

(i) was of general application; or

(ii) was limited to the extent specified in the certificate; or

65 Subsection 61(5)

Repeal the subsection, substitute:

(5) The Secretary may release to a national regulatory authority of another country, or an international organisation, being another country or an organisation with which the Commonwealth has cooperative arrangements relating to the assessment or regulation of therapeutic goods, the following information the release of which is consistent with those arrangements:

(a) therapeutic goods information;

(b) information relating to Australian conformity assessment bodies and either to conformity assessment body determinations or to certification-related activities of Australian conformity assessment bodies.

66 Application provisions

(1) The amendment of section 41EC of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to applications under section 41EB of that Act made on or after the commencement of this item.

(2) The amendments of section 41EE and subsections 41EF(1) and (2) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to a conformity assessment certificate issued on or after the commencement of this item.

(3) Subsections 41EF(3) to (6) of the *Therapeutic Goods Act 1989*, as added by this Schedule, apply in relation to:

(a) a conformity assessment certificate issued on or after the commencement of this item; and

(b) a conformity assessment certificate that was issued before that commencement and was in force immediately before that commencement.

(4) The amendment of section 41ET of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to revocations under that section on or after the commencement of this item where the breach referred to in subparagraph 41ET(1)(e)(viii), or the suspension or revocation referred to in subparagraph 41ET(1)(e)(ix), of that Act occurred on or after that commencement.

(5) The amendments of section 41FD of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to applications made under section 41FC of that Act on or after the commencement of this item.

(6) Section 41FDA of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to applications made under section 41FC of that Act on or after the commencement of this item.

(7) The amendments of section 41FN of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to kinds of medical devices included in the Register on or after the commencement of this item.

(8) The amendments of subsection 41JA(1) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under that subsection on or after the commencement of this item.

(9) The amendment of subsection 41KA(1) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to supplies of medical devices on or after the commencement of this item.

(10) The amendments of sections 41MH and 41MHA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to statements made on or after the commencement of this item.

(11) The amendments of sections 41MP and 41MPA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to restrictions, suspensions or revocations on or after the commencement of this item (whether the certificate or other document was issued before, on or after that commencement).

(12) Subsection 61(5) of the *Therapeutic Goods Act 1989*, as substituted by this Schedule, applies in relation to the release of information on or after the commencement of this item (whether the information was obtained before, on or after that commencement).

Schedule 6—Advertising

Part 1—Enforcement

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

advertise, in relation to therapeutic goods, includes make any statement, pictorial representation or design that is intended, whether directly or indirectly, to promote the use or supply of the goods, including where the statement, pictorial representation or design:

(a) is on the label of the goods; or

(b) is on the package in which the goods are contained; or

(c) is on any material included with the package in which the goods are contained.

2 Subsection 3(1) (definition of *advertisement*)

Repeal the definition.

3 Subsection 3(1)

Insert:

related body corporate has the same meaning as in the *Corporations Act 2001*.

4 At the end of section 21B

Add:

Civil penalty for advertising therapeutic goods for an indication

(4) A person contravenes this subsection if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

5 After subsection 22(1)

Insert:

(2) A person commits an offence if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion; and

(d) either:

(i) the use of the goods for the advertised indication has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods for the advertised indication, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(3) A person commits an offence if:

(a) the person, by any means, advertises therapeutic goods for an indication; and

(b) the therapeutic goods are included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion.

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

6 Subsection 22(5) (penalty)

Repeal the penalty, substitute:

Penalty: 100 penalty units.

7 After subsection 22(5)

Insert:

(5A) An offence against subsection (5) is an offence of strict liability.

8 Paragraph 29D(1)(b)

Omit "or (f)", substitute ", (f), (fa) or (fb)".

9 Paragraph 30(1)(f)

Repeal the paragraph, substitute:

(f) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the goods and the Secretary is satisfied that the contravention is significant; or

(fa) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the goods and the Secretary is satisfied that the contravention is significant; or

(fb) there is a breach, involving the goods, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 or under the regulations, and the Secretary is satisfied that:

(i) the breach is significant; and

(ii) as a result of the breach, the presentation of the goods is misleading to a significant extent; or

10 After subsection 30(1)

Insert:

(1AA) Paragraph (1)(fb) does not apply to medicines that are manufactured in Australia for export only, or are imported into Australia for export only.

11 Paragraph 30(1A)(b)

Omit "exempt; or", substitute "exempt.".

12 Paragraph 30(1A)(c)

Repeal the paragraph.

13 Subsection 30(1B)

Repeal the subsection.

14 After paragraph 30(2)(e)

Insert:

(eaa) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the goods; or

(eab) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the goods; or

15 After subsection 32BJ(2)

Insert:

Advertising biological for an indication

(2A) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and

(b) the biological is included in the Register; and

(c) the indication is not an indication accepted in relation to that inclusion; and

(d) either:

(i) the use of the biological for the advertised indication has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the biological for the advertised indication, if the biological were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2B) A person commits an offence if:

(a) the person, by any means, advertises a biological for an indication; and
(b) the biological is included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion.

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

16 Subsection 32BJ(3) (heading)

Repeal the heading.

17 Subsection 32BJ(3) (penalty)

Repeal the penalty, substitute:

Penalty: 100 penalty units.

18 After subsection 32BJ(3)

Insert:

(3A) An offence against subsection (3) is an offence of strict liability.

19 At the end of Division 2 of Part 3-2A

Add:

32BL Civil penalty for advertising biological for an indication

A person contravenes this section if:
(a) the person, by any means, advertises a biological for an indication; and
(b) the biological is included in the Register; and
(c) the indication is not an indication accepted in relation to that inclusion.

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

20 Paragraphs 32GA(1)(i) and (j)

Repeal the paragraphs, substitute:

(i) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the biological and the Secretary is satisfied that the contravention is significant; or

(j) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the biological and the Secretary is satisfied that the contravention is significant; or

(k) there is a breach, involving the biological, of an applicable provision of the Therapeutic Goods Advertising Code or any other requirement relating to advertising applicable under Part 5-1 or under the regulations, and the Secretary is satisfied that:

(i) the breach is significant; and

(ii) as a result of the breach, the presentation of the biological is misleading to a significant extent.

21 After paragraph 32GC(1)(f)

Insert:

(fa) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the biological; or

(fb) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the biological; or

22 Paragraph 41GL(g)

Repeal the paragraph, substitute:

(g) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the kind of device and the Secretary is satisfied that the contravention is significant; or

(ga) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the kind of device and the Secretary is satisfied that the contravention is significant; or

23 Paragraph 41GL(h)

Omit "serious".

24 At the end of subsection 41GN(1)

Add:

; or (i) the person contravenes a direction, or a condition of a direction, given to the person under subsection 42DV(1) in relation to the advertising of the kind of device; or

(j) if the person is a body corporate—a related body corporate of the person contravenes a direction, or a condition of a direction, given to the related body corporate under subsection 42DV(1) in relation to the advertising of the kind of device; or

(k) either of the following has not been complied with in relation to the kind of device:

(i) an applicable provision of the Therapeutic Goods Advertising Code;

(ii) any other requirement relating to advertising applicable under Part 5-1 or the regulations.

25 Section 41ML

Repeal the section, substitute:

41ML False advertising about medical devices

(1) A person commits an offence if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion; and

(d) either:

(i) the use of the medical device for the advertised purpose has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the medical device for the advertised purpose, if the medical device were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion.

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

(3) A person commits an offence if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and

(c) the purpose is not a purpose accepted in relation to that inclusion.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

26 After section 41MLA

Insert:

41MLB Civil penalty for false advertising about medical devices

A person contravenes this section if:

(a) the person, by any means, advertises a medical device as being for a purpose; and

(b) the device is of a kind included in the Register; and
(c) the purpose is not a purpose accepted in relation to that inclusion.

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

27 Subsection 42AC(2)

Omit "Section 42DKB applies", substitute "Sections 42DKB, 42DLA and 42DLC and Divisions 5 and 6 apply in relation".

28 Section 42DD

Omit "about therapeutic goods" (last occurring).

29 Section 42DD (note)

Repeal the note, substitute:

Note: See sections 42DL and 42DLB for offences and a civil penalty for advertising therapeutic goods, where the advertisement contains a restricted representation.

30 At the end of subsection 42DI(1)

Add:

; or (c) the use of the restricted representation is permitted under subsection 42DK(1).

31 Section 42DK

Repeal the section, substitute:

42DK Permitted use of restricted or prohibited representations

Restricted representations

(1) The Secretary may, by writing, permit the use of specified restricted representations in specified advertisements about specified therapeutic goods.

Prohibited representations

(2) The Secretary may, by writing, permit the use of specified prohibited representations:

(a) on the label of specified therapeutic goods; or

(b) on the package in which specified therapeutic goods are contained; or

(c) on any material included with the package in which specified therapeutic goods are contained;

if the Secretary is satisfied that the representations are necessary for the appropriate use of the goods.

(3) The Secretary may, by writing, permit the use of specified prohibited representations in specified advertisements about specified therapeutic goods if the Secretary is satisfied that the representations are necessary in the interests of public health.

Conditions

(4) A permission under this section may be subject to conditions specified in the permission.

Permission not a legislative instrument

(5) A permission under this section is not a legislative instrument.

Publication

(6) As soon as practicable after giving a permission under this section, the Secretary must cause the permission to be published on the Department's website.

32 Section 42DKB (heading)

Repeal the heading, substitute:

42DKB Certain representations not to be advertised

33 Subsection 42DKB(1)

Repeal the subsection, substitute:

(1) If a representation in an advertisement about therapeutic goods is false or misleading, the Secretary may, by notice given to a person apparently responsible for:

(a) advertising the therapeutic goods; or

(b) causing the advertising of the therapeutic goods;

prevent that person from advertising the therapeutic goods, or causing the advertising of the therapeutic goods, in circumstances where the advertisement contains that representation (whether in express terms or by necessary implication).

Note: See sections 42DLA and 42DLC for criminal offences and a civil penalty for contravening the notice.

34 At the end of section 42DKB

Add:

Publication

(3) As soon as practicable after giving a notice under subsection (1), the Secretary must cause the notice to be published on the Department's website.

35 Sections 42DL and 42DM

Repeal the sections, substitute:

42DL Advertising offences—general

(1) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement; and

(c) either:

(i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.

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

(3) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to the advertisement.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Contravening provisions

(5) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:

(a) no permission under section 42DK is in force in relation to the prohibited representation;

(b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.

(6) This subsection applies to the advertisement if it does not contain a required representation about the goods.

(7) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:

(a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;

(b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.

(8) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.

(9) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:

(a) a statement of the availability of the goods as a pharmaceutical benefit; or

(b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or

(c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.

(10) This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(11) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(12) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

Continuing offences

(13) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

(14) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DLA Advertising offences—contravening section 42DKB notice

(1) A person commits an offence if:

(a) the Secretary has given a notice to the person under section 42DKB in relation to therapeutic goods; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the Secretary has given a notice to the person under section 42DKB; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice.

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

(3) A person commits an offence if:

(a) the Secretary has given a notice to the person under section 42DKB; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

42DLB Civil penalty relating to advertisements—general

(1) A person contravenes this subsection if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) subsection (2), (3), (4), (5), (6), (7), (8) or (9) applies to the advertisement.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Contravening provisions

(2) This subsection applies to the advertisement if it contains a prohibited representation (whether in express terms or by necessary implication) about the goods and either of the following applies:

(a) no permission under section 42DK is in force in relation to the prohibited representation;

(b) a permission under section 42DK is in force in relation to the prohibited representation but the use of the prohibited representation is not in accordance with the permission or a condition of the permission.

(3) This subsection applies to the advertisement if it does not contain a required representation about the goods.

(4) This subsection applies to the advertisement if it contains a restricted representation (whether in express terms or by necessary implication) and either of the following applies:

(a) neither an approval under section 42DF nor a permission under section 42DK is in force in relation to the restricted representation;

(b) an approval under section 42DF or a permission under section 42DK is in force in relation to the restricted representation but the use of the restricted representation is not in accordance with the approval or permission or a condition of the approval or permission.

(5) This subsection applies to the advertisement if it contains a reference to this Act, other than in a statement of the registration number, listing number or device number of the goods.

(6) This subsection applies to the advertisement if it contains a statement, pictorial representation or design suggesting or implying the goods have been recommended or approved by or on behalf of a government or government authority (including a foreign government or foreign government authority), other than:

(a) a statement of the availability of the goods as a pharmaceutical benefit; or

(b) a statement, pictorial representation or design authorised or required by a government or government authority (not including a foreign government or foreign government authority); or

(c) a statement, pictorial representation or design prescribed by the regulations for the purposes of this paragraph.

(7) This subsection applies to the advertisement if it refers to substances, or goods containing substances, included in Schedule 3, 4 or 8 to the current Poisons Standard but not in

Appendix H of the current Poisons Standard, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(8) This subsection applies to the advertisement if it refers to a biological, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

(9) This subsection applies to the advertisement if it refers to therapeutic goods that are not entered in the Register and that are prescribed by the regulations for the purposes of this subsection, other than a reference authorised or required by a government or government authority (not including a foreign government or foreign government authority).

42DLC Civil penalty relating to advertisements—contravening section 42DKB notice

A person contravenes this section if:

(a) the Secretary has given a notice to the person under section 42DKB; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the notice.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

42DM Offences—non-compliance with the Therapeutic Goods Advertising Code

(1) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code; and

(c) either:

(i) the use of the goods in reliance on the advertisement has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods in reliance on the advertisement, if the goods were so used, would result in, or would be likely to result in, harm or injury to any person.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

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

(3) A person commits an offence if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

Continuing offences

(5) A person who contravenes subsection (1), (2) or (3) commits a separate offence in respect of each day (including a day of a conviction for the offence or any later day) during which the contravention continues.

(6) The maximum penalty for each day that an offence against subsection (1), (2) or (3) continues is 10% of the maximum pecuniary penalty that can be imposed in respect of that offence.

42DMA Civil penalty—non-compliance with the Therapeutic Goods Advertising Code

A person contravenes this section if:

(a) the person:

(i) advertises, by any means, therapeutic goods; or

(ii) causes the advertising, by any means, of therapeutic goods; and

(b) the advertisement does not comply with the Therapeutic Goods Advertising Code.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

36 Section 42DO

Omit "principles of the Therapeutic Goods Advertising Code specified in regulations made for the purposes of this section as if those principles", substitute "the provisions of the Therapeutic Goods Advertising Code that are prescribed by the regulations for the purposes of this section as if those provisions".

37 Section 42DP

Repeal the section, substitute:

42DP Offences—dissemination of generic information

(1) A person commits an offence if:

(a) the person disseminates, by any means, generic information about therapeutic goods to the public or a section of the public; and

(b) the dissemination of that generic information does not comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by regulations for the purposes of section 42DO.

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

(2) A person commits an offence if:

(a) the person disseminates, by any means, generic information about therapeutic goods to the public or a section of the public; and

(b) the dissemination of that generic information does not comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by regulations for the purposes of section 42DO.

Penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

42DQ Civil penalty for dissemination of generic information

A person contravenes this section if:

(a) the person disseminates, by any means, generic information about therapeutic goods to the public or a section of the public; and

(b) the dissemination of that generic information does not comply with the provisions of the Therapeutic Goods Advertising Code that are prescribed by regulations for the purposes of section 42DO.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

38 At the end of Part 5-1

Add:

Division 5—Secretary may require information or documents

42DR Secretary may require information or documents

Advertisements

(1) The Secretary may, by written notice given to a person apparently responsible for advertising therapeutic goods, or for causing the advertising of therapeutic goods, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the advertisement.

Generic information

(2) The Secretary may, by written notice given to a person apparently responsible for disseminating, or for causing the disseminating of, generic information about therapeutic goods to the public or a section of the public, require the person to give to the Secretary specified information, or to produce to the Secretary specified documents, relating to the dissemination.

Manner of compliance

(3) The person must give the information, or produce the documents, to the Secretary:

(a) within the period, of not less than 14 days after the day the notice is given, specified in the notice or within such longer period as the Secretary allows; and

(b) in the form specified in the notice.

Note: Section 42DS contains criminal offences for failing to comply with the notice and for giving false or misleading information or documents and section 42DT contains a civil penalty for giving false or misleading information or documents.

(4) The form may require or permit 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.

Notice not a legislative instrument

(5) A notice under subsection (1) or (2) is not a legislative instrument.

42DS Criminal offences for failing to comply with a notice etc.

(1) A person commits an offence if:
(a) the person is given a notice under section 42DR; and
(b) the person fails to comply with the notice.

Penalty: 500 penalty units.

(2) A person commits an offence if:
(a) the person is given a notice under section 42DR; and
(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

(4) A person commits an offence if:
(a) the person is given a notice under section 42DR; 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: Imprisonment for 12 months or 1,000 penalty units, or both.

(5) A person commits an offence if:
(a) the person is given a notice under section 42DR; 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.

(6) An offence against subsection (5) is an offence of strict liability.

42DT Civil penalty for giving false or misleading information or document in compliance with a notice

A person contravenes this section if:

(a) the person is given a notice under section 42DR; 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.

42DU Self-incrimination

(1) A person is not excused from giving information or producing a document under section 42DR on the ground that the information or the production of the document might tend to incriminate the person or expose the person to a penalty.

(2) However, in the case of an individual:

(a) the information given or the document produced; and

(b) giving the information or producing the document; and

(c) any information, document or thing obtained as a direct or indirect consequence of giving the information or producing the document;

are not admissible in evidence against the individual:

(d) in criminal proceedings, except proceedings for an offence against subsection 42DS(4) or (5); or

(e) in civil proceedings, except proceedings under section 42Y for a contravention of section 42DT.

Division 6—Directions about advertisements or generic information

42DV Directions about advertisements or generic information

Advertisements

(1) If, in relation to the advertising of therapeutic goods, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for advertising the therapeutic goods, or for causing the advertising of the therapeutic goods, to do one or more of the following:

(a) cease the advertisement;

(b) make a retraction;

(c) make a correction;

(d) recover any advertisement that is still in circulation;

(e) destroy the advertisement;

(f) cease making a particular claim or representation made by the advertisement.

Generic information

(2) If, in relation to the dissemination of generic information about therapeutic goods to the public or a section of the public, the Secretary is satisfied that there has been a contravention of this Act or the regulations, the Secretary may, in writing, direct a person apparently responsible for the dissemination, or for causing the dissemination, to do one or more of the following:

(a) withdraw the generic information;

(b) make a retraction;

(c) make a correction;

(d) recover any generic information that is still in circulation;

(e) destroy the generic information;

(f) cease making a particular claim or representation made by the generic information.

Conditions

(3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.

(4) Without limiting subsection (3), the conditions may relate to one or more of the following:

(a) the period for doing a thing the subject of the direction;

(b) in relation to the making of a retraction or correction, either or both of the following:

(i) the form and manner of the retraction or correction;

(ii) the period for which the retraction or correction must be made publicly available;

(c) the reporting to the Secretary of compliance with the direction.

Direction not a legislative instrument

(5) A direction under subsection (1) or (2) is not a legislative instrument.

Publication

(6) As soon as practicable after giving a direction under subsection (1) or (2), the Secretary must cause the direction to be published on the Department's website.

42DW Offences—contravening direction under section 42DV

(1) A person commits an offence if:

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2) in relation to therapeutic goods; and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction; and

(d) either:

(i) the use of the goods has resulted in, will result in, or is likely to result in, harm or injury to any person; or

(ii) the use of the goods, if the goods were used, would result in, or would be likely to result in, harm or injury to any person; and

(e) the harm or injury has resulted, will result, is likely to result, would result, or would be likely to result, because of the contravention.

Penalty: Imprisonment for 5 years or 4,000 penalty units, or both.

(2) A person commits an offence if:

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction.

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

(3) A person commits an offence if:

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction.

Penalty: 100 penalty units.

(4) An offence against subsection (3) is an offence of strict liability.

42DX Civil penalty for contravening direction under section 42DV

A person contravenes this section if:

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2); and

(b) the person does an act or omits to do an act; and

(c) the act or omission contravenes the direction or a condition of the direction.

Maximum civil penalty:

(a) for an individual—5,000 penalty units; and

(b) for a body corporate—50,000 penalty units.

Division 7—Public warning notices

42DY Secretary may issue a public warning notice

(1) The Secretary may issue to the public a written notice containing a warning about therapeutic goods if:

(a) the Secretary reasonably suspects that there has been a contravention of this Act or the regulations in relation to:

(i) the advertising of the therapeutic goods; or

(ii) the dissemination of generic information about the therapeutic goods to the public or a section of the public; and

(b) the Secretary is satisfied that it is in the public interest to issue the notice.

(2) If:

(a) the Secretary gives a person a notice (the ***substantiation notice***) under subsection 42DR(1) or (2); and

(b) the person fails to comply with the substantiation notice; and

(c) the Secretary is satisfied that it is in the public interest to issue a notice under this subsection;

the Secretary may issue to the public a written notice containing a warning that the person has failed to comply with the substantiation notice, and specifying the matter to which the substantiation notice related.

(3) Subsection (2) does not limit subsection (1).

(4) A notice under this section is not a legislative instrument.

39 Section 53A (after table item 9)

Insert:

9A	subsection 22(2)	subsection 22(3)

40 Section 53A (after table item 13E)

Insert:

13EA	subsection 32BJ(2A)	subsection 32BJ(2B)

41 Section 53A (after table item 29)

Insert:

29A	subsection 41ML(1)	subsection 41ML(2)

42 Section 53A (after table item 33)

Insert:

33A	subsection 42DL(1)	subsection 42DL(2)
33B	subsection 42DLA(1)	subsection 42DLA(2)
33C	subsection 42DM(1)	subsection 42DM(2)
33D	subsection 42DW(1)	subsection 42DW(2)

43 Section 54BA (table item 5)

Omit "22(7AB)", substitute "22(2) or (7AB)".

44 Section 54BA (before table item 18)

Insert:

17A	Subsection 32BJ(2A)

45 Section 54BA (after table item 39)

Insert:

39A	Subsection 41ML(1)

46 Section 54BA (after table item 43)

Insert:

43A	Subsection 42DL(1)
43B	Subsection 42DLA(1)
43C	Subsection 42DM(1)
43D	Subsection 42DW(1)

47 Subsection 60(1) (at the end of paragraph (l) of the definition of *initial decision*)

Add "or subsection 42DV(1) or (2)".

48 Application and saving provisions—therapeutic goods

(1) Subsections 21B(4) and 22(2), (3) and (5A) of the *Therapeutic Goods Act 1989*, as added or inserted by this Part, apply in relation to advertisements occurring on or after the commencement of this item.

(2) Despite the amendments made by this Part, paragraph 30(1)(f) 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 direction or requirement referred to in that paragraph that was given or made before that commencement.

(3) Paragraph 30(1)(fb) of the *Therapeutic Goods Act 1989*, as substituted by this Part, applies in relation to a breach occurring on or after the commencement of this item.

(4) Subsection 30(1AA) of the *Therapeutic Goods Act 1989*, as inserted by this Part, applies in relation to a breach occurring on or after the commencement of this item.

(5) Despite the amendments made by this Part, paragraph 30(1A)(c) and subsection 30(1B) of the *Therapeutic Goods Act 1989*, as in force immediately before the commencement of this item, continue to apply on and after that commencement in relation to a breach occurring before that commencement.

49 Application and saving provisions—biologicals

(1) Subsections 32BJ(2A), (2B) and (3A) and section 32BL of the *Therapeutic Goods Act 1989*, as inserted or added by this Part, apply in relation to advertisements occurring on or after the commencement of this item.

(2) Despite the amendments made by this Part, paragraph 32GA(1)(i) 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 direction or requirement referred to in that paragraph that was given or made before that commencement.

(3) Despite the amendments made by this Part, paragraph 32GA(1)(j) 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 breach occurring before that commencement.

(4) Paragraph 32GA(1)(k) of the *Therapeutic Goods Act 1989*, as substituted by this Part, applies in relation to a breach occurring on or after the commencement of this item.

50 Application and saving provisions—medical devices

(1) Despite the amendments made by this Part, paragraph 41GL(g) 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 direction or requirement referred to in that paragraph that was given or made before that commencement.

(2) The amendment of paragraph 41GL(h) of the *Therapeutic Goods Act 1989* made by this Part applies in relation to a breach occurring on or after the commencement of this item.

(3) Paragraph 41GN(1)(k) of the *Therapeutic Goods Act 1989*, as added by this Part, applies in relation to non-compliance occurring on or after the commencement of this item.

(4) Sections 41ML and 41MLB of the *Therapeutic Goods Act 1989*, as substituted or inserted by this Part, apply in relation to advertisements occurring on or after the commencement of this item.

51 Application and saving provisions—advertising and generic information

(1) The substitution of subsection 42DKB(1) of the *Therapeutic Goods Act 1989* made by this Part applies in relation to:

(a) an advertisement first-mentioned in that subsection that occurs on or after the commencement of this item; and

(b) an advertisement first-mentioned in that subsection that occurs in the 60 days ending at the end of the day before the commencement of this item, where no notice had been given under subsection 42DKB(1) of that Act in relation to the advertisement before that commencement.

(2) The repeal and substitution of subsection 42DKB(1) of the *Therapeutic Goods Act 1989* made by this Part does not affect the validity of a

notice given under that subsection before the commencement of this item.

(3) Subsection 42DKB(3) of the *Therapeutic Goods Act 1989*, as added by this Part, applies in relation to a notice given on or after the commencement of this item.

(4) The substitution of section 42DL of the *Therapeutic Goods Act 1989* made by this Part applies in relation to advertisements occurring on or after the commencement of this item.

(5) Section 42DL 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) an advertisement published or broadcast before that commencement; and

(b) an advertisement published or broadcast on or after that commencement, where a notice was given under section 42DKB of that Act before that commencement.

(6) Sections 42DLA and 42DLC of the *Therapeutic Goods Act 1989*, as substituted by this Part, apply in relation to notices given under section 42DKB of that Act on or after the commencement of this item.

(7) Sections 42DLB, 42DM and 42DMA of the *Therapeutic Goods Act 1989*, as substituted by this Part, apply in relation to advertisements occurring on or after the commencement of this item.

(8) Section 42DM 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 publications or broadcasts occurring before that commencement.

(9) Sections 42DP and 42DQ of the *Therapeutic Goods Act 1989*, as substituted by this Part, apply in relation to the dissemination of generic information about therapeutic goods occurring on or after the commencement of this item.

(10) Section 42DP 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 publications or broadcasts occurring before that commencement.

(11) Divisions 5, 6 and 7 of Part 5-1 of the *Therapeutic Goods Act 1989*, as added by this Part, apply in relation to:

(a) advertisements occurring before, on or after the commencement of this item; and

(b) the dissemination of generic information about therapeutic goods occurring before, on or after the commencement of this item.

Part 2—Removal of requirement for advertisements to be approved

Broadcasting Services Act 1992

52 Clause 6 of Schedule 2

Repeal the clause.

53 Paragraph 7(1)(j) of Schedule 2

Omit ", 5 and 6", substitute "and 5".

54 Paragraph 8(1)(i) of Schedule 2

Omit ", 5 and 6", substitute "and 5".

55 Paragraph 9(1)(i) of Schedule 2

Omit ", 5 and 6", substitute "and 5".

56 Paragraph 11(1)(d) of Schedule 2

Omit ", 5 and 6", substitute "and 5".

57 Paragraph 24(1)(a) of Schedule 6

Omit ", 5 and 6", substitute "and 5".

58 Subclause 24(4) of Schedule 6

Omit ", 5 and 6", substitute "and 5".

Therapeutic Goods Act 1989

59 Section 42B

Repeal the following definitions:

(a) definition of ***approval number***;
(b) definition of ***approved advertisement***;
(c) definition of ***broadcaster***;
(d) definition of ***broadcast media***;
(e) definition of ***mainstream media***;

(f) definition of ***publisher***;
(g) definition of ***publishing***;
(h) definition of ***specified media***;
(i) definition of ***visual broadcast media***.

60 Division 2 of Part 5-1

Repeal the Division.

61 Section 42DA

Repeal the section, substitute:

42DA Simplified outline of this Division

> Representations in advertisements about therapeutic goods may be restricted representations, required representations or prohibited representations. The offences and civil penalties in Division 3A refer to these 3 kinds of representations.

62 Paragraph 42DF(4)(a)

Repeal the paragraph.

63 Division 3A of Part 5-1 (heading)

Repeal the heading, substitute:

Division 3A—Advertising offences and civil penalties

64 Section 42DKA

Repeal the section.

65 Saving provisions

(1) Despite the amendments made by this Part, Divisions 1 and 2 of Part 5-1 of the *Therapeutic Goods Act 1989*, and the *Therapeutic Goods Regulations 1990*, as in force immediately before the commencement of this item, continue to apply on and after that commencement in relation to advertisements published or broadcast before that commencement.

(2) Despite the amendments made by this Part, clauses 6, 7, 8, 9 and 11 of Schedule 2 to the *Broadcasting Services Act 1992*, as in force immediately before the commencement of this item, continue to apply on and after that commencement in relation to advertisements relating to therapeutic goods that were broadcast before that commencement.

(3) Despite the amendments made by this Part, clause 24 of Schedule 6 to the *Broadcasting Services Act 1992*, as in force immediately before the commencement of this item, continues to apply on and after that commencement in relation to advertisements relating to therapeutic goods that were provided on a datacasting service before that commencement.

Schedule 7—Enforcement

Therapeutic Goods Act 1989

1 Subsection 3(1)

Insert:

Federal Circuit Court means the Federal Circuit Court of Australia.

2 Section 5A

Omit "subsections 21A(1), (2) and (4)", substitute "subsections 21A(1), (4) and (4A)".

3 Section 5A

After "22A,", insert "32DO,".

4 Subparagraph 9G(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

5 Subparagraph 9G(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

6 Subsections 9G(2) and (3)

Repeal the subsections.

7 At the end of section 9G

Add:

(5) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a request under section 9D for the variation of an entry in the Register in relation to therapeutic goods; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

8 Paragraph 14(1)(c)

After "to the goods", insert "(other than by reason of a matter relating to labelling or packaging)".

9 Subparagraph 14(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

10 Subparagraph 14(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

11 Paragraph 14(1)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

12 Subsections 14(2) and (3)

Repeal the subsections.

13 At the end of paragraph 14(4)(c)

Add "(other than by reason of a matter relating to labelling or packaging)".

14 After subsection 14(4)

Insert:

(4A) A person commits an offence if:

(a) the person imports therapeutic goods into Australia; and

(b) the goods are imported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than by reason of a matter relating to labelling or packaging).

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

15 Subsection 14(5)

Repeal the subsection.

16 Before subsection 14(5A)

Insert:

Exception

17 Subsection 14(5A)

Omit "Subsection (1), (2) or (4)", substitute "Subsection (1), (4) or (4A)".

18 Subparagraph 14(6)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

19 Subparagraph 14(6)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

20 Paragraph 14(6)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

21 Subsections 14(7) and (8)

Repeal the subsections.

22 After subsection 14(9)

Insert:

(9AA) A person commits an offence if:

(a) the person supplies therapeutic goods for use in Australia; and

(b) the goods are supplied without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods.

Penalty: 100 penalty units.

(9AB) An offence against subsection (9AA) is an offence of strict liability.

23 Subsection 14(9A)

Omit "Subsection (6), (7) or (9)", substitute "Subsection (6), (9) or (9AA)".

24 Subparagraph 14(10)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

25 Subparagraph 14(10)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

26 Paragraph 14(10)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

27 Subsections 14(11) and (12)

Repeal the subsections.

28 After subsection 14(13)

Insert:

(13AA) A person commits an offence if:

(a) the person exports therapeutic goods from Australia; and

(b) the goods are exported without the consent in writing of the Secretary; and

(c) the goods do not conform with a standard applicable to the goods (other than a standard relating to the labelling of the goods for supply in Australia).

Penalty: 100 penalty units.

(13AB) An offence against subsection (13AA) is an offence of strict liability.

29 Subsection 14(13A)

Omit "Subsection (10), (11) or (13)", substitute "Subsection (10), (13) or (13AA)".

30 Paragraph 14B(a)

Omit "subsection 14(1), (2), (4), (10), (11) or (13)", substitute "subsection 14(1), (4), (4A), (10), (13) or (13AA)".

31 Paragraph 15(2)(c)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

32 Subsections 15(3) and (4)

Repeal the subsections.

33 At the end of section 15

Add:

(6) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a condition of a consent.

Penalty: 100 penalty units.

(7) An offence against subsection (6) is an offence of strict liability.

34 Subparagraph 19B(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

35 Subparagraph 19B(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

36 Subsections 19B(2) and (3)

Repeal the subsections.

37 After subsection 19B(4)

Insert:

(4A) A person commits an offence if:

(a) the person:

(i) imports into Australia therapeutic goods for use in humans; or

(ii) exports from Australia therapeutic goods for use in humans; or

(iii) manufactures in Australia therapeutic goods for use in humans; or

(iv) supplies in Australia therapeutic goods for use in humans; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods in relation to the person;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19;

(v) the goods are the subject of an approval under section 19A.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

38 Subsection 19B(5)

Omit "subsection (1), (2) or (4)", substitute "subsection (1), (4) or (4A)".

39 Paragraph 19B(6)(a)

Omit "or will not,", substitute "will not, or is not likely to,".

40 Paragraph 19B(6)(b)

Omit "would not", substitute "would not, or would not be likely to,".

41 Paragraph 19B(7)(a)

Omit "subsection (1), (2) or (4)", substitute "subsection (1), (4) or (4A)".

42 After subsection 20(1B)

Insert:

(1BA) A person commits an offence if:

(a) the person is the sponsor of therapeutic goods for use in humans; and

(b) the person:

(i) imports the goods into Australia; or

(ii) exports the goods from Australia; or

(iii) manufactures the goods in Australia; or

(iv) supplies the goods in Australia; and

(c) the person has not, at the time of the importation, export, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the goods;

(ii) premises used in the manufacture of the goods.

Penalty: 100 penalty units.

(1BB) An offence against subsection (1BA) is an offence of strict liability.

43 Subsection 20(1C)

Omit "paragraph (1B)(c)", substitute "paragraphs (1B)(c) and (1BA)(c)".

44 Subparagraph 21A(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

45 Subparagraph 21A(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

46 Subsections 21A(2) and (3)

Repeal the subsections.

47 After subsection 21A(4)

Insert:

(4A) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in or in connection with a certification of any matter under subsection 26A(2) or 26AB(2); and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

48 Paragraph 21A(5)(d)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

49 Subsections 21A(6) and (7)

Repeal the subsections.

50 After subsection 21A(8)

Insert:

(8A) A person commits an offence if:

(a) therapeutic goods are registered or listed in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the registration or listing of the goods.

Penalty: 100 penalty units.

(8B) An offence against subsection (8A) is an offence of strict liability.

51 Subparagraph 21A(9)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

52 Subparagraph 21A(9)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

53 Paragraph 21A(9)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

54 Subsection 21A(9) (note)

Repeal the note.

55 Subsections 21A(10) and (11)

Repeal the subsections, substitute:

(9A) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: 500 penalty units.

(10) A person commits an offence if:

(a) the Secretary has authorised, under subsection 19(5), the person to supply therapeutic goods; and

(b) the person supplies those goods; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 19(7).

Penalty: 100 penalty units.

(11) An offence against subsection (10) is an offence of strict liability.

56 Subparagraph 21A(11A)(e)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

57 Subparagraph 21A(11A)(e)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

58 Paragraph 21A(11A)(f)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

59 Subsection 21A(11B)

Repeal the subsection.

60 After subsection 21A(11C)

Insert:

(11D) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 19(7A) rules; and

(c) the person supplies:

(i) therapeutic goods specified in those rules; or

(ii) therapeutic goods included in a class of therapeutic goods specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 100 penalty units.

(11E) An offence against subsection (11D) is an offence of strict liability.

61 Subparagraphs 21A(12)(e)(i) and (ii)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

62 Subsection 21A(12) (note)

Repeal the note.

63 Subsections 21A(13) and (14)

Repeal the subsections, substitute:

(12A) A person commits an offence if:

(a) the person uses therapeutic goods; and

(b) the goods are used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) the goods are not:

(i) exempt goods; or

(ii) listed goods; or

(iii) registered goods; or

(iv) goods exempt under section 18A; or

(v) goods that are the subject of an approval under section 19A; and

(d) the goods are not used in accordance with:

(i) an approval or authority under section 19; or

(ii) a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 500 penalty units.

(13) A person commits an offence if:

(a) the person uses therapeutic goods; and

(b) the goods are used:

(i) in the treatment of another person; or
(ii) solely for experimental purposes in humans; and

(c) the goods are not:
(i) exempt goods; or
(ii) listed goods; or
(iii) registered goods; or
(iv) goods exempt under section 18A; or
(v) goods that are the subject of an approval under section 19A; and

(d) the goods are not used in accordance with:
(i) an approval or authority under section 19; or
(ii) a condition applicable under regulations made for the purposes of subsection 19(4A).

Penalty: 100 penalty units.

(14) An offence against subsection (13) is an offence of strict liability.

64 Subsections 22(7A) and (8)

Repeal the subsections.

65 Subparagraph 22A(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

66 Subparagraph 22A(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

67 Subsections 22A(2) and (3)

Repeal the subsections.

68 At the end of section 22A

Add:

(5) A person commits an offence if:
(a) the person makes a statement; and

(b) the statement is made in or in connection with an application for registration of therapeutic goods; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

69 Subsection 30EA(1) (table item 5)

Omit "subsection 19B(1), (2) or (4)", substitute "subsection 19B(1), (4) or (4A)".

70 Paragraph 30EC(1)(c)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

71 Subsections 30EC(2) and (3)

Repeal the subsections.

72 At the end of section 30EC

Add:

(5) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 30EA.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

73 Subparagraph 30F(4B)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

74 Subparagraph 30F(4B)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

75 Paragraph 30F(4B)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

76 Subsections 30F(4C) and (4D)

Repeal the subsections.

77 Subsection 30F(6)

Repeal the subsection, substitute:

(6) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement.

Penalty: 100 penalty units.

(6A) An offence against subsection (6) is an offence of strict liability.

78 After subsection 31(4A)

Insert:

(4B) A person commits an offence if:

(a) either:

(i) the person is given a notice under subsection (1) and the person is covered by paragraph (1)(ab) or (ac); or

(ii) the person is given a notice under subsection (2) and the person is covered by paragraph (2)(ab) or (ac); and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

79 Subsection 31(5)

Omit "under subsection (4)", substitute "against subsection (4B)".

80 After subsection 31(5)

Insert:

(5AA) Subsection (4B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5AA): see subsection 13.3(3) of the *Criminal Code*.

81 Subparagraph 31(5A)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

82 Subparagraph 31(5A)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

83 Subsections 31(5B) to (6)

Repeal the subsections, substitute:

(6) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or 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: Imprisonment for 12 months or 1,000 penalty units, or both.

(7) A person commits an offence if:

(a) the person is given a notice under this section in relation to therapeutic goods; and

(b) the person gives information or 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.

(8) An offence against subsection (7) is an offence of strict liability.

84 Section 31C (heading)

Repeal the heading, substitute:

31C Criminal offences for failing to give information or documents sought under section 31A, 31AA, 31B or 31BA

85 Section 31C

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

86 Section 31C (note)

Repeal the note.

87 At the end of section 31C

Add:

(2) A person commits an offence if:

(a) the person is given a notice under section 31A, 31AA, 31B or 31BA; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

88 After subsection 31D(1)

Insert:

(1A) A person to whom a notice is given under section 31A, 31AA, 31B or 31BA commits an offence if:

(a) the person gives information to the Secretary in compliance or purported compliance with the notice; and

(b) the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

89 Subsection 31D(2)

After "Subsection (1)", insert "or (1A)".

90 Subsection 31D(2)

After "subparagraph (1)(b)(i)", insert "or (1A)(b)(i)".

91 Subsection 31D(2) (note)

Repeal the note, substitute:

Note: A defendant bears an evidential burden in relation to the matter in subsection (2): see subsection 13.3(3) of the *Criminal Code*.

92 Subsection 31D(3)

After "Subsection (1)", insert "or (1A)".

93 Subsection 31D(3)

After "subparagraph (1)(b)(ii)", insert "or (1A)(b)(ii)".

94 Subsection 31D(3) (note)

Repeal the note, substitute:

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

95 After subsection 31E(1)

Insert:

(1A) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the document is false or misleading; and

(c) the document is produced in compliance or purported compliance with a notice given under section 31A, 31AA, 31B or 31BA.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

96 Subsection 31E(2)

After "Subsection (1)", insert "or (1A)".

97 Subsection 31E(2) (note)

Repeal the note, substitute:

Note: A defendant bears an evidential burden in relation to the matter in subsection (2): see subsection 13.3(3) of the *Criminal Code*.

98 Subsection 31E(3)

After "Subsection (1)", insert "or (1A)".

99 Subsection 31E(3) (note)

Repeal the note, substitute:

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

100 Subsection 31F(1)

After "section", insert "31,".

101 Paragraph 31F(2)(d)

After "of,", insert "subsection 31(5A), (6) or (7) or".

102 Paragraph 31F(2)(e)

Repeal the paragraph, substitute:

(e) civil proceedings, except proceedings under section 42Y for a contravention of section 31AAA.

103 Subparagraph 32BA(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

104 Subparagraph 32BA(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

105 Subsections 32BA(2) and (3)

Repeal the subsections.

106 After subsection 32BA(4)

Insert:

(4A) A person commits an offence if:

(a) the person imports into Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the importation into Australia of the biological;

(v) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

107 Subsection 32BA(5)

Omit "Subsection (1), (2) or (4)", substitute "Subsection (1), (4) or (4A)".

108 Paragraph 32BA(6)(a)

Omit "or will not,", substitute "will not, or is not likely to,".

109 Paragraph 32BA(6)(b)

Omit "would not", substitute "would not, or would not be likely to,".

110 Subparagraph 32BB(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

111 Subparagraph 32BB(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

112 Subsections 32BB(2) and (3)

Repeal the subsections.

113 After subsection 32BB(4)

Insert:

(4A) A person commits an offence if:

(a) the person exports from Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the exportation from Australia of the biological.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

114 Subsection 32BB(5)

Omit "Subsection (1), (2) or (4)", substitute "Subsection (1), (4) or (4A)".

115 Paragraph 32BB(6)(a)

Omit "or will not,", substitute "will not, or is not likely to,".

116 Paragraph 32BB(6)(b)

Omit "would not", substitute "would not, or would not be likely to,".

117 After section 32BB

Insert:

32BBA Treating biologicals as prohibited imports or exports

If:

(a) the importation or exportation of a biological is an offence under subsection 32BA(1), (4) or (4A) or 32BB(1), (4) or (4A); 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 biological 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.

118 Subparagraph 32BC(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

119 Subparagraph 32BC(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

120 Subsections 32BC(2) and (3)

Repeal the subsections.

121 After subsection 32BC(4)

Insert:

(4A) A person commits an offence if:

(a) the person manufactures in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

122 Subsection 32BC(5)

Omit "Subsection (1), (2) or (4)", substitute "Subsection (1), (4) or (4A)".

123 Paragraph 32BC(6)(a)

Omit "or will not,", substitute "will not, or is not likely to,".

124 Paragraph 32BC(6)(b)

Omit "would not", substitute "would not, or would not be likely to,".

125 Subparagraph 32BD(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

126 Subparagraph 32BD(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

127 Subsections 32BD(2) and (3)

Repeal the subsections.

128 After subsection 32BD(4)

Insert:

(4A) A person commits an offence if:

(a) the person supplies in Australia a biological for use in humans; and

(b) none of the following subparagraphs applies:

(i) the biological is included in the Register in relation to the person;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CK(1) that is held by the person, being an approval covering the supply in Australia of the biological;

(v) the biological is the subject of an authority under subsection 32CM(1) or (7A) that covers the supply of the biological by the person;

(vi) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2) that is held by the person, being an approval covering the supply in Australia of the biological.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

129 Subsection 32BD(5)

Omit "Subsection (1), (2) or (4)", substitute "Subsection (1), (4) or (4A)".

130 Paragraph 32BD(6)(a)

Omit "or will not,", substitute "will not, or is not likely to,".

131 Paragraph 32BD(6)(b)

Omit "would not", substitute "would not be likely to,".

132 At the end of section 32BF

Add:

Application of the Customs Act 1901

(7) If:

(a) the importation or exportation of a biological contravenes subsection (1) or (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 biological 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.

133 Section 32BG (heading)

Repeal the heading, substitute:

32BG Criminal offences and civil penalty relating to a failure to notify the Secretary about manufacturing

134 Subsection 32BG(1) (heading)

Repeal the heading, substitute:

Criminal offences

135 After subsection 32BG(1)

Insert:

(1A) A person commits an offence if:

(a) the person:

(i) imports a biological into Australia for use in humans; or

(ii) exports a biological from Australia for use in humans; or

(iii) manufactures a biological in Australia for use in humans; or

(iv) supplies a biological in Australia for use in humans; and

(b) the person is the sponsor of the biological; and

(c) the person is not exempt under subsection 32CA(1) in relation to the biological and the biological is not exempt under subsection 32CA(2); and

(d) the person has not, at or before the time of the importation, exportation, manufacture or supply, properly notified to the Secretary either or both of the following:

(i) the manufacturer of the biological;

(ii) the premises used in the manufacture of the biological.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

136 Subparagraphs 32BI(1)(d)(i) and (ii)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

137 Subsections 32BI(2) and (3)

Repeal the subsections.

138 Subsection 32BI(4) (penalty)

Repeal the penalty, substitute:

Penalty: 500 penalty units.

139 At the end of section 32BI

Add:

(5) A person commits an offence if:

(a) the person uses a biological; and

(b) the biological is used:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans; and

(c) none of the following subparagraphs applies:

(i) the biological is included in the Register;

(ii) the person is exempt under subsection 32CA(1) in relation to the biological or the biological is exempt under subsection 32CA(2);

(iii) the biological is exempt under section 32CB;

(iv) the biological is the subject of an approval under subsection 32CO(1), (1A) or (2);

(v) the person uses the biological in accordance with an approval under subsection 32CK(1);

(vi) the person uses the biological in accordance with a condition applicable under regulations made for the purposes of section 32CL;

(vii) the person uses the biological in accordance with an authority under subsection 32CM(1) or (7A).

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

140 Subparagraph 32CJ(6)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

141 Subparagraph 32CJ(6)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

142 Paragraph 32CJ(6)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

143 Subsections 32CJ(7) and (8)

Repeal the subsections, substitute:

(7) A person commits an offence if:

(a) the Secretary gives a notice to the person under subsection (2); and

(b) the notice specifies a particular requirement mentioned in subsection (3); and

(c) the person fails to comply with that requirement.

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

144 Subsection 32CJ(9) (penalty)

Repeal the penalty, substitute:

Penalty: 100 penalty units.

145 Subparagraph 32CN(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

146 Subparagraph 32CN(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

147 Paragraph 32CN(1)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

148 Subsections 32CN(2) and (3)

Repeal the subsections.

149 After subsection 32CN(4)

Insert:

(4A) A person commits an offence if:

(a) the Secretary has authorised, under subsection 32CM(1), the person to supply a biological; and

(b) the person supplies the biological; and

(c) any of the following applies:

(i) the supply is not in accordance with the authority;

(ii) the supply is not in accordance with the conditions to which the authority is subject;

(iii) the supply is not in accordance with regulations made for the purpose of subsection 32CM(6).

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

150 Subparagraph 32CN(5)(e)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

151 Subparagraph 32CN(5)(e)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

152 Paragraph 32CN(5)(f)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

153 Subsection 32CN(6)

Repeal the subsection.

154 Subsection 32CN(7) (penalty)

Repeal the penalty, substitute:

Penalty: 500 penalty units.

155 At the end of section 32CN

Add:

(8) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 32CM(7A) rules; and

(c) the person supplies a biological specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 100 penalty units.

(9) An offence against subsection (8) is an offence of strict liability.

156 Subparagraph 32DO(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

157 Subparagraph 32DO(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

158 Subsections 32DO(2) and (3)

Repeal the subsections.

159 Subsection 32DO(4) (penalty)

Repeal the penalty, substitute:

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

160 At the end of section 32DO

Add:

(5) A person commits an offence if:

(a) the person makes a statement; and

(b) the statement is made in, or in connection with, an application for inclusion of a biological in the Register; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

161 Paragraph 32EF(1)(d)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

162 Subsections 32EF(2) and (3)

Repeal the subsections.

163 Subsection 32EF(4) (penalty)

Repeal the penalty, substitute:

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

164 At the end of section 32EF

Add:

(5) A person commits an offence if:

(a) a biological is included in the Register in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the inclusion of the biological in the Register.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

165 Paragraph 32HC(1)(c)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

166 Subsections 32HC(2) and (3)

Repeal the subsections.

167 Subsection 32HC(4) (penalty)

Repeal the penalty, substitute:

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

168 At the end of section 32HC

Add:

(5) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 32HA.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

169 After subsection 32JB(1A)

Insert:

(1B) A person commits an offence if:

(a) the person is given a notice under section 32JA; and

(b) the person is covered by paragraph 32JA(1)(b) or (c); and

(c) the person fails to comply with the notice.

Penalty: 100 penalty units.

(1C) An offence against subsection (1B) is an offence of strict liability.

(1D) Subsection (1B) does not apply if the person has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1D): see subsection 13.3(3) of the *Criminal Code*.

170 Subparagraph 32JB(2)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

171 Subparagraph 32JB(2)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

172 Subsections 32JB(3) and (4)

Repeal the subsections.

173 Subsection 32JB(5) (penalty)

Repeal the penalty, substitute:

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

174 At the end of section 32JB

Add:

(6) A person commits an offence if:

(a) the person is given a notice under section 32JA; 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.

(7) An offence against subsection (6) is an offence of strict liability.

175 Paragraph 32JD(2)(d)

Omit "(2), (3) or (5)", substitute "(1B), (2), (5) or (6)".

176 After subsection 32JI(1)

Insert:

(1A) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

177 Subsection 31JI(2) (penalty)

Repeal the penalty, substitute:

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

178 At the end of section 32JI

Add:

(3) A person commits an offence if:

(a) the person is given a notice under section 32JE, 32JF, 32JG or 32JH; 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.

(4) An offence against subsection (3) is an offence of strict liability.

179 Paragraph 32JK(2)(d)

Omit "subsection 32JI(1) or (2)", substitute "subsection 32JI(1), (1A), (2) or (3)".

180 Subparagraph 35(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

181 Subparagraph 35(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

182 Paragraph 35(1)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

183 Subsections 35(2) and (3)

Repeal the subsections.

184 After subsection 35(4)

Insert:

(4A) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods (other than goods exempt under section 18A or 32CB); and

(b) the goods are for supply for use in humans; and

(c) none of the following applies:

(i) the goods are exempt goods;

(ii) the person is an exempt person in relation to the manufacture of the goods;

(iii) the person is the holder of a licence that is in force that authorises the carrying out of that step in relation to the goods at those premises.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

185 Subparagraph 35(5)(e)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

186 Subparagraph 35(5)(e)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

187 Paragraph 35(5)(f)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

188 Subsections 35(6), (7) and (8)

Repeal the subsections.

189 Subsection 35(10)

Repeal the subsection, substitute:

(10) A person commits an offence if:

(a) the person, at premises in Australia, carries out a step in the manufacture of therapeutic goods; and

(b) the goods are for supply for use in humans; and

(c) the goods are exempt under section 18A or 32CB; and

(d) the person is not the holder of a licence that:

(i) is in force; and

(ii) authorises the carrying out of that step in relation to the goods at those premises.

Penalty: 100 penalty units.

(11) An offence against subsection (10) is an offence of strict liability.

190 Paragraph 35B(1)(d)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

191 Subsections 35B(2) and (3)

Repeal the subsections.

192 At the end of section 35B

Add:

(5) A person commits an offence if:

(a) the person holds a licence; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the licence.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

193 Subparagraph 41EI(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

194 Subparagraph 41EI(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

195 Subsections 41EI(2) and (3)

Repeal the subsections.

196 At the end of section 41EI

Add:

(5) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is in or in connection with an application for a conformity assessment certificate; and

(c) the statement is false or misleading in a material particular.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

197 Division 2 of Part 4-4 (note after heading)

Omit "(6) and (8)", substitute "(8) and (8A)".

198 Subparagraph 41FE(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

199 Subparagraph 41FE(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

200 Subsections 41FE(2) and (3)

Repeal the subsections.

201 At the end of section 41FE

Add:

(5) A person commits an offence if:

(a) the person makes a statement (whether orally, in a document or in any other way); and

(b) the statement is false or misleading in a material particular; and

(c) the statement is in or in connection with:

(i) an application for including a kind of medical device in the Register under this Chapter; or

(ii) a certification or purported certification under section 41FD.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

202 Division 2 of Part 4-5 (note after heading)

Omit "(2) and (4)", substitute "(4) and (4A)".

203 After subsection 41JB(3A)

Insert:

(3B) A person commits an offence if:

(a) the person is given a notice under section 41JA; and
(b) the person is covered by paragraph 41JA(1)(b), (ba), (d) or (da) or subsection 41JA(1E); and
(d) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3C) An offence against subsection (3B) is an offence of strict liability.

(3D) Subsection (3B) does not apply if the person has a reasonable excuse.

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

204 Subparagraph 41JB(4)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

205 Subparagraph 41JB(4)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

206 Subsections 41JB(5) and (6)

Repeal the subsections.

207 At the end of section 41JB

Add:

(8) A person commits an offence if:
(a) the person is given a notice under section 41JA; and
(b) the person gives information in purported compliance with the notice; and
(c) the information is false or misleading in a material particular.

Penalty: 100 penalty units.

(9) An offence against subsection (8) is an offence of strict liability.

208 Paragraph 41JC(2)(d)

Omit "(5) or (7)", substitute "(7) or (8)".

209 Section 41JG

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

210 Section 41JG (note)

Repeal the note.

211 At the end of section 41JG

Add:

(2) A person commits an offence if:

(a) the person is given a notice under section 41JCA, 41JD, 41JE, 41JF or 41JFA; and

(b) the person fails to comply with the notice.

Penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

212 Section 41JH

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

213 At the end of section 41JH

Add:

(2) A person to whom a notice is given under section 41JCA, 41JD, 41JE, 41JF or 41JFA commits an offence if:

(a) the person gives information to the Secretary; and

(b) the information:

(i) is false or misleading; or

(ii) omits any matter or thing without which the information is misleading; and

(c) the information is given in compliance or purported compliance with the notice.

Penalty: 100 penalty units.

(3) An offence against subsection (2) is an offence of strict liability.

(4) Subsection (1) or (2) does not apply as a result of subparagraph (1)(b)(i) or (2)(b)(i) if the information is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (4): see subsection 13.3(3) of the *Criminal Code*.

(5) Subsection (1) or (2) does not apply as a result of subparagraph (1)(b)(ii) or (2)(b)(ii) if the information did not omit any matter or thing without which the information is misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (5): see subsection 13.3(3) of the *Criminal Code*.

214 After subsection 41JI(1)

Insert:

(1A) A person commits an offence if:

(a) the person produces a document to the Secretary; and

(b) the document is false or misleading; and

(c) the document is produced in compliance or purported compliance with a notice given under section 41JCA, 41JD, 41JE, 41JF or 41JFA.

Penalty: 100 penalty units.

(1B) An offence against subsection (1A) is an offence of strict liability.

(1C) Subsection (1) or (1A) does not apply if the document is not false or misleading in a material particular.

Note: A defendant bears an evidential burden in relation to the matter in subsection (1C): see subsection 13.3(3) of the *Criminal Code*.

215 Subsection 41JI(2)

After "Subsection (1)", insert "or (1A)".

216 Paragraph 41KC(1)(c)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

217 Subsections 41KC(2) and (3)

Repeal the subsections.

218 At the end of section 41KC

Add:

(5) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a requirement imposed on the person under section 41KA.

Penalty: 100 penalty units.

(6) An offence against subsection (5) is an offence of strict liability.

219 Subparagraph 41MA(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

220 Subparagraph 41MA(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

221 Paragraph 41MA(1)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

222 Subsections 41MA(2) and (3)

Repeal the subsections.

223 After subsection 41MA(4)

Insert:

(4A) A person commits an offence if:

(a) the person imports a medical device into Australia; and

(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device; and

(c) the Secretary has not consented to the importation; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

224 Subparagraph 41MA(5)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

225 Subparagraph 41MA(5)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

226 Paragraph 41MA(5)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

227 Subsections 41MA(6) and (7)

Repeal the subsections.

228 After subsection 41MA(8)

Insert:

(8A) A person commits an offence if:

(a) the person supplies a medical device for use in Australia; and

(b) the medical device does not comply with the essential principles; and

(c) the Secretary has not consented to the supply; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(8B) An offence against subsection (8A) is an offence of strict liability.

229 Paragraph 41MA(9)(b)

After "principles", insert "relating to matters other than the labelling of the device for supply in Australia".

230 Subparagraph 41MA(9)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

231 Subparagraph 41MA(9)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

232 Paragraph 41MA(9)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

233 Subsections 41MA(10) and (11)

Repeal the subsections.

234 Paragraph 41MA(12)(b)

After "principles", insert "relating to matters other than the labelling of the device for supply in Australia".

235 Subsection 41MA(13)

Repeal the subsection, substitute:

(13) A person commits an offence if:

(a) the person exports a medical device from Australia; and

(b) the medical device does not comply with the essential principles relating to matters other than the labelling of the device for supply in Australia; and

(c) the Secretary has not consented to the exportation; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(14) An offence against subsection (13) is an offence of strict liability.

236 Paragraph 41MAA(3)(b)

After "principles", insert "relating to matters other than the labelling of the device for supply in Australia".

237 Paragraph 41MC(2)(c)

Omit "has resulted, or will result in,", substitute "has resulted in, will result in, or is likely to result in,".

238 Subsections 41MC(3) and (4)

Repeal the subsections.

239 At the end of section 41MC

Add:

(6) A person commits an offence if:

(a) the person does an act or omits to do an act; and

(b) the act or omission breaches a condition of a consent.

Penalty: 100 penalty units.

(7) An offence against subsection (6) is an offence of strict liability.

240 Paragraph 41MD(a)

Omit "subsection 41MA(1), (2), (4), (9), (10) or (12)", substitute "subsection 41MA(1), (4), (4A), (9), (12) or (13)".

241 Subparagraph 41ME(1)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

242 Subparagraph 41ME(1)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

243 Paragraph 41ME(1)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

244 Subsections 41ME(2) and (3)

Repeal the subsections.

245 After subsection 41ME(4)

Insert:

(4A) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person supplies the device in Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

246 Subparagraph 41ME(5)(d)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

247 Subparagraph 41ME(5)(d)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

248 Paragraph 41ME(5)(e)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

249 Subsections 41ME(6) and (7)

Repeal the subsections.

250 At the end of section 41ME

Add:

(9) A person commits an offence if:

(a) the person manufactures a medical device; and

(b) the person exports the device from Australia; and

(c) the conformity assessment procedures have not been applied to the device; and

(d) the device is not of a kind covered by an exemption in force under section 41GS.

Penalty: 100 penalty units.

(10) An offence against subsection (9) is an offence of strict liability.

251 Subparagraph 41MF(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

252 Subparagraph 41MF(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

253 Paragraph 41MF(1)(d)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

254 Subparagraph 41MF(3)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

255 Subparagraph 41MF(3)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

256 Paragraph 41MF(3)(d)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

257 Subparagraph 41MI(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

258 Subparagraph 41MI(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

259 Subsections 41MI(2) and (3)

Repeal the subsections.

260 Subsection 41MI(5)

Repeal the subsection, substitute:

(5) A person commits an offence if:

(a) the person:

(i) imports a medical device into Australia; or

(ii) exports a medical device from Australia; or

(iii) supplies a medical device in Australia; or

(iv) manufactures a medical device in Australia; and

(b) none of the following subparagraphs applies in relation to the device:

(i) the device is of a kind included in the Register in relation to the person;

(ii) the device is of a kind covered by an exemption in force under section 41GS;

(iii) the device is an exempt device;

(iv) the device is the subject of an approval under section 41HB or an authority under section 41HC;

(v) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that is held by the person.

Penalty: 100 penalty units.

(5A) An offence against subsection (5) is an offence of strict liability.

261 Subsection 41MI(6)

Omit "(2) or (4)", substitute "(4) or (5)".

262 Paragraph 41MI(7)(a)

Omit "or will not,", substitute "will not, or is not likely to,".

263 Paragraph 41MI(7)(b)

Omit "would not", substitute "would not, or would not be likely to,".

264 Paragraph 41MJ(a)

Omit "(2) or (4)", substitute "(4) or (5)".

265 Paragraph 41MN(1)(d)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

266 Subsections 41MN(2) and (3)

Repeal the subsections.

267 After subsection 41MN(4)

Insert:

(4A) A person commits an offence if:

(a) a kind of medical device is included in the Register in relation to the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the inclusion of the kind of device in the Register.

Penalty: 100 penalty units.

(4B) An offence against subsection (4A) is an offence of strict liability.

268 Paragraph 41MN(5)(d)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

269 Subsections 41MN(6) and (7)

Repeal the subsections.

270 After subsection 41MN(8)

Insert:

(8A) A person commits an offence if:

(a) a conformity assessment certificate is issued in respect of the person; and

(b) the person does an act or omits to do an act; and

(c) the act or omission breaches a condition of the conformity assessment certificate.

Penalty: 100 penalty units.

(8B) An offence against subsection (8A) is an offence of strict liability.

271 Subparagraph 41MO(1)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

272 Subparagraph 41MO(1)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

273 Paragraph 41MO(1)(d)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

274 Subsections 41MO(2) and (3)

Repeal the subsections.

275 After subsection 41MO(4)

Insert:

(4AA) A person commits an offence if:

(a) the person has been granted an authority under subsection 41HC(1) relating to a specified kind of medical device; and

(b) the person supplies a medical device of that kind:

(i) otherwise than in accordance with the authority; or

(ii) otherwise than in accordance with any conditions to which the authority is subject; or

(iii) otherwise than in accordance with any regulations made for the purpose of subsection 41HC(5).

Penalty: 100 penalty units.

(4AB) An offence against subsection (4AA) is an offence of strict liability.

276 Subparagraph 41MO(4A)(e)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

277 Subparagraph 41MO(4A)(e)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

278 Paragraph 41MO(4A)(f)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

279 Subsection 41MO(4B)

Repeal the subsection.

280 After subsection 41MO(4C)

Insert:

(4D) A person commits an offence if:

(a) the person is a health practitioner; and

(b) the person is included in a class of health practitioners specified in subsection 41HC(6) rules; and

(c) the person supplies a medical device of a kind specified in those rules; and

(d) any of the following applies:

(i) the supply is not in accordance with those rules;

(ii) the supply is not in the circumstances specified in those rules;

(iii) the supply is not in accordance with the conditions specified in those rules.

Penalty: 100 penalty units.

(4E) An offence against subsection (4D) is an offence of strict liability.

281 Subparagraph 41MO(5)(c)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

282 Subparagraph 41MO(5)(c)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

283 Subsections 41MO(6) and (7)

Repeal the subsections.

284 At the end of section 41MO

Add:

(9) A person commits an offence if:

(a) the person has been granted an approval under section 41HB relating to a specified medical device or specified kind of medical device; and

(b) the person uses a medical device of that kind:

(i) in the treatment of another person; or

(ii) solely for experimental purposes in humans;

otherwise than in accordance with the approval.

Penalty: 100 penalty units.

(10) An offence against subsection (9) is an offence of strict liability.

285 Subparagraph 42V(6)(b)(i)

Omit "or will result in,", substitute "will result in, or is likely to result in,".

286 Subparagraph 42V(6)(b)(ii)

Omit "would result in", substitute "would result in, or would be likely to result in,".

287 Paragraph 42V(6)(c)

Omit "or would result,", substitute "is likely to result, would result, or would be likely to result,".

288 Subsections 42V(6A) and (6B)

Repeal the subsections.

289 After subsection 42V(6C)

Insert:

(6D) A person commits an offence if the person fails to comply with a requirement under subsection (1) in relation to a supply of therapeutic goods.

Penalty: 100 penalty units.

(6E) An offence against subsection (6D) is an offence of strict liability.

290 After section 42YC

Insert:

42YCA Continuing contraventions of civil penalty provisions

(1) If an act or thing is required under a civil penalty provision to be done:

(a) within a particular period; or

(b) before a particular time;

then the obligation to do that act or thing continues until the act or thing is done (even if the period has expired or the time has passed).

(2) A person who contravenes a civil penalty provision that requires an act or thing to be done:

(a) within a particular period; or

(b) before a particular time;

commits a separate contravention of that provision in respect of each day during which the contravention occurs (including the day the order under subsection 42Y(2) is made or any later day).

291 Part 5A-2

Repeal the Part, substitute:

Part 5A-2—Infringement notices

42YJ Simplified outline of this Part

The Secretary can give a person an infringement notice for a contravention of a provision of this Act or the regulations that is an offence of strict liability or for a contravention of a civil penalty provision.

The person can choose to pay an amount as an alternative to having court proceedings brought against the person for the contravention. If the person does not choose to pay the amount, proceedings can be brought against the person in relation to the contravention.

42YK When an infringement notice may be given

(1) If the Secretary reasonably believes that a person has contravened:

(a) a provision of this Act or the regulations that is an offence of strict liability; or

(b) a civil penalty provision;

the Secretary may give to the person an infringement notice for the alleged contravention.

(2) The infringement notice must be given within 12 months after the day on which the contravention is alleged to have taken place.

(3) A single infringement notice must relate only to a single contravention of a single provision unless subsection (4) applies.

(4) The Secretary may give a person a single infringement notice relating to multiple contraventions of a single provision if:

(a) the provision requires the person to do a thing within a particular period or before a particular time; and

(b) the person fails or refuses to do that thing within that period or before that time; and

(c) the failure or refusal occurs on more than 1 day; and

(d) each contravention is constituted by the failure or refusal on one of those days.

Note: For continuing offences, see subsection 4K(2) of the *Crimes Act 1914*. For continuing contraventions of civil penalty provisions, see section 42YCA of this Act.

42YKA Matters to be included in an infringement notice

(1) An infringement notice must:

(a) be identified by a unique number; and

(b) state the day on which it is given; and

(c) state the name of the person to whom the notice is given; and

(d) state the name and contact details of the person who gave the notice; and

(e) give brief details of the alleged contravention, or each alleged contravention, to which the notice relates, including:

(i) the provision that was allegedly contravened; and

(ii) the maximum penalty that a court could impose for each contravention, if the provision were contravened; and

(iii) the time (if known) and day of, and the place of, each alleged contravention; and

(f) state the amount that is payable under the notice; and

(g) give an explanation of how payment of the amount is to be made; and

(h) state that, if the person to whom the notice is given pays the amount within 28 days after the day the notice is given, then (unless the notice is withdrawn):

(i) if the provision is an offence of strict liability—the person will not be liable to be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) will not be brought in relation to the alleged contravention; and

(i) state that payment of the amount is not an admission of guilt or liability; and

(j) state that the person may apply to the Secretary to have the period in which to pay the amount extended; and

(k) state that the person may choose not to pay the amount and, if the person does so:

(i) if the provision is an offence of strict liability—the person may be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may be brought in relation to the alleged contravention; and

(l) set out how the notice can be withdrawn; and

(m) state that if the notice is withdrawn:

(i) if the provision is an offence of strict liability—the person may be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may be brought in relation to the alleged contravention; and

(n) state that the person may make written representations to the Secretary seeking the withdrawal of the notice.

(2) If the notice relates to only one alleged contravention of the provision by the person, the amount to be stated in the notice for the purposes of paragraph (1)(f) is the lesser of:

(a) one-fifth of the maximum penalty that a court could impose on the person for that contravention; and

(b) 12 penalty units where the person is an individual, or 60 penalty units where the person is a body corporate.

(3) If the notice relates to more than one alleged contravention of the provision by the person, the amount to be stated in the notice for the purposes of paragraph (1)(f) is the lesser of:

(a) one-fifth of the amount worked out by adding together the maximum penalty that a court could impose on the person for each alleged contravention; and

(b) either:

(i) if the person is an individual—the number of penalty units worked out by multiplying the number of alleged contraventions by 12; or

(ii) if the person is a body corporate—the number of penalty units worked out by multiplying the number of alleged contraventions by 60.

Note: Under section 42YK, a single infringement notice may only deal with multiple contraventions if they are contraventions of a single provision continuing over a period.

42YKB Extension of time to pay amount

(1) A person to whom an infringement notice has been given may apply to the Secretary for an extension of the period referred to in paragraph 42YKA(1)(h).

(2) If the application is made before the end of that period, the Secretary may, in writing, extend that period. The Secretary may do so before or after the end of that period.

(3) If the Secretary extends that period, a reference in this Part, or in a notice or other instrument under this Part, to the period referred to in paragraph 42YKA(1)(h) is taken to be a reference to that period so extended.

(4) If the Secretary does not extend that period, a reference in this Part, or in a notice or other instrument under this Part, to the period referred to in paragraph 42YKA(1)(h) is taken to be a reference to the period that ends on the later of the following days:

(a) the day that is the last day of the period referred to in paragraph 42YKA(1)(h);

(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 extend the period more than once under subsection (2).

42YKC Withdrawal of an infringement notice

Representations seeking withdrawal of notice

(1) A person to whom an infringement notice has been given may make written representations to the Secretary seeking the withdrawal of the notice.

Withdrawal of notice

(2) The Secretary may withdraw an infringement notice given to a person (whether or not the person has made written representations seeking the withdrawal).

(3) When deciding whether or not to withdraw an infringement notice (the ***relevant infringement notice***), the Secretary:

(a) must take into account any written representations seeking the withdrawal that were given by the person to the Secretary; and

(b) may take into account the following:

(i) whether a court has previously imposed a penalty on the person for a contravention of a provision of this Act or the regulations that is an offence of strict liability or for a contravention of a civil penalty provision;

(ii) the circumstances of the alleged contravention;

(iii) whether the person has paid an amount, stated in an earlier infringement notice, for a contravention of a provision of this Act or the regulations that is an offence of strict liability or for a contravention of a civil penalty provision if the contravention is constituted by conduct that is the same, or substantially the same, as the conduct alleged to constitute the contravention in the relevant infringement notice;

(iv) any other matter the Secretary considers relevant.

Notice of withdrawal

(4) Notice of the withdrawal of the infringement notice must be given to the person. The withdrawal notice must state:

(a) the person's name and address; and

(b) the day the infringement notice was given; and

(c) the identifying number of the infringement notice; and

(d) that the infringement notice is withdrawn; and

(e) that:

(i) if the provision is an offence of strict liability—the person may be prosecuted in a court for the alleged contravention; or

(ii) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may be brought in relation to the alleged contravention.

Refund of amount if infringement notice withdrawn

(5) If:

(a) the Secretary withdraws the infringement notice; and

(b) the person has already paid the amount stated in the notice;

the Commonwealth must refund to the person an amount equal to the amount paid.

42YKD Effect of payment of amount

(1) If the person to whom an infringement notice for an alleged contravention of a provision is given pays the amount stated in the notice before the end of the period referred to in paragraph 42YKA(1)(h):

(a) any liability of the person for the alleged contravention is discharged; and

(b) if the provision is an offence of strict liability—the person may not be prosecuted in a court for the alleged contravention; and

(c) if the provision is a civil penalty provision—proceedings seeking an order under subsection 42Y(2) may not be brought in relation to the alleged contravention; and

(d) the person is not regarded as having admitted guilt or liability for the alleged contravention; and

(e) if the provision is an offence of strict liability—the person is not regarded as having been convicted of the alleged offence.

(2) Subsection (1) does not apply if the notice has been withdrawn.

42YKE Effect of this Part

This Part does not:

(a) require an infringement notice to be given to a person for an alleged contravention of a provision of this Act or the regulations that is an offence of strict liability or an alleged contravention of a civil penalty provision; or

(b) affect the liability of a person for an alleged contravention of a provision of this Act or the regulations that is an offence of strict liability or an alleged contravention of a civil penalty provision if:

(i) the person does not comply with an infringement notice given to the person for the contravention; or

(ii) an infringement notice is not given to the person for the contravention; or

(iii) an infringement notice is given to the person for the contravention and is subsequently withdrawn; or

(c) prevent the giving of 2 or more infringement notices to a person for an alleged contravention of a provision of this Act or the regulations that is an offence of strict liability or an alleged contravention of a civil penalty provision; or

(d) limit a court's discretion to determine the amount of a penalty to be imposed on a person who is found to have contravened a provision of this Act or the regulations that is an offence of strict liability or to have contravened a civil penalty provision.

292 At the end of Chapter 5A

Add:

Part 5A-4—Injunctions

42YM Simplified outline of this Part

The Secretary can seek injunctions from the Federal Court or Federal Circuit Court to restrain a person from contravening this Act or the regulations, or to compel compliance with this Act or the regulations.

Interim injunctions are also available.

42YN Grant of injunctions

Restraining injunctions

(1) If a person has engaged, is engaging or is proposing to engage, in conduct in contravention of this Act or the regulations, the Federal Court or Federal Circuit Court may, on application by the Secretary, grant an injunction:

(a) restraining the person from engaging in the conduct; and

(b) if, in the court's opinion, it is desirable to do so—requiring the person to do a thing.

Performance injunctions

(2) If:

(a) a person has refused or failed, or is refusing or failing, or is proposing to refuse or fail, to do a thing; and

(b) the refusal or failure was, is or would be a contravention of this Act or the regulations;

the Federal Court or Federal Circuit Court may, on application by the Secretary, grant an injunction requiring the person to do that thing.

42YO Interim injunctions

Grant of interim injunctions

(1) Before deciding an application for an injunction under section 42YN, the Federal Court or Federal Circuit Court may grant an interim injunction:

(a) restraining a person from engaging in conduct; or

(b) requiring a person to do a thing.

No undertakings as to damages

(2) The Federal Court or Federal Circuit Court must not require the Secretary to give an undertaking as to damages as a condition of granting an interim injunction.

42YP Discharging or varying injunctions

The Federal Court or Federal Circuit Court may discharge or vary an injunction granted by that court under this Part.

42YQ Certain limits on granting injunctions not to apply

Restraining injunctions

(1) The power of the Federal Court or Federal Circuit Court under this Part to grant an injunction restraining a person from engaging in conduct may be exercised:

(a) whether or not it appears to the court that the person intends to engage again, or to continue to engage, in conduct of that kind; and

(b) whether or not the person has previously engaged in conduct of that kind; and

(c) whether or not there is an imminent danger of substantial damage to any other person if the person engages in conduct of that kind.

Performance injunctions

(2) The power of the Federal Court or Federal Circuit Court under this Part to grant an injunction requiring a person to do a thing may be exercised:

(a) whether or not it appears to the court that the person intends to refuse or fail again, or to continue to refuse or fail, to do that thing; and

(b) whether or not the person has previously refused or failed to do that thing; and

(c) whether or not there is an imminent danger of substantial damage to any other person if the person refuses or fails to do that thing.

42YR Other powers of court unaffected

The powers conferred on the Federal Court or Federal Circuit Court under this Part are in addition to, and not instead of, any

other powers of the court, whether conferred by this Act or otherwise.

293 Section 46 (heading)

Repeal the heading, substitute:

46 Searches to monitor compliance with Act or regulations

294 At the end of paragraph 46(1)(b)

Add "and section 48BA".

295 After paragraph 46A(1)(a)

Insert:

(aa) examine or observe any activity conducted on the premises;

296 At the end of subsection 46A(1)

Add:

; (e) take extracts from or make copies of any such book, record or document.

297 Paragraph 47(1)(b)

Omit "and subsection 48(1)", substitute ", subsection 48(1) and section 48C".

298 After paragraph 48(1)(a)

Insert:

(aa) to examine or observe any activity conducted on the premises;

299 After section 48A

Insert:

48AA Completing execution of warrant under section 50 after temporary cessation

(1) This section applies if an authorised person who is executing a warrant under section 50 in relation to premises temporarily ceases its execution and leaves the premises.

(2) The authorised person may complete the execution of the warrant if:

(a) the warrant is still in force; and

(b) the authorised person is absent from the premises:

(i) for not more than 1 hour; or

(ii) if there is an emergency situation, for not more than 12 hours or such longer period as allowed by a magistrate under subsection (5); or

(iii) for a longer period if the occupier of the premises consents in writing.

Application for extension in emergency situation

(3) An authorised person may apply to a magistrate for an extension of the 12-hour period mentioned in subparagraph (2)(b)(ii) if:

(a) there is an emergency situation; and

(b) the authorised person believes on reasonable grounds that the authorised person will not be able to return to the premises within that period.

(4) If it is practicable to do so, before making the application, the authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension.

Extension in emergency situation

(5) A magistrate may extend the period during which the authorised person may be away from the premises if:

(a) an application is made under subsection (3); and

(b) the magistrate is satisfied, by information on oath or affirmation, that there are exceptional circumstances that justify the extension; and

(c) the extension would not result in the period ending after the warrant ceases to be in force.

300 After section 48B

Insert:

48BA Use of electronic equipment at premises for monitoring compliance with Act or regulations

(1) An authorised person may operate electronic equipment at the premises to see whether information relevant to determining whether this Act or the regulations have been complied with is accessible by doing so.

(2) If the authorised person, after operating the equipment, finds that information relevant to determining whether this Act or the regulations have been complied with is accessible by doing so, he or she may:

(a) operate electronic equipment on the premises to put the information in documentary form and remove the documents so produced from the premises; or

(b) operate electronic equipment on the premises to transfer the information to a disk, tape or other storage device that:

(i) is brought to the premises for the exercise of the power; or

(ii) is on the premises and the use of which for that purpose has been agreed in writing by the occupier of the premises;

and remove the disk, tape or other storage device from the premises.

(3) An authorised person may operate electronic equipment as mentioned in subsection (1) or (2) only if the authorised person believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

Note: For compensation for damage to electronic equipment, see section 48D.

(4) If the authorised person believes on reasonable grounds that:

(a) information relevant to determining whether this Act or the regulations have been complied with may be accessible by operating electronic equipment at the premises; and

(b) expert assistance is required to operate the equipment; and

(c) if he or she does not take action under this subsection, the information may be destroyed, altered or otherwise interfered with;

he or she may do whatever is necessary to secure the equipment, whether by locking it up, placing a guard or otherwise.

(5) The authorised person must give notice to the occupier of the premises of his or her intention to secure equipment and of the fact that the equipment may be secured for up to 24 hours.

(6) The equipment may be secured:

(a) for a period not exceeding 24 hours; or

(b) until the equipment has been operated by the expert;

whichever happens first.

(7) The authorised person may apply to a magistrate for an extension of the 24-hour period if the authorised person believes on reasonable grounds that the equipment needs to be secured for longer than that period.

(8) The authorised person must give notice to the occupier of the premises of his or her intention to apply for an extension, and the occupier is entitled to be heard in relation to the application.

(9) The 24-hour period may be extended more than once.

301 Section 48C (heading)

Repeal the heading, substitute:

48C Use of electronic equipment at premises relating to offences and civil penalty provisions

302 Subsection 48C(1)

Omit "The", substitute "An".

303 Subsection 48C(1)

Omit "if he or she believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment".

304 Subsection 48C(2)

Repeal the subsection, substitute:

(2) If the authorised person, after operating the equipment, finds that evidential material in respect of an offence against this Act, in respect of a contravention of a civil penalty provision or in respect of both is accessible by doing so, he or she may:

(a) seize the equipment and any disk, tape or other associated device; or

(b) operate electronic equipment on the premises to put the evidential material in documentary form and remove the documents so produced from the premises; or

(c) operate electronic equipment on the premises to transfer the evidential material to a disk, tape or other storage device that:

(i) is brought to the premises for the exercise of the power; or

(ii) is on the premises and the use of which for that purpose has been agreed in writing by the occupier of the premises;

and remove the disk, tape or other storage device from the premises.

(2A) An authorised person may operate electronic equipment as mentioned in subsection (1) or (2) only if the authorised person believes on reasonable grounds that the operation of the equipment can be carried out without damage to the equipment.

Note: For compensation for damage to electronic equipment, see section 48D.

305 Paragraph 48C(3)(a)

Omit "copy", substitute "transfer".

306 Subsection 48C(7)

Repeal the subsection, substitute:

(7) The authorised person may apply to a magistrate for an extension of the 24-hour period if the authorised person believes on reasonable grounds that the equipment needs to be secured for longer than that period.

307 At the end of section 48C

Add:

(9) The 24-hour period may be extended more than once.

308 Paragraph 48D(1)(a)

After "section", insert "48BA or".

309 Subsection 48E(2)

Repeal the subsection, substitute:

(2) Subsection (1) does not apply if possession of the document, film, computer file, thing or information by the occupier could constitute an offence against a law of the Commonwealth or contravention of a civil penalty provision.

310 After section 48F

Insert:

48FA Responsibility to provide facilities and assistance

(1) The occupier of premises to which a warrant relates, or another person who apparently represents the occupier, must provide an authorised person executing the warrant with all reasonable facilities and assistance for the effective exercise of the authorised person's powers.

(2) A person commits an offence if:

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

(b) the person fails to comply with that subsection.

Penalty for contravention of this subsection:30 penalty units.

311 Subparagraph 49(4)(a)(ii)

After "subsection 48(1)", insert "and section 48BA".

312 Subparagraph 50(4)(b)(ii)

After "48(1)", insert "and section 48C".

313 Section 51A (heading)

Repeal the heading, substitute:

51A Inspections for purposes of Mutual Recognition Convention

314 Section 53A (table items 8 and 9)

Repeal the items, substitute:

8	subsection 21A(9)	subsection 21A(9A)
9	subsection 21A(12)	subsection 21A(12A)

315 Section 53A (before table item 13F)

Insert:

13EB	subsection 32CJ(6)	subsection 32CJ(7)

316 After paragraph 54(3)(a)

Insert:

(aa) makes an order under section 19B of the *Crimes Act 1914* in respect of a person charged with an offence against this Act; or

317 Section 54BA (table items 1 to 4)

Repeal the items, substitute:

1	Subsection 9G(1)
2	Subsection 14(1), (6) or (10)
3	Subsection 15(2)
4	Subsection 19B(1)
4A	Subsection 21A(1) or (5)

318 Section 54BA (table item 6)

Repeal the item, substitute:

6	Subsection 22A(1)

319 Section 54BA (table items 9 to 11)

Repeal the items, substitute:

9	Subsection 30EC(1)
10	Subsection 30F(4B)

11	Subsection 31(5A)

320 Section 54BA (table items 14 to 17)

Repeal the items, substitute:

14	Subsection 32BA(1)
15	Subsection 32BB(1)
16	Subsection 32BC(1)
17	Subsection 32BD(1)

321 Section 54BA (table items 19 and 20)

Repeal the items, substitute:

19	Subsection 32CJ(6)
20	Subsection 32DO(1)

322 Section 54BA (table items 23 to 25)

Repeal the items, substitute:

23	Subsection 32EF(1)
24	Subsection 32HC(1)
25	Subsection 32JB(2)

323 Section 54BA (table item 27)

Repeal the item, substitute:

27	Subsection 35(1) or (5)
27AA	Subsection 35B(1)

324 Section 54BA (table items 28 to 31)

Repeal the items, substitute:

28	Subsection 41EI(1)
29	Subsection 41FE(1)
30	Subsection 41JB(4)
31	Subsection 41JH(1)

325 Section 54BA (table items 33 to 36)

Repeal the items, substitute:

33	Subsection 41KC(1)

34	Subsection 41MA(1), (5) or (9)
35	Subsection 41MC(2)
36	Subsection 41ME(1) or (5)

326 Section 54BA (table item 39)

Repeal the item, substitute:

39	Subsection 41MI(1)

327 Section 54BA (table item 40)

Repeal the item, substitute:

40	Subsection 41MN(1), (5) or (10)

328 Section 54BA (table item 46)

Repeal the item, substitute:

46	Subsection 42V(6)

329 Application provision—application of the *Criminal Code*

The amendments of section 5A of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to offences committed on or after the commencement of this item.

330 Application provision—Register

The amendments of section 9G of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to statements made on or after the commencement of this item.

331 Application provisions—therapeutic goods

(1) The amendments of section 14 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to therapeutic goods imported, exported or supplied on or after the commencement of this item.

(2) The amendment of section 14B of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to goods imported or exported on or after the commencement of this item.

(3) The amendments of section 15 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(4) The amendments of section 19B of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to therapeutic goods imported, exported, manufactured or supplied on or after the commencement of this item.

(5) Subsection 20(1BA) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to therapeutic goods imported, exported, manufactured or supplied on or after the commencement of this item.

(6) The amendments of subsection 21A(1), the repeal of subsections 21A(2) and (3) and the insertion of subsections 21A(4A) and (4B) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to statements made on or after the commencement of this item.

(7) The amendment of subsection 21A(5), the repeal of subsections 21A(6) and (7) and the insertion of subsections 21A(8A) and (8B) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(8) The amendments of subsections 21A(9) and (11A), the substitution of subsections 21A(9A), (10) and (11), the repeal of subsections 21A(11B) and 22(7A) and the insertion of subsections 21A(11D) and (11E) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to therapeutic goods supplied on or after the commencement of this item.

(9) The amendment of subsection 21A(12), the substitution of subsections 21A(12A), (13) and (14) and the repeal of subsection 22(8) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to the use of therapeutic goods on or after the commencement of this item.

(10) The amendments of section 22A of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to statements made on or after the commencement of this item.

(11) The amendment of section 30EA of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to goods supplied on or after the commencement of this item.

(12) The amendments of section 30EC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(13) The amendments of section 30F of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given on or after the commencement of this item.

(14) The amendments of section 31 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given on or after the commencement of this item.

(15) Subsections 31C(2) and (3) of the *Therapeutic Goods Act 1989*, as added by this Schedule, apply in relation to notices given on or after the commencement of this item.

(16) The amendments of sections 31D and 31E of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under section 31A, 31AA, 31B or 31BA of that Act on or after the commencement of this item.

(17) The amendments of section 31F of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under section 31, 31A, 31AA, 31B or 31BA of that Act on or after the commencement of this item.

332 Application provisions—biologicals

(1) The amendments of section 32BA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to biologicals imported on or after the commencement of this item.

(2) The amendments of section 32BB of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to biologicals exported on or after the commencement of this item.

(3) Section 32BBA and subsection 32BF(7) of the *Therapeutic Goods Act 1989*, as inserted or added by this Schedule, apply in relation to biologicals imported or exported on or after the commencement of this item.

(4) The amendments of section 32BC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to biologicals manufactured on or after the commencement of this item.

(5) The amendments of section 32BD of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to biologicals supplied on or after the commencement of this item.

(6) Subsections 32BG(1A) and (1B) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, apply in relation to biologicals imported, exported, manufactured or supplied on or after the commencement of this item.

(7) The amendments of section 32BI of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to the use of biologicals on or after the commencement of this item.

(8) The amendments of section 32CJ of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given on or after the commencement of this item.

(9) The amendments of section 32CN of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to biologicals supplied on or after the commencement of this item.

(10) The amendments of section 32DO of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to statements made on or after the commencement of this item.

(11) The amendments of sections 32EF and 32HC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(12) The amendments of sections 32JB and 32JD of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under section 32JA of that Act on or after the commencement of this item.

(13) The amendments of sections 32JI and 32JK of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under section 32JE, 32JF, 32JG or 32JH of that Act on or after the commencement of this item.

333 Application provisions—manufacturing of therapeutic goods

(1) The amendments of section 35 of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to steps in the manufacture of therapeutic goods that are carried out on or after the commencement of this item.

(2) The amendments of section 35B of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

334 Application provisions—medical devices

(1) The amendments of sections 41EI and 41FE of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to statements made on or after the commencement of this item.

(2) The amendments of sections 41JB and 41JC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under section 41JA of that Act on or after the commencement of this item.

(3) The amendments of sections 41JG, 41JH and 41JI of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to notices given under section 41JCA, 41JD, 41JE, 41JF or 41JFA of that Act on or after the commencement of this item.

(4) The amendments of section 41KC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(5) The amendments of sections 41MA and 41MAA of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to medical devices imported, supplied or exported on or after the commencement of this item.

(6) The amendments of section 41MC of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(7) The amendments of sections 41MD and 41MJ of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to medical devices imported or exported on or after the commencement of this item.

(8) The amendments of section 41ME of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to medical devices manufactured on or after the commencement of this item.

(9) The amendments of section 41MF of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to medical devices supplied or exported on or after the commencement of this item.

(10) The amendments of section 41MI of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to medical devices imported, exported, supplied or manufactured on or after the commencement of this item.

(11) The amendments of section 41MN of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to acts or omissions occurring on or after the commencement of this item.

(12) The amendments of subsections 41MO(1) and (4A), the repeal of subsections 41MO(2), (3) and (4B) and the insertion of subsections 41MO(4AA), (4AB), (4D) and (4E) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to a medical device supplied on or after the commencement of this item.

(13) The amendments of subsection 41MO(5), the repeal of subsections 41MO(6) and (7) and the addition of subsections 41MO(9) and (10) of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to use of a medical device on or after the commencement of this item.

335 Application provision—product tampering

The amendments of section 42V of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to requirements imposed on or after the commencement of this item.

336 Application provision—civil penalties

Section 42YCA of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to an act or thing required to be done within a particular period, or before a particular time, where the period ends, or the time occurs, on or after the commencement of this item.

337 Application and saving provisions—infringement notices

(1) Part 5A-2 of the *Therapeutic Goods Act 1989*, as substituted by this Schedule, applies in relation to an alleged contravention of a provision of that Act or the regulations under that Act that is an offence of strict liability, or an alleged contravention of a civil penalty provision, occurring on or after the commencement of this item.

(2) Part 5A-2 of the *Therapeutic Goods Act 1989*, and the *Therapeutic Goods Regulations 1990*, as in force immediately before the commencement of this item, continue to apply on and after that commencement in relation to:

(a) an alleged commission of an offence occurring before that commencement; and

(b) an alleged contravention of a civil penalty provision occurring before that commencement.

338 Application provision—injunctions

Part 5A-4 of the *Therapeutic Goods Act 1989*, as added by this Schedule, applies in relation to contraventions occurring, or proposed to occur, on or after the commencement of this item.

339 Application and saving provisions—entry, searches and warrants

(1) The amendments of sections 46, 46A, 48, 48C, 48D and 48E of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to entries to premises on or after the commencement of this item.

(2) Section 48AA of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to warrants issued under section 50, or signed under section 51, of that Act on or after the commencement of this item.

(3) Section 48BA of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to entries to premises on or after the commencement of this item.

(4) The repeal and substitution of subsection 48C(2) of the *Therapeutic Goods Act 1989* made by this Schedule does not affect the validity of

anything done under that subsection before the commencement of this item.

(5) Section 48FA of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to warrants issued under section 49 or 50, or signed under section 51, of that Act on or after the commencement of this item.

(6) The amendment of section 49 of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to applications for a warrant made on or after the commencement of this item.

340 Application provision—offences and forfeiture

Paragraph 54(3)(aa) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to an order referred to in that paragraph that is made on or after the commencement of this item (whether the person was charged with the offence before, on or after that commencement).

341 Saving provision—personal liability of an executive officer of a body corporate

Despite the amendments made by this Schedule, the table in section 54BA 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 the application of section 54B of that Act on or after that commencement in relation to offences committed by bodies corporate before that commencement.

Schedule 8—Record-keeping etc.

Therapeutic Goods Act 1989

1 Subparagraph 32EA(1)(a)(i)

After "biological", insert ", complies with record-keeping conditions under paragraph 32EC(2)(c) or keeps documents that relate to the biological".

2 At the end of paragraph 32EA(1)(a)

Add:

(iv) while on those premises, to inspect, and make copies of, any records kept in compliance with a condition under paragraph 32EC(2)(c); and

(v) while on those premises, to inspect, and make copies of, any documents that relate to the biological; and

3 At the end of subsection 32EA(1)

Add:

; and (c) if requested to do so by an authorised person, make any record kept in compliance with a condition under paragraph 32EC(2)(c) available to the authorised person for inspection:

(i) if the authorised person requires the record to be made available immediately—immediately; and

(ii) if the authorised person requires the record to be made available at or before a time specified by the authorised person—at or before that time; and

(iii) in the form required by the authorised person.

4 After paragraph 32EC(2)(c)

Insert:

(ca) reporting requirements relating to the biological; or

5 Subparagraph 46A(4)(a)(vi)

Omit "paragraph 28(5)(c) or (ca)", substitute "a condition under paragraph 28(5)(c) or (ca) or 32EC(2)(c)".

6 Application provision

The amendments made by this Schedule apply in relation to biologicals included in the Register before, on or after the commencement of this item.

Schedule 9—Other amendments

Therapeutic Goods Act 1989

1 After subsection 19(1)

Insert:

(1AA) An approval for use of the kind referred to in paragraph (1)(a) must not be granted to a person unless the person is a health practitioner.

2 Paragraph 19(2)(a)

After "be", insert "in a form (if any) approved, in writing, by the Secretary and be".

3 After subsection 19(5)

Insert:

(5AA) An application for an authority under subsection (5) must be in a form (if any) approved, in writing, by the Secretary.

4 Subsection 22(6)

Repeal the subsection, substitute:

(6) A person commits an offence if:

(a) the person claims, by any means, that the person or another person can arrange the supply of therapeutic goods; and

(b) none of the following subparagraphs applies in relation to the goods:

(i) the goods are registered goods or listed goods;

(ii) the goods are exempt goods;

(iii) the goods are exempt under section 18A;

(iv) the goods are the subject of an approval or authority under section 19 that covers the supply of the goods by the person or other person;

(v) the goods are the subject of an approval under section 19A that covers the supply of the goods by the person or other person.

Penalty: 60 penalty units.

5 At the end of subsection 28(5)

Add:

; and (h) deliver a reasonable number of samples of the subject goods if the Secretary so requests:

(i) within the period specified in the request (which must include at least 10 working days); and

(ii) in accordance with any other requirements specified in the request.

6 Subsection 28(5A)

Repeal the subsection.

7 Paragraph 29D(1)(b)

Omit "or (fb)", substitute ", (fb) or (g)".

8 Subsection 30(3)

Omit "otherwise than as a result of a failure to pay the annual registration or listing charge".

9 Subparagraph 32BH(b)(v)

Omit "that is held", substitute "or (7A) that covers the supply of the biological".

10 Subparagraph 32BI(1)(c)(vii)

After "subsection 32CM(1)", insert "or (7A)".

11 At the end of subparagraph 32BI(4)(c)(vii)

Add "or (7A)".

12 Subparagraph 32BJ(4)(b)(i)

Omit "in relation to the person".

13 Subparagraph 32BJ(4)(b)(ii)

After "person", insert "or other person".

14 Subparagraph 32BJ(4)(b)(iv)

After "person", insert "or other person".

15 Subparagraph 32BJ(4)(b)(v)

Omit "that is held by the person", substitute "or (7A) that covers the supply of the biological by the person or other person".

16 Subparagraph 32BJ(4)(b)(vi)

After "person", insert "or other person".

17 Paragraph 32BK(2)(e)

After "subsection 32CM(1)", insert "or (7A)".

18 After subsection 32CK(1)

Insert:

(1A) An approval for use of the kind referred to in paragraph (1)(d) must not be granted to a person unless the person is a health practitioner.

19 After paragraph 32CK(3)(a)

Insert:

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

20 After subsection 32CM(1)

Insert:

(1A) An application for an authority under subsection (1) must be in a form (if any) approved, in writing, by the Secretary.

21 Paragraph 32FA(1)(b)

Omit "or (d)", substitute ", (d) or (g)".

22 Subsection 32HA(1) (table items 3, 4 and 5)

After "subsection 32CM(1)", insert "or (7A)".

23 After subsection 40B(9)

Insert:

Removal of manufacturing sites

(9A) The holder of a licence may apply to the Secretary for a variation of the licence so that it ceases to cover one or more manufacturing sites specified in the application.

(9B) An application under subsection (9A) must:

(a) be made in accordance with a form approved by the Secretary; and

(b) be delivered to an office of the Department specified in the form; and

(c) be accompanied by the prescribed application fee.

(9C) If an application is made under subsection (9A), the Secretary may, by notice in writing given to the holder of the licence, vary the licence so that the licence does not cover each manufacturing site specified in the notice.

(9D) A variation under subsection (9C) takes effect on the day specified in the notice.

24 Subsection 40B(10)

Omit "or (6)", substitute ", (6) or (9A)".

25 Paragraph 40B(10)(b)

Before "to allow", insert "for an application under subsection (1) or (6)—".

26 Subsection 40B(11)

Omit "or (7)(a)", substitute ", (7)(a) or (9B)(a)".

27 At the end of section 41EC

Add:

(6) The Secretary may, by written notice given to the applicant, require the applicant:

(a) to deliver to the office to which the application was made a reasonable number of samples of the kind of medical device to which the application relates within the period, of not less

than 14 days after the day the notice is given, specified in the notice; and

(b) to do so in a manner specified in the notice.

28 Paragraph 41EG(b)

After "by the Secretary", insert "under subsection 41EC(6)".

29 After subsection 41FI(1)

Insert:

(1A) In auditing the application, the Secretary may, by written notice given to the applicant, require the applicant:

(a) to deliver to the office to which the application was made a reasonable number of samples of the kind of medical device to which the application relates within the period, of not less than 14 days after the day the notice is given, specified in the notice; and

(b) to do so in a manner specified in the notice.

30 Paragraph 41FK(b)

After "by the Secretary", insert "under subsection 41FI(1A)".

31 Paragraph 41GA(1)(b)

Omit "or (d)", substitute ", (d) or (f)".

32 After subsection 41HB(1)

Insert:

(1A) An approval for use of the kind referred to in paragraph (1)(d) must not be granted to a person unless the person is a health practitioner.

33 Subsection 41HB(4)

After "be", insert "in a form (if any) approved, in writing, by the Secretary and be".

34 After subsection 41HC(1)

Insert:

(1A) An application for an authority under subsection (1) must be in a form (if any) approved, in writing, by the Secretary.

35 Section 41MM

Repeal the section, substitute:

41MM Claims about arranging supplies of medical devices

A person commits an offence if:

(a) the person claims, by any means, that the person or another person can arrange the supply of a medical device; and

(b) none of the following subparagraphs applies in relation to the device:

(i) the device is of a kind included in the Register;

(ii) the device is of a kind covered by an exemption in force under section 41GS;

(iii) the device is an exempt device;

(iv) the device is the subject of an approval under section 41HB or an authority under section 41HC that covers the supply of the device by the person or other person;

(v) the device is the subject of an approval under subsection 41HD(1), (1A) or (2) that covers the supply of the device by the person or other person.

Penalty: 60 penalty units.

36 Subparagraph 46A(4)(a)(i)

Omit "section 19", substitute "subsection 19(1) or (5)".

37 Subparagraph 46A(4)(a)(iia)

Omit "section 41HB or 41HC", substitute "subsection 41HB(1) or 41HC(1)".

38 Application provisions—therapeutic goods

(1) Subsection 19(1AA) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to approvals granted on or after the commencement of this item.

(2) The amendment of paragraph 19(2)(a) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to applications made on or after the commencement of this item.

(3) Subsection 19(5AA) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to applications made on or after the commencement of this item.

(4) The repeal and substitution of subsection 22(6) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to claims made on or after the commencement of this item.

(5) The amendment of subsection 28(5) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to the registration or listing of therapeutic goods before, on or after the commencement of this item.

(6) 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 request referred to in subsection 28(5A) of that Act that was made before that commencement.

(7) The amendment of paragraph 29D(1)(b) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to suspensions made on or after the commencement of this item (whether the therapeutic goods were included in the Register before, on or after that commencement).

39 Application provisions—biologicals

(1) The amendment of subparagraph 32BH(b)(v) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to supplies of a biological occurring on or after the commencement of this item.

(2) The amendments of section 32BI of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to uses of a biological on or after the commencement of this item.

(3) The amendments of section 32BJ of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to claims made on or after the commencement of this item.

(4) The amendment of paragraph 32BK(2)(e) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to representations made on or after the commencement of this item.

(5) Subsection 32CK(1A) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to approvals granted on or after the commencement of this item.

(6) The amendment of subsection 32CK(3) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to applications made on or after the commencement of this item.

(7) Subsection 32CM(1A) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to applications made on or after the commencement of this item.

(8) The amendment of paragraph 32FA(1)(b) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to suspensions made on or after the commencement of this item (whether the biological was included in the Register before, on or after that commencement).

(9) The amendment of subsection 32HA(1) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to supplies of a biological occurring on or after the commencement of this item.

40 Application provisions—medical devices

(1) The amendments of sections 41EC and 41EG of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to:

(a) an application for a conformity assessment certificate that is made on or after the commencement of this item; and

(b) an application for a conformity assessment certificate that was pending immediately before the commencement of this item.

(2) The amendments of sections 41FI and 41FK of the *Therapeutic Goods Act 1989* made by this Schedule apply in relation to:

(a) an application for a kind of medical device to be included in the Register that is made on or after the commencement of this item; and

(b) an application for a kind of medical device to be included in the Register that was pending immediately before the commencement of this item.

(3) The amendment of paragraph 41GA(1)(b) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to suspensions made on

or after the commencement of this item (whether the kind of medical device was included in the Register before, on or after that commencement).

(4) Subsection 41HB(1A) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to approvals granted on or after the commencement of this item.

(5) The amendment of subsection 41HB(4) of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to applications made on or after the commencement of this item.

(6) Subsection 41HC(1A) of the *Therapeutic Goods Act 1989*, as inserted by this Schedule, applies in relation to applications made on or after the commencement of this item.

(7) The repeal and substitution of section 41MM of the *Therapeutic Goods Act 1989* made by this Schedule applies in relation to claims made on or after the commencement of this item.