

EXPOSURE DRAFT

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

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1
2 **A Bill for an Act to amend the *Therapeutic Goods***
3 ***Act 1989, and for related purposes***

4 The Parliament of Australia enacts:

5 **1 Short title**

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

8 **2 Commencement**

9 (1) Each provision of this Act specified in column 1 of the table
10 commences, or is taken to have commenced, in accordance with
11 column 2 of the table. Any other statement in column 2 has effect
12 according to its terms.
13

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	

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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.	

1 Note: This table relates only to the provisions of this Act as originally
2 enacted. It will not be amended to deal with any later amendments of
3 this Act.

4 (2) Any information in column 3 of the table is not part of this Act.
5 Information may be inserted in this column, or information in it
6 may be edited, in any published version of this Act.

3 Schedules

8 Legislation that is specified in a Schedule to this Act is amended or
9 repealed as set out in the applicable items in the Schedule
10 concerned, and any other item in a Schedule to this Act has effect
11 according to its terms.

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Provisional registration of medicine **Schedule 1**

1 **Schedule 1—Provisional registration of**
2 **medicine**
3

4 ***Therapeutic Goods Act 1989***

5 **1 Subsection 3(1) (definition of *registered goods*)**

6 Repeal the definition, substitute:

7 ***registered goods*** means:

- 8 (a) therapeutic goods included in the part of the Register for
9 goods known as registered goods; or
10 (b) therapeutic goods included in the part of the Register for
11 goods known as provisionally registered goods.

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

16 **2 At the end of section 3**

17 Add:

18 (8) To avoid doubt:

- 19 (a) a reference in this Act to therapeutic goods that are registered
20 includes a reference to a medicine that is provisionally
21 registered; and
22 (b) a reference in this Act to the registration of therapeutic goods
23 includes a reference to the provisional registration of a
24 medicine.

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

26 **3 After paragraph 6AAE(6)(a)**

27 Insert:

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

30 **4 Subsection 9A(3)**

31 Omit “4 parts”, substitute “5 parts”.

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Schedule 1 Provisional registration of medicine

1 **5 After paragraph 9A(3)(a)**

2 Insert:

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

5 **6 After subsection 9D(1)**

6 Insert:

7 (1A) If:

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

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

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

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

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

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

22 (1B) If:

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

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

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

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

33 (1C) If the Secretary proposes to make a variation under subsection (1A)
34 or (1B), the Secretary must:

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Provisional registration of medicine **Schedule 1**

- 1 (a) give the person in relation to whom the medicine is registered
2 written notice of the proposed variation and of the reasons for
3 the proposed variation; and
4 (b) give the person a reasonable opportunity to make a
5 submission to the Secretary in relation to the proposed
6 variation; and
7 (c) if the person makes a submission in accordance with
8 paragraph (b)—take the submission into account before
9 making a decision whether or not to make the variation.

10 (1D) Subsections (1A) and (1B) apply despite subsection 16(1).

11 **7 After Division 1 of Part 3-2**

12 Insert:

13 **Division 1A—Provisional determinations for medicine**

14 **22C Applications for provisional determination**

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

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

- 22 (2) An application under subsection (1) must:
23 (a) be made in accordance with a form approved, in writing, by
24 the Secretary; and
25 (b) be accompanied by the prescribed application fee; and
26 (c) contain the information that the form requires, and any
27 further information, statement or document the Secretary
28 requires, whether in the form or otherwise; and
29 (d) satisfy any other requirement prescribed by the regulations
30 for the purposes of this paragraph.
- 31 (3) An approval of a form may require or permit an application or
32 information to be given in accordance with specified software
33 requirements:

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Schedule 1 Provisional registration of medicine

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

3 **22D Provisional determinations**

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

8 *Criteria*

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

12 *Content of determination*

- 13 (3) The determination must specify:
14 (a) the person to whom the determination relates; and
15 (b) the medicine to which the determination relates; and
16 (c) the indication of the medicine to which the determination
17 relates; and
18 (d) each active ingredient of the medicine to which the
19 determination relates.

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

22 *Notice of decision*

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

28 **22E Period during which provisional determination is in force**

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

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Provisional registration of medicine **Schedule 1**

- 1 (a) comes into force on the day on which the Secretary gives the
2 person notice under subsection 22D(4); and
3 (b) subject to this section and section 22F, remains in force for
4 the initial period.

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

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

8 *Extensions*

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

- 11 (4) The application must:

- 12 (a) be in a form approved, in writing, by the Secretary; and
13 (b) be made at least 28 days before the determination would
14 otherwise cease to be in force; and
15 (c) be accompanied by the prescribed application fee.

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

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

- 21 (a) is still satisfied that the criteria prescribed by the regulations
22 for the purposes of subsection 22D(2) are met in relation to
23 the medicine; and
24 (b) is satisfied that, if the Secretary were to make the extension,
25 the person would make an application under section 23 for
26 provisional registration of the medicine before the end of the
27 extended period.

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

- 30 (a) give the person written notice of the decision; and
31 (b) if the Secretary refuses to extend the initial period—set out
32 the reasons for the refusal in the notice.

- 33 (8) Only one extension may be given.
-

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Schedule 1 Provisional registration of medicine

1

Effect of application under section 23

2

(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:

3

4

5

6

(a) the person withdraws the application; or

7

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

8

(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

9

10

11

(d) the application is finally determined.

12

(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.

13

14

15

16

22F Revocation of provisional determination

17

Revocation on Secretary's own initiative

18

(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.

19

20

21

22

23

Revocation on request

24

(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.

25

26

27

Notice of revocation

28

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

29

30

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

31

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

32

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Provisional registration of medicine **Schedule 1**

1 *Day revocation takes effect*

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

4 **8 After section 23**

5 Insert:

6 **23AA Applications for provisional registration of medicine**

7 If:

- 8 (a) a person makes an application under section 23 for the
9 registration of a medicine; and
10 (b) a provisional determination under section 22D relating to the
11 person, the medicine and the indication to which the
12 application relates is in force when the application is made;
13 then, for the purposes of this Act, the application is taken to be an
14 application for provisional registration of the medicine.

15 **9 Paragraph 25(1)(d)**

16 Repeal the paragraph, substitute:

- 17 (c) unless the application is one referred to in paragraph (d)—
18 whether the quality, safety and efficacy of the goods for the
19 purposes for which they are to be used have been
20 satisfactorily established; and
21 (d) for an application for provisional registration of a medicine:
22 (i) whether, based on preliminary clinical data, the safety
23 and efficacy of the medicine for the purposes for which
24 it is to be used have been satisfactorily established; and
25 (ii) whether the quality of the medicine for the purposes for
26 which it is to be used has been satisfactorily established;
27 and
28 (iii) whether, if the Secretary were to register the medicine,
29 the Secretary is satisfied with the applicant's plan to
30 submit comprehensive clinical data on the safety and
31 efficacy of the medicine before the end of the 6 years
32 that would start on the day that registration would
33 commence; and

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Schedule 1 Provisional registration of medicine

1 **10 After paragraph 28(2A)(a)**

2 Insert:

3 (aa) the provisional registration of medicine; and

4 **11 Section 29**

5 Omit “Where”, substitute “(1) Subject to this section, if”.

6 **12 At the end of section 29**

7 Add:

8 *Provisionally registered medicine*

9 (2) If:

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

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

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

16 then:

17 (d) the medicine is provisionally registered; and

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

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

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

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

27 *Extension of provisional registration upon application*

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

31 (5) The application must:

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Provisional registration of medicine **Schedule 1**

- 1 (a) be in a form approved, in writing, by the Secretary; and
2 (b) contain the information that the form requires, and any
3 further information, statement or document the Secretary
4 requires, whether in the form or otherwise; and
5 (c) be made at least 6 months before the provisional registration
6 of the medicine is due to end; and
7 (d) be accompanied by the prescribed application fee.
- 8 (6) On receiving the application, the Secretary must decide to grant, or
9 to refuse to grant, an extension of the provisional registration
10 period. In making that decision, the Secretary must have regard to:
11 (a) whether the Secretary is satisfied with the applicant's plan to
12 submit comprehensive clinical data on the safety and efficacy
13 of the medicine before the end of the 6 years starting on the
14 day the provisional registration commenced; and
15 (b) such other matters (if any) as the Secretary considers
16 relevant.
- 17 (7) As soon as practicable after making the decision, the Secretary
18 must:
19 (a) give the applicant written notice of the decision; and
20 (b) if the Secretary decides to extend the provisional registration
21 period—specify in the notice the period of the extension
22 (which must not exceed 2 years and may be less than the
23 period sought by the applicant); and
24 (c) if the Secretary refuses to extend the provisional registration
25 period—set out the reasons for the refusal in the notice.
- 26 Note: At the time of granting an extension, the Secretary may impose new
27 conditions on the provisional registration or vary the existing
28 conditions: see subsection 28(3).
- 29 (8) No more than 2 extensions may be granted on applications under
30 subsection (4).
- 31 Note: Under subsection (9) the Secretary may extend the provisional
32 registration period on his or her own initiative.

33 *Effect on provisional registration of later section 23 application*

- 34 (9) If:
-

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Schedule 1 Provisional registration of medicine

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

5 (b) the application is for the medicine to be included in the part
6 of the Register for goods known as registered goods;
7 then the Secretary may, in connection with the application, end or
8 extend the provisional registration period as the Secretary
9 considers appropriate.

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

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

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

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

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

25 **13 After paragraph 56A(1)(d)**

26 Insert:

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

29 **14 Subsection 60(2)**

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

32 **15 After subsection 60(2A)**

33 Insert:

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Provisional registration of medicine **Schedule 1**

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

6 (2AB) If the Secretary or a delegate of the Secretary:
7 (a) makes a decision under section 22D in relation to an
8 application under section 22C; or
9 (b) makes a decision under section 22E in relation to an
10 application under subsection 22E(3); or
11 (c) makes a decision under section 23B in relation to an
12 application for provisional registration of a medicine; or
13 (d) makes a decision under subsection 25(3) in relation to an
14 application for provisional registration of a medicine;
15 a person is not entitled to request the Minister to reconsider the
16 decision unless the person made the application.

17 (2AC) If the Secretary or a delegate of the Secretary makes a decision
18 under section 22F to revoke a provisional determination under
19 section 22D, a person is not entitled to request the Minister to
20 reconsider the decision unless the person made the application for
21 that provisional determination.

22 **16 Subsection 60(2B)**

23 After “the Secretary”, insert “or a delegate of the Secretary”.

24 **17 Before subsection 60(3)**

25 Insert:

26 (2D) If the Secretary or a delegate of the Secretary:
27 (a) makes a decision under subsection 29(6) in relation to an
28 application under subsection 29(4); or
29 (b) makes a decision under subsection 29(9) to end, or extend,
30 the provisional registration period for a medicine;
31 a person is not entitled to request the Minister to reconsider the
32 decision unless the person is the person in relation to whom the
33 medicine is provisionally registered.

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Schedule 2 Indications and ingredients for listed medicines

Part 1 Amendments

1 **Schedule 2—Indications and ingredients for**
2 **listed medicines**

3 **Part 1—Amendments**

4 *Therapeutic Goods Act 1989*

5 **1 After paragraph 26A(2)(fb)**

6 Insert:

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

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

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

13 **2 After paragraph 26A(2)(fc)**

14 Insert:

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

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

23 **3 Paragraph 26A(2)(j)**

24 Repeal the paragraph, substitute:

25 (j) both:

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

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

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Indications and ingredients for listed medicines **Schedule 2**
Amendments **Part 1**

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:

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Schedule 2 Indications and ingredients for listed medicines

Part 1 Amendments

- 1 (a) give the Secretary such further information in connection
2 with the application as is specified in the notice; and
3 (b) do so within such reasonable period as is specified in the
4 notice.

5 *Lapsing of application for recommendation*

- 6 (2B) An application made under subsection (1) lapses if:
7 (a) the Secretary requires further information to be given in
8 relation to the application within a period specified in a
9 notice under subsection (2A); and
10 (b) the information is not given within that period.

11 **10 After paragraph 26BE(3)(b)**

12 Insert:

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

16 **11 After subsection 26BE(5)**

17 Insert:

- 18 (5A) If the Secretary refuses to make the recommendation, the Secretary
19 must:
20 (a) notify the applicant in writing of his or her decision; and
21 (b) state in the notice the reasons for the decision.

22 *Partial refund of application fee in certain circumstances*

- 23 (5B) If:
24 (a) an application fee is prescribed for the purposes of
25 paragraph (2)(d); and
26 (b) regulations made for the purposes of paragraph 63(2)(daaa)
27 prescribe a period within which recommendations under this
28 section must be made; and
29 (c) the Secretary makes a recommendation in relation to an
30 application under subsection (1), but not within that period;
31 then 25% of the application fee must be refunded to the applicant.

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Indications and ingredients for listed medicines **Schedule 2**
Amendments **Part 1**

Deemed refusal of applications in certain circumstances

1
2 (5C) If:

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

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

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

11 (5D) A notice under subsection (5C) may be given at any time before
12 the recommendation in relation to the application is made.

13 (5E) If a notice has been given under subsection (5C), this Act (except
14 subsection 60(5)) has effect as if:

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

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

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

12 Subsection 26BE(8)

21 Repeal the subsection.
22

13 Subsection 26BE(9)

23 Omit "subsection (8)", substitute "subsection (2A)".
24

14 After section 26BE

25 Insert:
26

26BF Permissible indications

27
28 (1) The Minister may, by legislative instrument, make a determination
29 in relation to either or both of the following:

30 (a) indications;

31 (b) requirements in relation to indications.

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Schedule 2 Indications and ingredients for listed medicines

Part 1 Amendments

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

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

8 (a) maintaining health;

9 (b) enhancing health;

10 (c) preventing a dietary deficiency;

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

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

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

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

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

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

23 **26BG Limitations on determination under section 26BF**

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

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

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

EXPOSURE DRAFT

Indications and ingredients for listed medicines **Schedule 2**
Amendments **Part 1**

1 **26BH Variation of determination under section 26BF—Minister’s**
2 **initiative**

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

5 **26BJ Variation of determination under section 26BF—application**
6 **by person**

7 *Application for recommendation to vary section 26BF*
8 *determination*

- 9 (1) A person may apply to the Secretary for a recommendation that the
10 Minister vary a determination under section 26BF.
- 11 (2) An application under subsection (1) must:
- 12 (a) be made in accordance with a form approved, in writing, by
13 the Secretary; and
 - 14 (b) set out the recommendation sought; and
 - 15 (c) be delivered to an office of the Department specified in the
16 form; and
 - 17 (d) be accompanied by the prescribed application fee (if any).

18 *Limits on kinds of applications that can be made*

- 19 (3) A person cannot make an application under subsection (1) for a
20 recommendation the effect of which would be for the
21 determination to cover any of the following:
- 22 (a) an indication specified in a determination under
23 section 26BG;
 - 24 (b) an indication that is or contains a restricted representation
25 (within the meaning of Part 5-1);
 - 26 (c) unless subsection (4) applies—an indication that is or
27 contains a prohibited representation (within the meaning of
28 Part 5-1);
 - 29 (d) unless subsection (5) applies—an indication that refers to
30 preventing, curing or alleviating a disease, ailment, defect or
31 injury.
- 32 (4) For the purposes of paragraph (3)(c), this subsection applies if:
-

EXPOSURE DRAFT

Schedule 2 Indications and ingredients for listed medicines

Part 1 Amendments

- 1 (a) the indication is a therapeutic use that relates to sun
2 protection; and
3 (b) the prohibited representation relates to the prevention of skin
4 cancer; and
5 (c) the use of the prohibited representation is permitted under
6 section 42DK.

- 7 (5) For the purposes of paragraph (3)(d), this subsection applies if the
8 indication refers to:
9 (a) the prevention of a dietary deficiency; or
10 (b) the prevention of skin cancer or sun damage.

11 *Further information about application for recommendation*

- 12 (6) The Secretary may, by written notice given to a person who has
13 made an application under subsection (1), require the person to:
14 (a) give the Secretary such further information in connection
15 with the application as is specified in the notice; and
16 (b) do so within such reasonable time as is specified in the
17 notice.

18 *Lapsing of application for recommendation*

- 19 (7) An application made under subsection (1) lapses if:
20 (a) the Secretary requires further information to be given in
21 relation to the application within a time specified in a notice
22 under subsection (6); and
23 (b) the information is not given within that time.

24 *Decision on application for recommendation*

- 25 (8) If:
26 (a) an application is made under subsection (1); and
27 (b) any applicable prescribed application fee has been paid; and
28 (c) if further information is required to be given under
29 subsection (6) within a specified time—the information is
30 given within that time;
31 the Secretary must decide whether to make the recommendation or
32 refuse to make the recommendation.

EXPOSURE DRAFT

Indications and ingredients for listed medicines **Schedule 2**
Amendments **Part 1**

- 1 (9) In deciding whether to make the recommendation, the Secretary
2 may have regard to whether the indication to which the application
3 relates is a therapeutic use that relates to one or more of the
4 following:
5 (a) maintaining health;
6 (b) enhancing health;
7 (c) preventing a dietary deficiency;
8 (d) a disease, ailment, defect or injury, other than a serious form
9 of the disease, ailment, defect or injury;
10 (e) sun protection.
- 11 (10) If the Secretary refuses to make the recommendation, the Secretary
12 must:
13 (a) notify the applicant in writing of his or her decision; and
14 (b) state in the notice the reasons for the decision.
- 15 *Minister may vary section 26BF determination*
- 16 (11) If the Secretary makes a recommendation under subsection (8), the
17 Minister must:
18 (a) by legislative instrument, vary the determination under
19 subsection 26BF(1); or
20 (b) refuse to vary the determination.
- 21 (12) In deciding whether to vary a determination under
22 subsection 26BF(1) to include an indication not already covered by
23 the determination, the Minister may have regard to:
24 (a) the recommendation made under subsection (8) of this
25 section; and
26 (b) whether the indication is a therapeutic use that relates to one
27 or more of the matters in paragraphs (9)(a) to (e) of this
28 section.
- 29 (13) Subsection (12) does not limit the matters to which the Minister
30 may have regard in deciding whether to vary the determination.
- 31 *Applications or information may be given electronically*
- 32 (14) An approval of a form mentioned in paragraph (2)(a), or a notice
33 mentioned in subsection (6), may require or permit an application
-

EXPOSURE DRAFT

Schedule 2 Indications and ingredients for listed medicines

Part 1 Amendments

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

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

5 **15 Subsections 28(6) and (7)**

6 Repeal the subsections, substitute:

- 7 (6) If in, or in connection with, an application for the listing of
8 therapeutic goods, a claim (other than a claim that is an indication)
9 is made by the applicant in relation to the goods, the listing of the
10 goods is subject to the following conditions:
11 (a) a condition that the sponsor of the goods had, at the time
12 when the claim was made, information or evidence that
13 supported the claim and complied with the requirements (if
14 any) specified in a determination made under
15 subsection 26A(2B);
16 (b) a condition that the sponsor retains the information or
17 evidence at all times while the goods remain listed;
18 (c) a condition that, at any time while the goods remain listed,
19 the sponsor will, if asked to do so by the Secretary, give the
20 information or evidence to the Secretary.

21 **16 At the end of section 28**

22 Add:

- 23 (7) If:
24 (a) a medicine is listed under section 26A; and
25 (b) an indication is accepted in relation to the inclusion of the
26 medicine in the Register;
27 the listing of the medicine is subject to the following conditions:
28 (c) a condition that the person in relation to whom the medicine
29 is listed has, at all times while the medicine remains listed,
30 information or evidence that supports the indication and
31 complies with the requirements (if any) specified in a
32 determination under subsection 26A(2B);
33 (d) a condition that, at any time while the medicine remains
34 listed, the person will, if asked to do so by the Secretary, give
35 the information or evidence to the Secretary.
-

EXPOSURE DRAFT

Indications and ingredients for listed medicines **Schedule 2**
Amendments **Part 1**

1 **17 Paragraph 30(1)(e)**

2 Omit “(e)”, substitute “(e), (fba), (fd), (fe)”.

3 **18 Paragraph 30(2)(ba)**

4 After “(j)”, insert “, (ja)”.

5 **19 After subsection 60(2B)**

6 Insert:

7 (2C) If the Secretary or a delegate of the Secretary decides, under
8 subsection 26BJ(8), to refuse to make a recommendation, a person
9 is not entitled to request the Minister to reconsider the decision
10 unless the person made an application under subsection 26BJ(1)
11 for the recommendation.

12 **20 Before paragraph 63(2)(daa)**

13 Insert:

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

EXPOSURE DRAFT

Schedule 2 Indications and ingredients for listed medicines

Part 2 Application and transitional provisions

1 **Part 2—Application and transitional provisions**

2 **21 Definitions**

3 In this Part:

4 *Act* means the *Therapeutic Goods Act 1989*.

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

7 **22 Application of amendments**

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

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

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

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

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

23 **23 Transitional provisions**

24 *Scope of transitional provisions*

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

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

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Indications and ingredients for listed medicines **Schedule 2**
Application and transitional provisions **Part 2**

- 1 (a) a person has made an application under section 23 of the Act
2 for the listing of the medicine before the commencement of
3 this Schedule; and
4 (b) the application has not been finally determined before that
5 commencement; and
6 (c) after that commencement, the Secretary lists the medicine in
7 relation to the person under section 26A of the Act.

- 8 (3) This item also applies in relation to a medicine if the medicine:
9 (a) was listed under section 26 of the Act before 11 June 1996;
10 and
11 (b) is, immediately before the commencement of this Schedule,
12 listed goods; and
13 (c) is not subject to a condition that it must not be supplied in
14 Australia; and
15 (d) is, is intended to be, or has been supplied in Australia.

16 *Reapplying for listing of certain medicines to include permissible*
17 *indications*

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

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

- 23 (5) Subitem (6) applies if, during the transition period, one of the following
24 events does not occur in relation to the medicine:
25 (a) the medicine is listed in relation to the person under
26 section 26A of the Act;
27 (b) the medicine is listed in relation to the person under
28 section 26AE of the Act;
29 (c) the listing of the medicine is cancelled;
30 (d) an application for the listing of the medicine in relation to the
31 person under section 26AE of the Act that complies with
32 section 23C of the Act has been made, but not yet decided.

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Schedule 2 Indications and ingredients for listed medicines

Part 2 Application and transitional provisions

- 1 (6) The listing of the medicine is cancelled, and the medicine ceases to be
2 listed, by force of this subitem immediately after the end of the
3 transition period.
- 4 (7) If:
- 5 (a) during the transition period, an application for the listing of
6 the medicine in relation to the person under section 26AE of
7 the Act has been made; and
- 8 (b) after the transition period, the application lapses;
9 the listing of the medicine is cancelled, and the medicine ceases to be
10 listed, by force of this subitem immediately after the application lapses.
- 11 (8) Paragraph 26A(1)(e) of the Act does not apply to an application for the
12 listing of a medicine under section 26A of the Act if the medicine had
13 its listing cancelled only because of the operation of subitem (6) or (7).
- 14 (9) Paragraph 26AB(1)(g) of the Act does not apply to an application for
15 the listing of a medicine under section 26AE of the Act if the medicine
16 had its listing cancelled only because of the operation of subitem (6) or
17 (7).
- 18 *Cancellation of listing under section 26A if application under*
19 *section 26AE made but not decided during transition period*
- 20 (10) Subitem (11) applies if an application for the listing of the medicine in
21 relation to the person under section 26AE of the Act that complies with
22 section 23C of the Act has been made, but not yet decided, during the
23 transition period.
- 24 (11) The listing of the medicine under section 26A of the Act is cancelled,
25 and the medicine ceases to be listed under that section, by force of this
26 subitem at the same time as the Secretary makes a decision under
27 subsection 26AE(3) of the Act in relation to the medicine.

EXPOSURE DRAFT

New pathway for listed medicines **Schedule 3**

1 **Schedule 3—New pathway for listed**
2 **medicines**
3

4 *Therapeutic Goods Act 1989*

5 **1 Paragraphs 21A(1)(b) and (4)(b)**

6 After “subsection 26A(2)”, insert “or 26AB(2)”.

7 **2 Subsection 21B(1)**

8 After “subsection 26A(2)”, insert “or 26AB(2)”.

9 **3 At the end of paragraph 26(1)(ba)**

10 Add “or 26AE”.

11 **4 After section 26A**

12 Insert:

13 **26AB Application for listing of certain medicines following efficacy**
14 **evaluation**

15 (1) If:

- 16 (a) an application is made under section 23 for the listing of
17 medicine in relation to a person; and
18 (b) the application passes preliminary assessment; and
19 (c) the requirements of subsections (2), (3), (4) and (6) have
20 been complied with; and
21 (d) the medicine is not a medicine which may be listed under
22 section 26A; and
23 (e) the medicine is not export only medicine; and
24 (f) the medicine is not one that has previously had its
25 registration or listing cancelled;

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

28 (2) The applicant must certify that:

- 29 (a) the medicine is eligible for listing; and

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Schedule 3 New pathway for listed medicines

- 1 (b) the medicine is safe for the purposes for which it is to be
2 used; and
- 3 (c) the presentation of the medicine is not unacceptable; and
- 4 (d) the medicine does not contain an ingredient that is not
5 specified in a determination under paragraph 26BB(1)(a); and
- 6 (e) if a determination under paragraph 26BB(1)(b) specifies
7 requirements in relation to ingredients being contained in the
8 medicine—none of the requirements have been contravened;
9 and
- 10 (f) the medicine conforms to every standard (if any) applicable
11 to the medicine; and
- 12 (g) both of the following are complied with in relation to the
13 medicine:
- 14 (i) the applicable provisions of the Therapeutic Goods
15 Advertising Code;
- 16 (ii) the other requirements (if any) relating to advertising
17 applicable under Part 5-1 or under the regulations; and
- 18 (h) if the medicine has been manufactured in Australia—each
19 step in the manufacture of the medicine has been carried out
20 by a person who is the holder of a licence to carry out that
21 step; and
- 22 (i) the medicine complies with all prescribed quality or safety
23 criteria that are applicable to the medicine; and
- 24 (j) the medicine's specifications comply with any requirements
25 that are prescribed by the regulations for the purposes of this
26 paragraph and that are applicable to the medicine; and
- 27 (k) the medicine's label:
- 28 (i) complies with any requirements that are prescribed by
29 the regulations for the purposes of this subparagraph
30 and that are applicable to the medicine; and
- 31 (ii) does not make a claim that is inconsistent with any
32 claim made by the applicant in relation to the medicine
33 in, or in connection with, the application; and
- 34 (l) the applicant holds information or evidence showing the
35 medicine's specifications will be maintained under the
36 conditions set out on the medicine's label until the
37 medicine's expiry date; and
-

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New pathway for listed medicines **Schedule 3**

- 1 (m) the applicant has available sufficient information to
2 substantiate each claim and each indication proposed to be
3 accepted in relation to the inclusion of the medicine in the
4 Register; and
- 5 (n) the medicine does not contain substances that are prohibited
6 imports for the purposes of the *Customs Act 1901*; and
- 7 (o) all the manufacturers of the medicine are nominated as
8 manufacturers in the application; and
- 9 (p) the applicant has, with manufacturers of the medicine who
10 are manufacturers of the prescribed kind, written agreements
11 containing such matters as are prescribed; and
- 12 (q) the information included in or with the application is
13 complete and correct.
- 14 (3) The applicant must also certify any other matters prescribed by the
15 regulations for the purposes of this subsection.
- 16 (4) Subject to subsection (9), if a step in the manufacture of the
17 medicine has been carried out outside Australia, the Secretary must
18 have certified, prior to the application being made, that the
19 manufacturing and quality control procedures used in each such
20 step are acceptable.
- 21 (5) In deciding whether to certify for the purposes of subsection (4),
22 the matters that may be taken into account include:
- 23 (a) whether the applicant has provided:
- 24 (i) if a step in the manufacture of the medicine has been
25 carried out in a country that is a member of the
26 European Community or a member of EFTA—an
27 EC/EFTA attestation of conformity in relation to the
28 medicine; or
- 29 (ii) if a step in the manufacture of the medicine has been
30 carried out in a country declared by the Minister under
31 section 3B to be covered by a non-EC/EFTA MRA—a
32 non-EC/EFTA attestation of conformity, for the
33 non-EC/EFTA MRA, in relation to the medicine; or
- 34 (iii) in any other case—an acceptable form of evidence from
35 a relevant overseas authority establishing that the
36 manufacture of the medicine is of an acceptable
37 standard; and
-

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Schedule 3 New pathway for listed medicines

- 1 (b) whether the applicant has agreed to provide, if the Secretary
2 considers inspection of the manufacturing procedures used in
3 the manufacture of the medicine to be necessary:
4 (i) funds for the carrying out of that inspection by the
5 Department; and
6 (ii) evidence that the manufacturer has agreed to such an
7 inspection; and
8 (c) whether the applicant has complied with any requirements
9 made by the Secretary under section 31 in relation to the
10 manufacture or preparation of the medicine.
- 11 (6) If the medicine includes any ingredient of animal origin, the
12 Secretary must have certified, prior to the application being made,
13 that he or she is satisfied of the safety of the ingredient.
- 14 (7) If a medicine is exempt from the operation of Part 3-3 or a person
15 is exempt from the operation of that Part in relation to the
16 manufacture of the medicine, subsection (2) has effect, in relation
17 to the medicine, as if paragraph (2)(h) were omitted.
- 18 (8) If a person (the *manufacturer*) is exempt from the operation of
19 Part 3-3 in relation to a step in the manufacture of a medicine,
20 subsection (2) has effect, in relation to the medicine, as if the
21 reference in paragraph (2)(h) to a person who is the holder of a
22 licence were a reference to the manufacturer to the extent that
23 Part 3-3 applies to the manufacturer in relation to the manufacture
24 of the medicine.
- 25 (9) If:
26 (a) a medicine was made outside Australia; and
27 (b) had the medicine been made in Australia, it would have been
28 exempt from the operation of Part 3-3;
29 subsection (4) does not apply in relation to the medicine.

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

- 30 (1) This section applies if:
31 (a) an application is made under section 23 in relation to a
32 medicine for listing under section 26AE; and
33 (b) the application has passed preliminary assessment.
34
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New pathway for listed medicines **Schedule 3**

- 1 (2) A fee (the *evaluation fee*) specified in or determined in accordance
2 with the regulations is payable by the applicant in respect of the
3 evaluation of a medicine for listing under section 26AE.
- 4 (3) The Secretary must notify each applicant of the amount of the
5 evaluation fee.
- 6 (4) The evaluation fee payable by an applicant:
7 (a) is due and payable on the day on which the applicant is
8 notified of the amount of the evaluation fee; and
9 (b) may be recovered by the Commonwealth as a debt due to the
10 Commonwealth.
- 11 (5) If:
12 (a) an application is made under section 23 in relation to a
13 medicine for listing under section 26AE; and
14 (b) the applicant has paid the whole of the evaluation fee; and
15 (c) regulations made for the purposes of paragraph 63(2)(daaaa)
16 prescribe a period within which evaluations under
17 section 26AE in relation to the medicine must be completed;
18 and
19 (d) the evaluation is completed, but not within that period;
20 then 25% of the evaluation fee must be refunded to the applicant.
- 21 (6) For the purposes of paragraph (5)(d), the evaluation is taken to be
22 completed when the applicant is notified of the Secretary's
23 decision under subsection 26AE(3) in relation to the medicine.

24 **26AD Lapsing and deemed refusal of applications for listing of** 25 **medicine under section 26AE**

26 *Lapsing of applications*

- 27 (1) An application for the listing of a medicine under section 26AE
28 lapses if:
29 (a) any part of the evaluation fee referred to in section 26AC
30 remains unpaid at the end of 28 days after the day on which
31 the amount became due and payable; or
32 (b) the application contains information that is inaccurate or
33 misleading in a material particular; or

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Schedule 3 New pathway for listed medicines

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

4 *Deemed refusal of applications*

- 5 (2) If:
6 (a) regulations made for the purposes of paragraph 63(2)(daaaa)
7 prescribe a period within which evaluations under
8 section 26AE in relation to the medicine must be completed;
9 and
10 (b) at the end of that period, the evaluation has not been
11 completed;
12 the applicant may give the Secretary written notice that the
13 applicant wishes to treat the application as having been refused.
- 14 (3) A notice under subsection (2) may be given at any time before the
15 evaluation is completed.
- 16 (4) If a notice has been given, this Act (except subsection 60(5)) has
17 effect as if:
18 (a) the Secretary had decided not to list the medicine which is
19 the subject of the application; and
20 (b) the Minister had made a decision under subsection 60(3)
21 confirming the decision of the Secretary; and
22 (c) the Minister's decision had been made on the day on which
23 notice was given to the Secretary under subsection (2).

24 **26AE Evaluation and listing of certain medicines**

25 *Evaluation*

- 26 (1) If:
27 (a) an application is made under section 23 for the listing of a
28 medicine in relation to a person under this section; and
29 (b) the application has passed preliminary assessment;
30 the Secretary must evaluate the medicine having regard to:
31 (c) whether the efficacy of the medicine for the purposes for
32 which it is to be used has been satisfactorily established; and

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New pathway for listed medicines **Schedule 3**

- 1 (d) such other matters (if any) as the Secretary considers
2 relevant.
- 3 (2) If a period in relation to which an evaluation under this section
4 must be completed has been prescribed under
5 paragraph 63(2)(daaaa), the evaluation must be completed within
6 that period.
- 7 *Secretary must decide whether to list medicine*
- 8 (3) After an evaluation under this section of goods has been
9 completed, the Secretary must decide:
10 (a) to list the medicine; or
11 (b) not to list the medicine.
- 12 *Decision to list*
- 13 (4) If the Secretary decides under subsection (3) to list the medicine,
14 the Secretary must, in accordance with subsection (5), notify the
15 applicant in writing of the decision within 28 days of making the
16 decision.
- 17 (5) The notice must:
18 (a) set out the decision under subsection (3) to list the medicine
19 in relation to the person; and
20 (b) inform the applicant that the medicine will not be included in
21 the Register unless and until the applicant gives the
22 Secretary:
23 (i) the certificate required under subsection 26B(1); or
24 (ii) a notice (in accordance with a form approved, in
25 writing, by the Secretary) that a certificate under that
26 subsection is not required in relation to the application.
- 27 (6) If the applicant gives the Secretary the certificate referred to in
28 subparagraph (5)(b)(i) or the notice referred to in
29 subparagraph (5)(b)(ii), the Secretary must:
30 (a) include the medicine in the Register; and
31 (b) give the applicant a certificate of listing.
- 32 (7) To avoid doubt, if the applicant gives the Secretary the certificate
33 referred to in subparagraph (5)(b)(i) or the notice referred to in
-

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

4 *Date listing commences*

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

7 *Refusal to list medicine*

8 (9) If:

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

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

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

16 **5 Section 26BA**

17 Omit “or 26A(1)”, substitute “, 26A(1) or 26AE(5)”.

18 **6 Subsection 26BB(1) (note)**

19 After “section 26A”, insert “or 26AB”.

20 **7 Subsection 28(5B)**

21 After “26A”, insert “or 26AE”.

22 **8 Paragraph 28(5B)(b)**

23 After “26A(3)”, insert “, 26AB(4)”.

24 **9 At the end of section 28**

25 Add:

26 (8) If:

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

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

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New pathway for listed medicines **Schedule 3**

- 1 the listing of the medicine is subject to the following conditions:
2 (c) a condition that the person in relation to whom the medicine
3 is listed has, at all times while the medicine remains listed,
4 information or evidence that supports the indication;
5 (d) a condition that, at any time while the medicine remains
6 listed, the person will, if asked to do so by the Secretary, give
7 the information or evidence to the Secretary.

8 **10 Subsection 28A(1)**

9 After “section 26A”, insert “or 26AE”.

10 **11 Subsection 28A(3)**

11 Repeal the subsection, substitute:

- 12 (3) In deciding whether to give the certification:
13 (a) subsection 26A(4) applies in a way corresponding to the way
14 in which it applies for the purposes of subsection 26A(3); and
15 (b) subsection 26AB(5) applies in a way corresponding to the
16 way in which it applies for the purposes of
17 subsection 26AB(4).

18 **12 Paragraph 29D(1)(b)**

19 After “(e)”, insert “, (ea)”.

20 **13 Paragraph 29D(1)(b)**

21 After “(1C)”, insert “, (1D)”.

22 **14 After paragraph 30(1)(e)**

23 Insert:

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

29 **15 Subsection 30(1A)**

30 After “section 26A”, insert “or 26AE”.

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1 **16 After subsection 30(1C)**

2 Insert:

- 3 (1D) The Secretary may, by notice in writing given to a person in
4 relation to whom a medicine is listed under section 26AE, cancel
5 the listing of the medicine if:
- 6 (a) the Secretary, under section 31, gives to the person a notice
7 requiring the person to give to the Secretary information or
8 documents relating to the medicine; and
 - 9 (b) the notice is given for the purposes of ascertaining whether
10 any of the certifications by the person under
11 subsection 26AB(2) or (3) in relation to the medicine are
12 incorrect; and
 - 13 (c) the person fails to comply with the notice within 20 working
14 days after the notice is given.

15 **17 After paragraph 30(2)(ba)**

16 Insert:

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

21 **18 Paragraph 30(5)(a)**

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

23 **19 Paragraph 31(2)(fa)**

24 Omit “are medicine”, substitute “are listed under section 26A”.

25 **20 After paragraph 31(2)(fa)**

26 Insert:

- 27 (fab) if the goods are or were listed under section 26AE—any of
28 the matters covered by a certification by the person under
29 subsection 26AB(2) or (3) in relation to the medicine;
- 30 (fac) if the goods are or were listed under section 26AE—the
31 efficacy of the goods in relation to the purposes for which
32 they are to be used;

EXPOSURE DRAFT

New pathway for listed medicines **Schedule 3**

1 **21 After paragraph 63(2)(da)**

2 Insert:

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

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 1 Therapeutic goods

1 **Schedule 4—Preliminary assessment of**
2 **applications**

3 **Part 1—Therapeutic goods**

4 *Therapeutic Goods Act 1989*

5 **1 Subparagraph 19A(1)(b)(ii)**

6 Omit “that complies with section 23 has been made under that section
7 for registration of the goods”, substitute “under section 23 has been
8 made for registration of the goods and the application has passed
9 preliminary assessment”.

10 **2 Paragraph 19A(2)(b)**

11 Omit “that complies with section 23 has been made under that section”,
12 substitute “under section 23 has been made”.

13 **3 After paragraph 19A(2)(b)**

14 Insert:

15 (ba) the application has passed preliminary assessment; and

16 **4 Paragraph 19A(9)(a)**

17 After “(2)(a), (b),”, insert “(ba),”.

18 **5 Section 23**

19 Repeal the section, substitute:

20 **23 Applications generally**

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

23 **6 Before section 24**

24 Insert:

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Therapeutic goods **Part 1**

1 **23A Classes of therapeutic goods**

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

4 **23B Requirements relating to applications for registration of**
5 **therapeutic goods and listing of medicines under**
6 **section 26AE**

- 7 (1) If an application is made under section 23 for:
8 (a) registration of therapeutic goods (including an application for
9 provisional registration of a medicine); or
10 (b) the listing of a medicine under section 26AE;
11 the Secretary must carry out an assessment of whether the
12 requirements set out in subsection (2) have been met in relation to
13 the application.
- 14 (2) The requirements are as follows:
15 (a) the application must be made:
16 (i) in accordance with the form approved, in writing, by the
17 Secretary for that class of therapeutic goods; or
18 (ii) in such other manner as is approved, in writing, by the
19 Secretary for that class of therapeutic goods;
20 (b) the prescribed application fee for that class of therapeutic
21 goods must be paid;
22 (c) the application must be delivered to an office of the
23 Department specified by the Secretary;
24 (d) the application must be accompanied by information that is:
25 (i) of a kind determined under subsection (9) for that class
26 of therapeutic goods; and
27 (ii) in a form determined under subsection (10) for that
28 class of therapeutic goods;
29 (e) if the application is for the registration of restricted
30 medicine—the application must be accompanied by product
31 information, in relation to the medicine, that is in the form
32 approved under section 7D in relation to the medicine;
33 (f) if the Secretary so requires—the applicant must:
34 (i) deliver to the Department a reasonable number of
35 samples of the goods; and
-

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 1 Therapeutic goods

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

3 *Passing preliminary assessment*

- 4 (3) An application *passes preliminary assessment* if the Secretary:
5 (a) has carried out an assessment, under subsection (1), in
6 relation to the application; and
7 (b) is satisfied that the requirements set out in subsection (2)
8 have been met in relation to the application.
- 9 (4) If the application has passed preliminary assessment, the Secretary
10 must give a written notice to the applicant stating that the
11 application has passed preliminary assessment.
- 12 (5) Subsection (4) does not apply if the period within which the
13 Secretary must, under section 25, evaluate the goods to which the
14 application relates is prescribed by reference to the prescribed
15 period within which the Secretary is required to consider an
16 application under subsection 9D(3) to vary an entry in the Register.
- 17 (6) If the application has not passed preliminary assessment, the
18 Secretary must, by written notice given to the applicant, refuse the
19 application.

20 *Approval of forms etc.*

- 21 (7) For the purposes of paragraph (2)(a), the Secretary may approve
22 different forms and different manners for making applications for
23 different classes of therapeutic goods that are specified under
24 section 23A.
- 25 (8) An approval of a form may require or permit an application or
26 information to be given in accordance with specified software
27 requirements:
28 (a) on a specified kind of data processing device; or
29 (b) by way of a specified kind of electronic transmission.

30 *Determination of kinds and forms of information*

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

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Therapeutic goods **Part 1**

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

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

7 **23C Requirements relating to applications for listing of therapeutic** 8 **goods under section 26 or 26A**

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

11 (2) The application complies with this section if:

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

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

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

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

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

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

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

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

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

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

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 1 Therapeutic goods

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:

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Therapeutic goods **Part 1**

1 (aa) the application has passed preliminary assessment; and

2 **13 Paragraph 25AC(a)**

3 Omit “in accordance with”, substitute “under”.

4 **14 After paragraph 25AC(a)**

5 Insert:

6 (aa) the application has passed preliminary assessment; and

7 **15 Paragraph 25B(1)(a)**

8 Omit “in accordance with”, substitute “under”.

9 **16 After paragraph 25B(1)(a)**

10 Insert:

11 (aa) the application has passed preliminary assessment; and

12 **17 Paragraph 26(1)(a)**

13 Omit “in accordance with”, substitute “under”.

14 **18 After paragraph 26(1)(a)**

15 Insert:

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

17 **19 After paragraph 26(1AA)(b)**

18 Insert:

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

20 **20 Paragraph 26(1A)(a)**

21 Omit “in accordance with”, substitute “under”.

22 **21 After paragraph 26(1A)(a)**

23 Insert:

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

25 **22 Paragraph 26AA(1)(a)**

26 Omit “in accordance with”, substitute “under”.

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 1 Therapeutic goods

1 **23 After paragraph 26AA(1)(a)**

2 Insert:

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

4 **24 Paragraph 26A(1)(a)**

5 Omit “in accordance with”, substitute “under”.

6 **25 After paragraph 26A(1)(a)**

7 Insert:

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

9 **26 After paragraph 26A(1A)(a)**

10 Insert:

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

12 **27 Subsection 30C(1)**

13 Repeal the subsection, substitute:

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

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

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

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

23 **28 Paragraph 31(1B)(a)**

24 Omit “23(1)(a)”, substitute “23B(2)(a)”.

25 **29 After paragraph 31(1B)(a)**

26 Insert:

27 (aa) the application has passed preliminary assessment; and

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Therapeutic goods **Part 1**

1 **30 Application and transitional provisions**

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

5 (2) If regulations:

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

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

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

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 2 Biologicals

1 **Part 2—Biologicals**

2 *Therapeutic Goods Act 1989*

3 **31 Section 32AA (note 2)**

4 Omit “section 32DD”, substitute “section 32DDA”.

5 **32 Paragraph 32CO(1)(d)**

6 Omit “either”, substitute “any of the following conditions is satisfied”.

7 **33 Subparagraph 32CO(1)(d)(i)**

8 Omit “or” (second occurring).

9 **34 Subparagraph 32CO(1)(d)(ii)**

10 Omit “or 32DD”.

11 **35 Subparagraph 32CO(1)(d)(ii)**

12 Omit “and”.

13 **36 After subparagraph 32CO(1)(d)(ii)**

14 Insert:

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

18 **37 Paragraph 32CO(2)(d)**

19 Repeal the paragraph, substitute:

20 (d) either:

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

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

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Biologicals **Part 2**

1 **38 Subsection 32DD(1)**

2 Omit “(1)”.

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

4 Repeal the subsections.

5 **40 After section 32DD**

6 Insert:

7 **32DDA Preliminary assessment of applications**

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

12 (2) The requirements are as follows:

13 (a) the application must be made:

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

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

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

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

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

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

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

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

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

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

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 2 Biologicals

1

Passing preliminary assessment

2

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

3

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

4

5

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

6

7

(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.

8

9

10

(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.

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

17

18

19

Approval of different forms etc.

20

(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.

21

22

23

24

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

25

26

27

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

28

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

29

Determination of kinds and forms of information

30

(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.

31

32

33

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Biologicals **Part 2**

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

5 **41 Subsection 32DE(1)**

6 Omit “in accordance with”, substitute “under”.

7 **42 Subsection 32DE(1)**

8 After “a person,”, insert “and the application has passed preliminary
9 assessment,”.

10 **43 Paragraph 32DF(1)(a)**

11 Omit “in accordance with”, substitute “under”.

12 **44 After paragraph 32DF(1)(a)**

13 Insert:

14 (aa) the application has passed preliminary assessment; and

15 **45 Paragraph 32DG(a)**

16 Omit “subsection 32DD(1)”, substitute “section 32DD”.

17 **46 After paragraph 32DG(a)**

18 Insert:

19 (aa) the application has passed preliminary assessment; and

20 **47 Subsection 32DH(1)**

21 Omit “subsection 32DD(1)”, substitute “section 32DD”.

22 **48 Subsection 32DI(1)**

23 Omit “in accordance with” (first occurring), substitute “under”.

24 **49 Subsection 32DI(1)**

25 After “in the Register” (first occurring), insert “, and the application has
26 passed preliminary assessment”.

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 2 Biologicals

1 **50 Application provisions**

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

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Medical devices **Part 3**

1 **Part 3—Medical devices**

2 *Therapeutic Goods Act 1989*

3 **51 Section 41E (note)**

4 Repeal the note, substitute:

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

8 **52 Division 3 of Part 4-4 (note to Division heading)**

9 Repeal the note.

10 **53 Division 4 of Part 4-4 (note to Division heading)**

11 Repeal the note.

12 **54 Section 41FA**

13 Omit “automatically once a proper”, substitute “once an”.

14 **55 Section 41FA**

15 After “required certification”, insert “and the application passes
16 preliminary assessment”.

17 **56 Section 41FA (note 1)**

18 Repeal the note, substitute:

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

23 **57 Section 41FB**

24 Repeal the section.

25 **58 Section 41FC**

26 Repeal the section, substitute:

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 3 Medical devices

1 **41FC Making an application**

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

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

6 Note: A person might also commit an offence, or contravene a civil penalty
7 provision, if the person makes a statement in an application that is
8 false or misleading in a material particular: see sections 41FE and
9 41FEA.

10 **59 Before section 41FE**

11 Insert:

12 **41FDB Preliminary assessment of applications**

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

18 (2) The requirements are as follows:

19 (a) the application must be made:

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

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

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

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

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

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

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

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

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Medical devices **Part 3**

- 1 assessment certificate relating to the kind of medical device
2 before an application under section 41FC can be made—such
3 a certificate is in force;
4 (f) the applicant has certified the matters in section 41FD.

5 *Passing preliminary assessment*

- 6 (3) An application *passes preliminary assessment* if the Secretary:
7 (a) has carried out an assessment, under subsection (1), in
8 relation to the application; and
9 (b) is satisfied that the requirements set out in subsection (2)
10 have been met in relation to the application.
- 11 (4) If the application has not passed preliminary assessment, the
12 Secretary must refuse the application.

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

15 *Approval of forms etc.*

- 16 (5) For the purposes of paragraph (2)(a), the Secretary may approve
17 different forms and different manners for making applications for
18 different medical device classifications.
- 19 (6) An approval of a form may require or permit an application or
20 information to be given in accordance with specified software
21 requirements:
22 (a) on a specified kind of data processing device; or
23 (b) by way of a specified kind of electronic transmission.

24 *Determination of kinds and forms of information*

- 25 (7) The Secretary may, by legislative instrument, determine a kind of
26 information for the purposes of the application of
27 subparagraph (2)(d)(i) to medical devices of a particular
28 classification.
- 29 (8) The Secretary may, by legislative instrument, determine a form of
30 information for the purposes of the application of
31 subparagraph (2)(d)(ii) to medical devices of a particular
32 classification.

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 3 Medical devices

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

2 Repeal the paragraphs, substitute:

- 3 (a) an application for a kind of medical device to be included in
4 the Register in relation to a person has passed preliminary
5 assessment; and
6 (b) the application has not been selected for audit under
7 section 41FH;

8 **61 Subsection 41FF(1)**

9 Omit “, unless the application has been selected under section 41FH for
10 audit”.

11 **62 Subsection 41FF(2)**

12 Omit “must give to the applicant”, substitute “must make available to
13 the applicant”.

14 **63 Section 41FG**

15 Repeal the section, substitute:

16 **41FG Notification of unsuccessful applications**

- 17 (1) This section applies if an application under subsection 41FC(1) for
18 a kind of medical device to be included in the Register:
19 (a) is refused under subsection 41FDB(5); or
20 (b) is refused under subsection 41FF(1A).
21 (2) The Secretary must notify the applicant in writing, of the refusal
22 within 20 working days after the application has been received and
23 the prescribed application fee has been paid.

24 **64 Before subsection 41FH(1)**

25 Insert:

- 26 (1A) This section applies to applications that have passed preliminary
27 assessment.

28 **65 Subparagraph 41FH(2)(a)(ii)**

29 After “information”, insert “or documents”.

EXPOSURE DRAFT

Preliminary assessment of applications **Schedule 4**
Medical devices **Part 3**

1 **66 At the end of paragraph 41FH(3)(a)**

2 Add “and the prescribed application fee has been paid”.

3 **67 At the end of subsection 41FM(1)**

4 Add “or 41FJ”.

5 **68 Subparagraph 41HD(1)(d)(ii)**

6 After “includes the medical device”, insert “and the application has
7 passed preliminary assessment”.

8 **69 Paragraph 41HD(2)(d)**

9 After “includes the medical device”, insert “and the application has
10 passed preliminary assessment”.

11 **70 Application and transitional provisions**

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

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

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

EXPOSURE DRAFT

Schedule 4 Preliminary assessment of applications

Part 4 Consequential amendments

1 **Part 4—Consequential amendments**

2 *Therapeutic Goods Act 1989*

3 **71 Subsection 3(1)**

4 Insert:

5 *passed preliminary assessment:*

- 6 (a) when used in relation to a section 23 application for
7 registration—has the meaning given by subsection 23B(3);
8 and
9 (b) when used in relation to a section 23 application for listing
10 under section 26AE—has the meaning given by
11 subsection 23B(3); and
12 (c) when used in relation to a section 32DD application—has the
13 meaning given by subsection 32DDA(3); and
14 (d) when used in relation to a section 41FC application—has the
15 meaning given by subsection 41FDB(3).

16 **72 Before paragraph 60(1A)(a)**

17 Insert:

- 18 (aa) a preliminary assessment under section 23B, 32DDA or
19 41FDB;

EXPOSURE DRAFT

Conformity assessment procedures and certificates **Schedule 5**

1 **Schedule 5—Conformity assessment**
2 **procedures and certificates**
3

4 *Therapeutic Goods Act 1989*

5 **1 Subsection 3(1)**

6 Insert:

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

10 *conformity assessment document* means:

- 11 (a) a conformity assessment certificate; or
12 (b) an Australian conformity assessment body certificate; or
13 (c) an overseas regulator conformity assessment document.

14 *overseas regulator* has the meaning given by section 41BIB.

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

19 **2 Subsection 3(6)**

20 Omit “or an annual licensing charge”, substitute “, an annual licensing
21 charge or an annual conformity assessment body determination charge”.

22 **3 At the end of paragraph 41BA(b)**

23 Add “or requirements comparable to conformity assessment
24 procedures”.

25 **4 After paragraph 41BB(a)**

26 Insert:

- 27 (aa) making conformity assessment body determinations; and

28 **5 At the end of Division 2 of Part 4-1**

29 Add:

EXPOSURE DRAFT

Schedule 5 Conformity assessment procedures and certificates

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*.

EXPOSURE DRAFT

Conformity assessment procedures and certificates **Schedule 5**

1 **6 Subparagraphs 41EC(3)(a)(viii) and (ix)**

2 Omit “certificate”, substitute “document”.

3 **7 At the end of section 41EE**

4 Add:

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

8 **8 At the end of subsection 41EF(1)**

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

11 **9 Paragraph 41EF(2)(b)**

12 Omit “(if any) specified in the certificate”, substitute “specified in the
13 certificate, or if the Secretary extends that period, until the end of that
14 extended period”.

15 **10 At the end of section 41EF**

16 Add:

17 *Extensions*

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

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

22 (5) Only one extension may be given.

23 (6) The Secretary:

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

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

28 **11 Subparagraphs 41ET(1)(e)(viii) and (ix)**

29 Omit “certificate”, substitute “document”.

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Schedule 5 Conformity assessment procedures and certificates

1 **12 Subparagraphs 41EWA(4)(b)(i) and (ii)**

2 Omit “kinds of”.

3 **13 After subsection 41EWA(4)**

4 Insert:

5 (4A) If under the regulations the Secretary makes a conformity
6 assessment body determination, the Secretary must assign a unique
7 identification number to the body.

8 (4B) The Secretary must publish a list of the Australian conformity
9 assessment bodies on the Department’s website.

10 (4C) The Secretary may also publish on the Department’s website any
11 information relating to Australian conformity assessment bodies
12 and either to conformity assessment body determinations or to
13 certification-related activities of Australian conformity assessment
14 bodies.

15 **14 At the end of subsection 41EWA(5)**

16 Add:

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

19 **15 After subsection 41EWA(6)**

20 Insert:

21 (6A) The regulations may make provision for and in relation to the
22 effect on an Australian conformity assessment body certificate of
23 the Australian conformity assessment body ceasing to carry on
24 certification-related activities.

25 (6B) Without limiting subsection (6A), regulations made for the
26 purposes of that subsection may make provision in relation to a
27 matter by conferring on the Secretary a power to make a decision
28 of an administrative character.

29 **16 Subsection 41EWA(7)**

30 After “revoke”, insert “, suspend”.

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Conformity assessment procedures and certificates **Schedule 5**

1 **17 After subsection 41EWA(7)**

2 Insert:

3 (7A) If under the regulations the Secretary suspends a conformity
4 assessment body determination, the conditions referred to in
5 subsection (5) continue during the suspension.

6 **18 At the end of Part 4-4A**

7 Add:

8 **41EWB Content of Australian conformity assessment body**
9 **certificates**

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

- 13 (a) all medical devices manufactured by the manufacturer; or
14 (b) only specified medical devices manufactured by the
15 manufacturer.

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

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

21 **41EWC Duration of Australian conformity assessment body**
22 **certificates**

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

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

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

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- 1 (b) until the end of the period specified in the certificate, or if the
2 Australian conformity assessment body extends that period,
3 until the end of that extended period; or
4 (c) until the certificate is revoked by the Australian conformity
5 assessment body.

6 *Extensions*

- 7 (3) An Australian conformity assessment body that has issued an
8 Australian conformity assessment body certificate may, in writing
9 and on its own initiative, extend the period for which the certificate
10 is in force.
- 11 (4) An extension must be no longer than 12 months.
- 12 (5) Only one extension may be given.
- 13 (6) The Australian conformity assessment body must give notice of an
14 extension to the person to whom the certificate was issued.

15 **41EWD Record-keeping**

- 16 (1) If an Australian corporation:
17 (a) is an Australian conformity assessment body; and
18 (b) is required by a condition referred to in
19 subsection 41EWA(5) to keep records relating to
20 certification-related activities carried on by the corporation;
21 the Australian corporation must keep the records at all times while
22 the corporation is an Australian conformity assessment body.
- 23 (2) If the Australian corporation ceases to be an Australian conformity
24 assessment body, the corporation must keep the records referred to
25 in subsection (1) for 15 years after that cessation.

26 *Offences*

- 27 (3) An Australian corporation commits an offence if:
28 (a) the corporation is subject to a requirement under this section;
29 and
30 (b) the corporation contravenes the requirement.

31 Penalty: 1,200 penalty units.

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- 1 (4) An Australian corporation commits an offence if:
2 (a) the corporation is subject to a requirement under this section;
3 and
4 (b) the corporation contravenes the requirement.

5 Penalty: 300 penalty units.

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

7 **19 Section 41F**

8 After “of devices”, insert “or requirements, comparable to those
9 procedures, have been applied to the kinds of devices by an overseas
10 regulator”.

11 **20 Paragraph 41FD(f)**

12 Repeal the paragraph, substitute:

- 13 (f) either:
14 (i) appropriate conformity assessment procedures have
15 been applied to devices of that kind; or
16 (ii) requirements, comparable to the conformity assessment
17 procedures, have been applied to devices of that kind by
18 an overseas regulator; and

19 **21 Subparagraph 41FD(g)(i)**

20 Omit “those conformity assessment procedures”, substitute “the
21 procedures referred to in subparagraph (f)(i) or the requirements
22 referred to in subparagraph (f)(ii)”.

23 **22 Section 41FD (note)**

24 Repeal the note, substitute:

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

30 **23 After section 41FD**

31 Insert:

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1 **41FDA Basis of certification of conformity assessment procedures**

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

- 5 (a) on a conformity assessment certificate that is in force; or
6 (b) on an Australian conformity assessment body certificate that
7 is in force; or
8 (c) on an overseas regulator conformity assessment document
9 that is in force.

10 **24 Section 41FIA**

11 Repeal the section, substitute:

12 **41FIA Certificates issued by Australian conformity assessment**
13 **bodies**

14 (1) If:

- 15 (a) a section 41FC application is made for a kind of medical
16 device to be included in the Register; and
17 (b) the application has been selected for audit; and
18 (c) a person has obtained a certificate issued by an Australian
19 conformity assessment body to the effect that the body is
20 satisfied that an appropriate conformity assessment procedure
21 has been applied to devices of that kind; and
22 (d) the certificate was issued under a contract between the person
23 and the body; and
24 (e) the certificate has been given to the Secretary; and
25 (f) if the conformity assessment body determination that relates
26 to the body is limited as mentioned in
27 paragraph 41EWA(4)(b)—the Secretary is satisfied that the
28 certificate has been issued consistently with the
29 determination;

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

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

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1 **25 Subparagraph 41FN(3)(b)(i)**

2 After “device”, insert “or that requirements, comparable to those
3 procedures, have been applied to the kind of medical device by an
4 overseas regulator”.

5 **26 Subparagraph 41FN(3)(e)(i)**

6 After “procedures”, insert “or requirements comparable to those
7 procedures”.

8 **27 Section 41G**

9 Omit “certificate”, substitute “document”.

10 **28 Subdivision B of Division 1 of Part 4-6 (heading)**

11 Repeal the heading, substitute:

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

14 **29 Section 41GF (heading)**

15 Repeal the heading, substitute:

16 **41GF Suspension where conformity assessment certificate**
17 **suspended**

18 **30 After section 41GF**

19 Insert:

20 **41GFA Suspension where other certificates or documents are**
21 **suspended**

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

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

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- 1 (b) an overseas regulator conformity assessment document that
2 applies to the kind of device is suspended by the overseas
3 regulator.
- 4 (2) However, before suspending the kind of device from the Register,
5 the Secretary must:
- 6 (a) inform the person in writing that the Secretary proposes the
7 suspension and set out the reasons for it; and
- 8 (b) give the person a reasonable opportunity to make
9 submissions to the Secretary in relation to the proposed
10 suspension.
- 11 (3) The Secretary is not to make a decision relating to the proposed
12 suspension until the Secretary has had regard to any submissions
13 the person makes under paragraph (2)(b).
- 14 (4) The Secretary must cause to be published on the Department's
15 website, as soon as practicable after the suspension, a notice setting
16 out particulars of the suspension.

31 Subsection 41GG(1)

17
18 Omit "The suspension", substitute "A suspension under section 41GF or
19 41GFA".

32 Subsection 41GH(1)

20
21 Omit "revoke the suspension", substitute "revoke a suspension under
22 section 41GF".

33 After subsection 41GH(1)

23
24 Insert:

- 25 (1A) The Secretary may revoke a suspension under section 41GFA if:
26 (a) either:
27 (i) the suspension referred to in paragraph 41GFA(1)(a) or
28 (b) ends; or
29 (ii) the person in relation to whom the kind of medical
30 device is included in the Register provides the Secretary
31 with another conformity assessment document that
32 applies to the kind of device; and
-

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

3 **34 Subsection 41GH(2)**

4 Omit “revoking the suspension”, substitute “making a revocation under
5 subsection (1) or (1A)”.

6 **35 Paragraph 41GN(1)(f)**

7 Omit “particular.”, substitute “particular; or”.

8 **36 Paragraph 41GN(1)(f) (note)**

9 Repeal the note.

10 **37 At the end of subsection 41GN(1) (after the note)**

11 Add:

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

14 (h) either of the following applies:

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

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

21 **38 Section 41J**

22 After “procedures”, insert “or requirements comparable to those
23 procedures”.

24 **39 Paragraphs 41JA(1)(b) and (ba)**

25 After “certificate”, insert “, or an Australian conformity assessment
26 body certificate,”.

27 **40 Paragraph 41JA(1)(f)**

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

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1 **41 After subsection 41JA(1D)**

2 Insert:

3 (1E) The Secretary may, by written notice given to an Australian
4 corporation that has been an Australian conformity assessment
5 body require the corporation to give to the Secretary specified
6 information, or specified documents, relating to:

- 7 (a) the certification-related activities carried on by the
8 corporation while the corporation was an Australian
9 conformity assessment body; or
10 (b) the conditions referred to in subsection 41EWA(5) that
11 applied while the corporation was an Australian conformity
12 assessment body.

13 **42 Paragraph 41JB(3)(aa)**

14 After “(da)”, insert “or subsection 41JA(1E)”.

15 **43 Subsection 41KA(1) (table items 2 and 4)**

16 After “applied to medical devices of that kind”, insert “and that
17 requirements, comparable to those procedures, have not been applied to
18 medical devices of that kind by an overseas regulator”.

19 **44 Section 41M**

20 After “devices”, insert “or requirements, comparable to those
21 procedures, have been applied to kinds of medical devices by an
22 overseas regulator”.

23 **45 After subsection 41MG(2) (before the notes)**

24 Insert:

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

28 **46 Paragraph 41MH(a)**

29 After “procedures”, insert “, or the application of requirements
30 comparable to those procedures by an overseas regulator,”.

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1 **47 Paragraph 41MHA(b)**

2 After “procedures”, insert “, or the application of requirements
3 comparable to those procedures by an overseas regulator,”.

4 **48 At the end of section 41MN**

5 Add:

6 *Offences relating to breaching a condition of a conformity*
7 *assessment body determination*

- 8 (10) An Australian corporation commits an offence if:
9 (a) the corporation does an act or omits to do an act; and
10 (b) the act or omission breaches a condition referred to in
11 subsection 41EWA(5); and
12 (c) the act or omission has resulted in, will result in, or is likely
13 to result in, harm or injury to any person.

14 Penalty: 20,000 penalty units.

- 15 (11) An Australian corporation commits an offence if:
16 (a) the corporation does an act or omits to do an act; and
17 (b) the act or omission breaches a condition referred to in
18 subsection 41EWA(5).

19 Penalty: 5,000 penalty units.

- 20 (12) An Australian corporation commits an offence if:
21 (a) the corporation does an act or omits to do an act; and
22 (b) the act or omission breaches a condition referred to in
23 subsection 41EWA(5).

24 Penalty: 500 penalty units.

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

26 **49 At the end of section 41MNA**

27 Add:

- 28 (3) An Australian corporation contravenes this subsection if:
29 (a) the corporation does an act or omits to do an act; and
-

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

3 Maximum civil penalty: 50,000 penalty units.

4 **50 Paragraph 41MP(2)(d)**

5 Omit “(other than one issued”, substitute “or other document (other than
6 a certificate or other document issued by the Secretary”.

7 **51 Subparagraph 41MP(2)(d)(ii)**

8 Omit “particular device”, substitute “device of that kind or the
9 application of requirements, comparable to those procedures, to a
10 device of that kind by an overseas regulator”.

11 **52 Paragraph 41MPA(2)(d)**

12 Omit “(other than one issued”, substitute “or other document (other than
13 a certificate or other document issued by the Secretary”.

14 **53 Subparagraph 41MPA(2)(d)(ii)**

15 Omit “particular device”, substitute “device of that kind or the
16 application of requirements, comparable to those procedures, to a
17 device of that kind by an overseas regulator”.

18 **54 At the end of section 43**

19 Add:

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

24 **55 After subsection 44(2)**

25 Insert:

26 *Annual conformity assessment body determination charge*

27 (2A) An annual conformity assessment body determination charge for a
28 financial year becomes payable:

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- 1 (a) if the conformity assessment body determination was made
2 in that financial year—on the 28th day after the
3 determination came into force; and
4 (b) in any other case:
5 (i) on 1 October in that year; or
6 (ii) if the regulations specify another day for the purposes of
7 this subparagraph—on that other day in that year.
8 This subsection is subject to subsection (3).

56 Subsection 44(3)

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

57 Section 44B

11 Omit “or an annual licensing charge”, substitute “, an annual licensing
12 charge or an annual conformity assessment body determination charge”.

58 Paragraph 45(3)(a)

14 Omit “and annual licensing charge”, substitute “, annual licensing
15 charge and annual conformity assessment body determination charge”.

59 At the end of subsection 46A(4)

17 Add:
18 ; and (d) premises of a person who has been issued with, or who has
19 applied for, an Australian conformity assessment body
20 certificate.
21

60 Section 53A (after table item 31)

22 Insert:
23 31A subsection 41MN(10) subsection 41MN(11)

61 Subsection 54B(2)

24 Repeal the subsection, substitute:
25 (2) The maximum penalty for an offence against subsection (1) is:
26 (a) the maximum penalty that a court could impose in respect of
27 an individual for the offence committed by the body
28 corporate; or
29

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- 1 (b) if the offence committed by the body corporate is an offence
2 against subsection 41MN(10)—imprisonment for 5 years or
3 4,000 penalty units, or both.

4 **62 Subsection 54B(4)**

5 Repeal the subsection, substitute:

- 6 (4) The maximum civil penalty for a contravention of subsection (3)
7 is:
8 (a) the maximum civil penalty that a court could impose in
9 respect of an individual for the civil penalty provision
10 contravened by the body corporate; or
11 (b) if the civil penalty provision contravened by the body
12 corporate is subsection 41MNA(3)—5,000 penalty units.

13 **63 Section 54BA (table item 40)**

14 Repeal the item, substitute:

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

15 **64 After paragraph 56A(1)(I)**

16 Insert:

- 17 (1a) there was no conformity assessment body determination in
18 force in respect of a particular Australian corporation; or
19 (1b) a conformity assessment body determination was in force in
20 respect of a particular Australian corporation and the
21 determination:
22 (i) was of general application; or
23 (ii) was limited to the extent specified in the certificate; or

24 **65 Subsection 61(5)**

25 Repeal the subsection, substitute:

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

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

5 **66 Application provisions**

- 6 (1) The amendment of section 41EC of the *Therapeutic Goods Act 1989*
7 made by this Schedule applies in relation to applications under
8 section 41EB of that Act made on or after the commencement of this
9 item.
- 10 (2) The amendments of section 41EE and subsections 41EF(1) and (2) of
11 the *Therapeutic Goods Act 1989* made by this Schedule apply in
12 relation to a conformity assessment certificate issued on or after the
13 commencement of this item.
- 14 (3) Subsections 41EF(3) to (6) of the *Therapeutic Goods Act 1989*, as
15 added by this Schedule, apply in relation to:
- 16 (a) a conformity assessment certificate issued on or after the
17 commencement of this item; and
- 18 (b) a conformity assessment certificate that was issued before
19 that commencement and was in force immediately before that
20 commencement.
- 21 (4) The amendment of section 41ET of the *Therapeutic Goods Act 1989*
22 made by this Schedule applies in relation to revocations under that
23 section on or after the commencement of this item where the breach
24 referred to in subparagraph 41ET(1)(e)(viii), or the suspension or
25 revocation referred to in subparagraph 41ET(1)(e)(ix), of that Act
26 occurred on or after that commencement.
- 27 (5) The amendments of section 41FD of the *Therapeutic Goods Act 1989*
28 made by this Schedule apply in relation to applications made under
29 section 41FC of that Act on or after the commencement of this item.
- 30 (6) Section 41FDA of the *Therapeutic Goods Act 1989*, as inserted by this
31 Schedule, applies in relation to applications made under section 41FC
32 of that Act on or after the commencement of this item.

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- 1 (7) The amendments of section 41FN of the *Therapeutic Goods Act 1989*
2 made by this Schedule apply in relation to kinds of medical devices
3 included in the Register on or after the commencement of this item.
- 4 (8) The amendments of subsection 41JA(1) of the *Therapeutic Goods Act*
5 *1989* made by this Schedule apply in relation to notices given under that
6 subsection on or after the commencement of this item.
- 7 (9) The amendment of subsection 41KA(1) of the *Therapeutic Goods Act*
8 *1989* made by this Schedule applies in relation to supplies of medical
9 devices on or after the commencement of this item.
- 10 (10) The amendments of sections 41MH and 41MHA of the *Therapeutic*
11 *Goods Act 1989* made by this Schedule apply in relation to statements
12 made on or after the commencement of this item.
- 13 (11) The amendments of sections 41MP and 41MPA of the *Therapeutic*
14 *Goods Act 1989* made by this Schedule apply in relation to restrictions,
15 suspensions or revocations on or after the commencement of this item
16 (whether the certificate or other document was issued before, on or after
17 that commencement).
- 18 (12) Subsection 61(5) of the *Therapeutic Goods Act 1989*, as substituted by
19 this Schedule, applies in relation to the release of information on or
20 after the commencement of this item (whether the information was
21 obtained before, on or after that commencement).

1 **Schedule 6—Advertising**

2 **Part 1—Enforcement**

3 *Therapeutic Goods Act 1989*

4 **1 Subsection 3(1)**

5 Insert:

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

- 11 (a) is on the label of the goods; or
12 (b) is on the package in which the goods are contained; or
13 (c) is on any material included with the package in which the
14 goods are contained.

15 **2 Subsection 3(1) (definition of *advertisement*)**

16 Repeal the definition.

17 **3 Subsection 3(1)**

18 Insert:

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

21 **4 At the end of section 21B**

22 Add:

23 *Civil penalty for advertising therapeutic goods for an indication*

- 24 (4) A person contravenes this subsection if:
25 (a) the person, by any means, advertises therapeutic goods for an
26 indication; and
27 (b) the therapeutic goods are included in the Register; and

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Schedule 6 Advertising Part 1 Enforcement

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

3 Maximum civil penalty:

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

6 **5 After subsection 22(1)**

7 Insert:

8 (2) A person commits an offence if:

- 9 (a) the person, by any means, advertises therapeutic goods for an
10 indication; and
11 (b) the therapeutic goods are included in the Register; and
12 (c) the indication is not an indication accepted in relation to that
13 inclusion; and
14 (d) either:
15 (i) the use of the goods for the advertised indication has
16 resulted in, will result in, or is likely to result in, harm
17 or injury to any person; or
18 (ii) the use of the goods for the advertised indication, if the
19 goods were so used, would result in, or would be likely
20 to result in, harm or injury to any person.

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

22 (3) A person commits an offence if:

- 23 (a) the person, by any means, advertises therapeutic goods for an
24 indication; and
25 (b) the therapeutic goods are included in the Register; and
26 (c) the indication is not an indication accepted in relation to that
27 inclusion.

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

30 **6 Subsection 22(5) (penalty)**

31 Repeal the penalty, substitute:

32 Penalty: 100 penalty units.

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1 **7 After subsection 22(5)**

2 Insert:

3 (5A) An offence against subsection (5) is an offence of strict liability.

4 **8 Paragraph 29D(1)(b)**

5 Omit “or (f)”, substitute “, (f), (fa) or (fb)”.

6 **9 Paragraph 30(1)(f)**

7 Repeal the paragraph, substitute:

- 8 (f) the person contravenes a direction, or a condition of a
9 direction, given to the person under subsection 42DV(1) in
10 relation to the advertising of the goods and the Secretary is
11 satisfied that the contravention is significant; or
12 (fa) if the person is a body corporate—a related body corporate of
13 the person contravenes a direction, or a condition of a
14 direction, given to the related body corporate under
15 subsection 42DV(1) in relation to the advertising of the
16 goods and the Secretary is satisfied that the contravention is
17 significant; or
18 (fb) there is a breach, involving the goods, of an applicable
19 provision of the Therapeutic Goods Advertising Code or any
20 other requirement relating to advertising applicable under
21 Part 5-1 or under the regulations, and the Secretary is
22 satisfied that:
23 (i) the breach is significant; and
24 (ii) as a result of the breach, the presentation of the goods is
25 misleading to a significant extent; or

26 **10 After subsection 30(1)**

27 Insert:

28 (1AA) Paragraph (1)(fb) does not apply to medicines that are
29 manufactured in Australia for export only, or are imported into
30 Australia for export only.

31 **11 Paragraph 30(1A)(b)**

32 Omit “exempt; or”, substitute “exempt.”.

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Schedule 6 Advertising

Part 1 Enforcement

1 **12 Paragraph 30(1A)(c)**

2 Repeal the paragraph.

3 **13 Subsection 30(1B)**

4 Repeal the subsection.

5 **14 After paragraph 30(2)(e)**

6 Insert:

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

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

15 **15 After subsection 32BJ(2)**

16 Insert:

17 *Advertising biological for an indication*

18 (2A) A person commits an offence if:

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

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

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

24 (d) either:

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

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

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

32 (2B) A person commits an offence if:

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

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

8 **16 Subsection 32BJ(3) (heading)**

9 Repeal the heading.

10 **17 Subsection 32BJ(3) (penalty)**

11 Repeal the penalty, substitute:

12 Penalty: 100 penalty units.

13 **18 After subsection 32BJ(3)**

14 Insert:

15 (3A) An offence against subsection (3) is an offence of strict liability.

16 **19 At the end of Division 2 of Part 3-2A**

17 Add:

18 **32BL Civil penalty for advertising biological for an indication**

19 A person contravenes this section if:

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

25 Maximum civil penalty:

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

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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

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

7 **23 Paragraph 41GL(h)**

8 Omit “serious”.

9 **24 At the end of subsection 41GN(1)**

10 Add:

- 11 ; or (i) the person contravenes a direction, or a condition of a
12 direction, given to the person under subsection 42DV(1) in
13 relation to the advertising of the kind of device; or
14 (j) if the person is a body corporate—a related body corporate of
15 the person contravenes a direction, or a condition of a
16 direction, given to the related body corporate under
17 subsection 42DV(1) in relation to the advertising of the kind
18 of device; or
19 (k) either of the following has not been complied with in relation
20 to the kind of device:
21 (i) an applicable provision of the Therapeutic Goods
22 Advertising Code;
23 (ii) any other requirement relating to advertising applicable
24 under Part 5-1 or the regulations.

25 **25 Section 41ML**

26 Repeal the section, substitute:

27 **41ML False advertising about medical devices**

- 28 (1) A person commits an offence if:
29 (a) the person, by any means, advertises a medical device as
30 being for a purpose; and
31 (b) the device is of a kind included in the Register; and
32 (c) the purpose is not a purpose accepted in relation to that
33 inclusion; and

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- 1 (d) either:
2 (i) the use of the medical device for the advertised purpose
3 has resulted in, will result in, or is likely to result in,
4 harm or injury to any person; or
5 (ii) the use of the medical device for the advertised purpose,
6 if the medical device were so used, would result in, or
7 would be likely to result in, harm or injury to any
8 person.

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

- 10 (2) A person commits an offence if:
11 (a) the person, by any means, advertises a medical device as
12 being for a purpose; and
13 (b) the device is of a kind included in the Register; and
14 (c) the purpose is not a purpose accepted in relation to that
15 inclusion.

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

- 18 (3) A person commits an offence if:
19 (a) the person, by any means, advertises a medical device as
20 being for a purpose; and
21 (b) the device is of a kind included in the Register; and
22 (c) the purpose is not a purpose accepted in relation to that
23 inclusion.

24 Penalty: 100 penalty units.

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

26 After section 41MLA

27 Insert:

28 41MLB Civil penalty for false advertising about medical devices

29 A person contravenes this section if:

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

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

4 Maximum civil penalty:

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

7 **27 Subsection 42AC(2)**

8 Omit “Section 42DKB applies”, substitute “Sections 42DKB, 42DLA
9 and 42DLC and Divisions 5 and 6 apply in relation”.

10 **28 Section 42DD**

11 Omit “about therapeutic goods” (last occurring).

12 **29 Section 42DD (note)**

13 Repeal the note, substitute:

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

17 **30 At the end of subsection 42DI(1)**

18 Add:

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

21 **31 Section 42DK**

22 Repeal the section, substitute:

23 **42DK Permitted use of restricted or prohibited representations**

24 *Restricted representations*

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

EXPOSURE DRAFT

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Part 1 Enforcement

1

Prohibited representations

2

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

3

4

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

5

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

6

7

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

8

9

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

10

11

(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.

12

13

14

15

Conditions

16

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

17

18

Permission not a legislative instrument

19

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

20

Publication

21

(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.

22

23

24

32 Section 42DKB (heading)

25

Repeal the heading, substitute:

26

42DKB Certain representations not to be advertised

27

33 Subsection 42DKB(1)

28

Repeal the subsection, substitute:

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- 1 (1) If a representation in an advertisement about therapeutic goods is
2 false or misleading, the Secretary may, by notice given to a person
3 apparently responsible for:
4 (a) advertising the therapeutic goods; or
5 (b) causing the advertising of the therapeutic goods;
6 prevent that person from advertising the therapeutic goods, or
7 causing the advertising of the therapeutic goods, in circumstances
8 where the advertisement contains that representation (whether in
9 express terms or by necessary implication).

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

12 **34 At the end of section 42DKB**

13 Add:

14 *Publication*

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

18 **35 Sections 42DL and 42DM**

19 Repeal the sections, substitute:

20 **42DL Advertising offences—general**

- 21 (1) A person commits an offence if:
22 (a) the person:
23 (i) advertises, by any means, therapeutic goods; or
24 (ii) causes the advertising, by any means, of therapeutic
25 goods; and
26 (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to
27 the advertisement; and
28 (c) either:
29 (i) the use of the goods in reliance on the advertisement has
30 resulted in, will result in, or is likely to result in, harm
31 or injury to any person; or

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

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

5 (2) A person commits an offence if:

6 (a) the person:

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

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

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

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

14 (3) A person commits an offence if:

15 (a) the person:

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

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

19 (b) subsection (5), (6), (7), (8), (9), (10), (11) or (12) applies to
20 the advertisement.

21 Penalty: 100 penalty units.

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

23 *Contravening provisions*

24 (5) This subsection applies to the advertisement if it contains a
25 prohibited representation (whether in express terms or by necessary
26 implication) about the goods and either of the following applies:

27 (a) no permission under section 42DK is in force in relation to
28 the prohibited representation;

29 (b) a permission under section 42DK is in force in relation to the
30 prohibited representation but the use of the prohibited
31 representation is not in accordance with the permission or a
32 condition of the permission.

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- 1 (6) This subsection applies to the advertisement if it does not contain a
2 required representation about the goods.
- 3 (7) This subsection applies to the advertisement if it contains a
4 restricted representation (whether in express terms or by necessary
5 implication) and either of the following applies:
6 (a) neither an approval under section 42DF nor a permission
7 under section 42DK is in force in relation to the restricted
8 representation;
9 (b) an approval under section 42DF or a permission under
10 section 42DK is in force in relation to the restricted
11 representation but the use of the restricted representation is
12 not in accordance with the approval or permission or a
13 condition of the approval or permission.
- 14 (8) This subsection applies to the advertisement if it contains a
15 reference to this Act, other than in a statement of the registration
16 number, listing number or device number of the goods.
- 17 (9) This subsection applies to the advertisement if it contains a
18 statement, pictorial representation or design suggesting or implying
19 the goods have been recommended or approved by or on behalf of
20 a government or government authority (including a foreign
21 government or foreign government authority), other than:
22 (a) a statement of the availability of the goods as a
23 pharmaceutical benefit; or
24 (b) a statement, pictorial representation or design authorised or
25 required by a government or government authority (not
26 including a foreign government or foreign government
27 authority); or
28 (c) a statement, pictorial representation or design prescribed by
29 the regulations for the purposes of this paragraph.
- 30 (10) This subsection applies to the advertisement if it refers to
31 substances, or goods containing substances, included in
32 Schedule 3, 4 or 8 to the current Poisons Standard but not in
33 Appendix H of the current Poisons Standard, other than a reference
34 authorised or required by a government or government authority
35 (not including a foreign government or foreign government
36 authority).
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1 (11) This subsection applies to the advertisement if it refers to a
2 biological, other than a reference authorised or required by a
3 government or government authority (not including a foreign
4 government or foreign government authority).

5 (12) This subsection applies to the advertisement if it refers to
6 therapeutic goods that are not entered in the Register and that are
7 prescribed by the regulations for the purposes of this subsection,
8 other than a reference authorised or required by a government or
9 government authority (not including a foreign government or
10 foreign government authority).

11 *Continuing offences*

12 (13) A person who contravenes subsection (1), (2) or (3) commits a
13 separate offence in respect of each day (including a day of a
14 conviction for the offence or any later day) during which the
15 contravention continues.

16 (14) The maximum penalty for each day that an offence against
17 subsection (1), (2) or (3) continues is 10% of the maximum
18 pecuniary penalty that can be imposed in respect of that offence.

19 **42DLA Advertising offences—contravening section 42DKB notice**

- 20 (1) A person commits an offence if:
- 21 (a) the Secretary has given a notice to the person under
 - 22 section 42DKB in relation to therapeutic goods; and
 - 23 (b) the person does an act or omits to do an act; and
 - 24 (c) the act or omission contravenes the notice; and
 - 25 (d) either:
 - 26 (i) the use of the goods has resulted in, will result in, or is
 - 27 likely to result in, harm or injury to any person; or
 - 28 (ii) the use of the goods, if the goods were used, would
 - 29 result in, or would be likely to result in, harm or injury
 - 30 to any person; and
 - 31 (e) the harm or injury has resulted, will result, is likely to result,
 - 32 would result, or would be likely to result, because of the
 - 33 contravention.

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

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- 1 (2) A person commits an offence if:
2 (a) the Secretary has given a notice to the person under
3 section 42DKB; and
4 (b) the person does an act or omits to do an act; and
5 (c) the act or omission contravenes the notice.

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

- 8 (3) A person commits an offence if:
9 (a) the Secretary has given a notice to the person under
10 section 42DKB; and
11 (b) the person does an act or omits to do an act; and
12 (c) the act or omission contravenes the notice.

13 Penalty: 100 penalty units.

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

15 **42DLB Civil penalty relating to advertisements—general**

- 16 (1) A person contravenes this subsection if:
17 (a) the person:
18 (i) advertises, by any means, therapeutic goods; or
19 (ii) causes the advertising, by any means, of therapeutic
20 goods; and
21 (b) subsection (2), (3), (4), (5), (6), (7), (8) or (9) applies to the
22 advertisement.

23 Maximum civil penalty:

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

26 *Contravening provisions*

- 27 (2) This subsection applies to the advertisement if it contains a
28 prohibited representation (whether in express terms or by necessary
29 implication) about the goods and either of the following applies:
30 (a) no permission under section 42DK is in force in relation to
31 the prohibited representation;

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- 1 (b) a permission under section 42DK is in force in relation to the
2 prohibited representation but the use of the prohibited
3 representation is not in accordance with the permission or a
4 condition of the permission.
- 5 (3) This subsection applies to the advertisement if it does not contain a
6 required representation about the goods.
- 7 (4) This subsection applies to the advertisement if it contains a
8 restricted representation (whether in express terms or by necessary
9 implication) and either of the following applies:
- 10 (a) neither an approval under section 42DF nor a permission
11 under section 42DK is in force in relation to the restricted
12 representation;
- 13 (b) an approval under section 42DF or a permission under
14 section 42DK is in force in relation to the restricted
15 representation but the use of the restricted representation is
16 not in accordance with the approval or permission or a
17 condition of the approval or permission.
- 18 (5) This subsection applies to the advertisement if it contains a
19 reference to this Act, other than in a statement of the registration
20 number, listing number or device number of the goods.
- 21 (6) This subsection applies to the advertisement if it contains a
22 statement, pictorial representation or design suggesting or implying
23 the goods have been recommended or approved by or on behalf of
24 a government or government authority (including a foreign
25 government or foreign government authority), other than:
- 26 (a) a statement of the availability of the goods as a
27 pharmaceutical benefit; or
- 28 (b) a statement, pictorial representation or design authorised or
29 required by a government or government authority (not
30 including a foreign government or foreign government
31 authority); or
- 32 (c) a statement, pictorial representation or design prescribed by
33 the regulations for the purposes of this paragraph.
- 34 (7) This subsection applies to the advertisement if it refers to
35 substances, or goods containing substances, included in
36 Schedule 3, 4 or 8 to the current Poisons Standard but not in
-

EXPOSURE DRAFT

1 Appendix H of the current Poisons Standard, other than a reference
2 authorised or required by a government or government authority
3 (not including a foreign government or foreign government
4 authority).

5 (8) This subsection applies to the advertisement if it refers to a
6 biological, other than a reference authorised or required by a
7 government or government authority (not including a foreign
8 government or foreign government authority).

9 (9) This subsection applies to the advertisement if it refers to
10 therapeutic goods that are not entered in the Register and that are
11 prescribed by the regulations for the purposes of this subsection,
12 other than a reference authorised or required by a government or
13 government authority (not including a foreign government or
14 foreign government authority).

15 **42DLC Civil penalty relating to advertisements—contravening** 16 **section 42DKB notice**

17 A person contravenes this section if:

- 18 (a) the Secretary has given a notice to the person under
19 section 42DKB; and
20 (b) the person does an act or omits to do an act; and
21 (c) the act or omission contravenes the notice.

22 Maximum civil penalty:

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

25 **42DM Offences—non-compliance with the Therapeutic Goods** 26 **Advertising Code**

27 (1) A person commits an offence if:

- 28 (a) the person:
29 (i) advertises, by any means, therapeutic goods; or
30 (ii) causes the advertising, by any means, of therapeutic
31 goods; and
32 (b) the advertisement does not comply with the Therapeutic
33 Goods Advertising Code; and
-

EXPOSURE DRAFT

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- 1 (c) either:
2 (i) the use of the goods in reliance on the advertisement has
3 resulted in, will result in, or is likely to result in, harm
4 or injury to any person; or
5 (ii) the use of the goods in reliance on the advertisement, if
6 the goods were so used, would result in, or would be
7 likely to result in, harm or injury to any person.

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

- 9 (2) A person commits an offence if:
10 (a) the person:
11 (i) advertises, by any means, therapeutic goods; or
12 (ii) causes the advertising, by any means, of therapeutic
13 goods; and
14 (b) the advertisement does not comply with the Therapeutic
15 Goods Advertising Code.

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

- 18 (3) A person commits an offence if:
19 (a) the person:
20 (i) advertises, by any means, therapeutic goods; or
21 (ii) causes the advertising, by any means, of therapeutic
22 goods; and
23 (b) the advertisement does not comply with the Therapeutic
24 Goods Advertising Code.

25 Penalty: 100 penalty units.

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

27 *Continuing offences*

- 28 (5) A person who contravenes subsection (1), (2) or (3) commits a
29 separate offence in respect of each day (including a day of a
30 conviction for the offence or any later day) during which the
31 contravention continues.

- 1 (6) The maximum penalty for each day that an offence against
2 subsection (1), (2) or (3) continues is 10% of the maximum
3 pecuniary penalty that can be imposed in respect of that offence.

4 **42DMA Civil penalty—non-compliance with the Therapeutic Goods**
5 **Advertising Code**

6 A person contravenes this section if:

- 7 (a) the person:
8 (i) advertises, by any means, therapeutic goods; or
9 (ii) causes the advertising, by any means, of therapeutic
10 goods; and
11 (b) the advertisement does not comply with the Therapeutic
12 Goods Advertising Code.

13 Maximum civil penalty:

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

16 **36 Section 42DO**

17 Omit “principles of the Therapeutic Goods Advertising Code specified
18 in regulations made for the purposes of this section as if those
19 principles”, substitute “the provisions of the Therapeutic Goods
20 Advertising Code that are prescribed by the regulations for the purposes
21 of this section as if those provisions”.

22 **37 Section 42DP**

23 Repeal the section, substitute:

24 **42DP Offences—dissemination of generic information**

- 25 (1) A person commits an offence if:
26 (a) the person disseminates, by any means, generic information
27 about therapeutic goods to the public or a section of the
28 public; and
29 (b) the dissemination of that generic information does not
30 comply with the provisions of the Therapeutic Goods
31 Advertising Code that are prescribed by regulations for the
32 purposes of section 42DO.

EXPOSURE DRAFT

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

3 (2) A person commits an offence if:

4 (a) the person disseminates, by any means, generic information
5 about therapeutic goods to the public or a section of the
6 public; and

7 (b) the dissemination of that generic information does not
8 comply with the provisions of the Therapeutic Goods
9 Advertising Code that are prescribed by regulations for the
10 purposes of section 42DO.

11 Penalty: 100 penalty units.

12 (3) An offence against subsection (2) is an offence of strict liability.

13 **42DQ Civil penalty for dissemination of generic information**

14 A person contravenes this section if:

15 (a) the person disseminates, by any means, generic information
16 about therapeutic goods to the public or a section of the
17 public; and

18 (b) the dissemination of that generic information does not
19 comply with the provisions of the Therapeutic Goods
20 Advertising Code that are prescribed by regulations for the
21 purposes of section 42DO.

22 Maximum civil penalty:

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

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

25 **38 At the end of Part 5-1**

26 Add:

1 **Division 5—Secretary may require information or**
2 **documents**

3 **42DR Secretary may require information or documents**

4 *Advertisements*

- 5 (1) The Secretary may, by written notice given to a person apparently
6 responsible for advertising therapeutic goods, or for causing the
7 advertising of therapeutic goods, require the person to give to the
8 Secretary specified information, or to produce to the Secretary
9 specified documents, relating to the advertisement.

10 *Generic information*

- 11 (2) The Secretary may, by written notice given to a person apparently
12 responsible for disseminating, or for causing the disseminating of,
13 generic information about therapeutic goods to the public or a
14 section of the public, require the person to give to the Secretary
15 specified information, or to produce to the Secretary specified
16 documents, relating to the dissemination.

17 *Manner of compliance*

- 18 (3) The person must give the information, or produce the documents,
19 to the Secretary:
20 (a) within the period, of not less than 14 days after the day the
21 notice is given, specified in the notice or within such longer
22 period as the Secretary allows; and
23 (b) in the form specified in the notice.

24 Note: Section 42DS contains criminal offences for failing to comply with
25 the notice and for giving false or misleading information or documents
26 and section 42DT contains a civil penalty for giving false or
27 misleading information or documents.

- 28 (4) The form may require or permit the information to be given, or the
29 documents to be produced, in accordance with specified software
30 requirements:
31 (a) on a specified kind of data processing device; or
32 (b) by way of a specified kind of electronic transmission.

EXPOSURE DRAFT

Schedule 6 Advertising
Part 1 Enforcement

1

Notice not a legislative instrument

2

(5) A notice under subsection (1) or (2) is not a legislative instrument.

3

42DS Criminal offences for failing to comply with a notice etc.

4

(1) A person commits an offence if:

5

(a) the person is given a notice under section 42DR; and

6

(b) the person fails to comply with the notice.

7

Penalty: 500 penalty units.

8

(2) A person commits an offence if:

9

(a) the person is given a notice under section 42DR; and

10

(b) the person fails to comply with the notice.

11

Penalty: 100 penalty units.

12

(3) An offence against subsection (2) is an offence of strict liability.

13

(4) A person commits an offence if:

14

(a) the person is given a notice under section 42DR; and

15

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

16

17

(c) the information or document is false or misleading in a material particular.

18

19

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

20

21

(5) A person commits an offence if:

22

(a) the person is given a notice under section 42DR; and

23

(b) the person gives information or produces a document in compliance or purported compliance with the notice; and

24

25

(c) the information or document is false or misleading in a material particular.

26

27

Penalty: 100 penalty units.

28

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

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1 **42DT Civil penalty for giving false or misleading information or**
2 **document in compliance with a notice**

3 A person contravenes this section if:

- 4 (a) the person is given a notice under section 42DR; and
5 (b) the person gives information or produces a document in
6 compliance or purported compliance with the notice; and
7 (c) the information or document is false or misleading in a
8 material particular.

9 Maximum civil penalty:

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

12 **42DU Self-incrimination**

13 (1) A person is not excused from giving information or producing a
14 document under section 42DR on the ground that the information
15 or the production of the document might tend to incriminate the
16 person or expose the person to a penalty.

17 (2) However, in the case of an individual:

- 18 (a) the information given or the document produced; and
19 (b) giving the information or producing the document; and
20 (c) any information, document or thing obtained as a direct or
21 indirect consequence of giving the information or producing
22 the document;

23 are not admissible in evidence against the individual:

- 24 (d) in criminal proceedings, except proceedings for an offence
25 against subsection 42DS(4) or (5); or
26 (e) in civil proceedings, except proceedings under section 42Y
27 for a contravention of section 42DT.

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Schedule 6 Advertising
Part 1 Enforcement

1 **Division 6—Directions about advertisements or generic**
2 **information**

3 **42DV Directions about advertisements or generic information**

4 *Advertisements*

- 5 (1) If, in relation to the advertising of therapeutic goods, the Secretary
6 is satisfied that there has been a contravention of this Act or the
7 regulations, the Secretary may, in writing, direct a person
8 apparently responsible for advertising the therapeutic goods, or for
9 causing the advertising of the therapeutic goods, to do one or more
10 of the following:
11 (a) cease the advertisement;
12 (b) make a retraction;
13 (c) make a correction;
14 (d) recover any advertisement that is still in circulation;
15 (e) destroy the advertisement;
16 (f) cease making a particular claim or representation made by
17 the advertisement.

18 *Generic information*

- 19 (2) If, in relation to the dissemination of generic information about
20 therapeutic goods to the public or a section of the public, the
21 Secretary is satisfied that there has been a contravention of this Act
22 or the regulations, the Secretary may, in writing, direct a person
23 apparently responsible for the dissemination, or for causing the
24 dissemination, to do one or more of the following:
25 (a) withdraw the generic information;
26 (b) make a retraction;
27 (c) make a correction;
28 (d) recover any generic information that is still in circulation;
29 (e) destroy the generic information;
30 (f) cease making a particular claim or representation made by
31 the generic information.

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1

Conditions

2

(3) A direction under subsection (1) or (2) may be subject to conditions specified in the direction.

3

4

(4) Without limiting subsection (3), the conditions may relate to one or more of the following:

5

6

(a) the period for doing a thing the subject of the direction;

7

(b) in relation to the making of a retraction or correction, either or both of the following:

8

9

(i) the form and manner of the retraction or correction;

10

(ii) the period for which the retraction or correction must be made publicly available;

11

12

(c) the reporting to the Secretary of compliance with the direction.

13

14

Direction not a legislative instrument

15

(5) A direction under subsection (1) or (2) is not a legislative instrument.

16

17

Publication

18

(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.

19

20

21

42DW Offences—contravening direction under section 42DV

22

(1) A person commits an offence if:

23

(a) the Secretary has given a direction to the person under subsection 42DV(1) or (2) in relation to therapeutic goods;

24

and

25

26

(b) the person does an act or omits to do an act; and

27

(c) the act or omission contravenes the direction or a condition of the direction; and

28

29

(d) either:

30

(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

31

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Schedule 6 Advertising
Part 1 Enforcement

- 1 (ii) the use of the goods, if the goods were used, would
2 result in, or would be likely to result in, harm or injury
3 to any person; and
4 (e) the harm or injury has resulted, will result, is likely to result,
5 would result, or would be likely to result, because of the
6 contravention.

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

- 8 (2) A person commits an offence if:
9 (a) the Secretary has given a direction to the person under
10 subsection 42DV(1) or (2); and
11 (b) the person does an act or omits to do an act; and
12 (c) the act or omission contravenes the direction or a condition
13 of the direction.

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

- 16 (3) A person commits an offence if:
17 (a) the Secretary has given a direction to the person under
18 subsection 42DV(1) or (2); and
19 (b) the person does an act or omits to do an act; and
20 (c) the act or omission contravenes the direction or a condition
21 of the direction.

22 Penalty: 100 penalty units.

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

24 **42DX Civil penalty for contravening direction under section 42DV**

- 25 A person contravenes this section if:
26 (a) the Secretary has given a direction to the person under
27 subsection 42DV(1) or (2); and
28 (b) the person does an act or omits to do an act; and
29 (c) the act or omission contravenes the direction or a condition
30 of the direction.

31 Maximum civil penalty:

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

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

2 **Division 7—Public warning notices**

3 **42DY Secretary may issue a public warning notice**

4 (1) The Secretary may issue to the public a written notice containing a
5 warning about therapeutic goods if:

6 (a) the Secretary reasonably suspects that there has been a
7 contravention of this Act or the regulations in relation to:

8 (i) the advertising of the therapeutic goods; or

9 (ii) the dissemination of generic information about the
10 therapeutic goods to the public or a section of the
11 public; and

12 (b) the Secretary is satisfied that it is in the public interest to
13 issue the notice.

14 (2) If:

15 (a) the Secretary gives a person a notice (the *substantiation*
16 *notice*) under subsection 42DR(1) or (2); and

17 (b) the person fails to comply with the substantiation notice; and

18 (c) the Secretary is satisfied that it is in the public interest to
19 issue a notice under this subsection;

20 the Secretary may issue to the public a written notice containing a
21 warning that the person has failed to comply with the
22 substantiation notice, and specifying the matter to which the
23 substantiation notice related.

24 (3) Subsection (2) does not limit subsection (1).

25 (4) A notice under this section is not a legislative instrument.

26 **39 Section 53A (after table item 9)**

27 Insert:

9A subsection 22(2) subsection 22(3)

28 **40 Section 53A (after table item 13E)**

29 Insert:

13EA subsection 32BJ(2A) subsection 32BJ(2B)

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Schedule 6 Advertising
Part 1 Enforcement

1 **41 Section 53A (after table item 29)**

2 Insert:

29A subsection 41ML(1) subsection 41ML(2)

3 **42 Section 53A (after table item 33)**

4 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)

5 **43 Section 54BA (table item 5)**

6 Omit “22(7AB)”, substitute “22(2) or (7AB)”.

7 **44 Section 54BA (before table item 18)**

8 Insert:

17A Subsection 32BJ(2A)

9 **45 Section 54BA (after table item 39)**

10 Insert:

39A Subsection 41ML(1)

11 **46 Section 54BA (after table item 43)**

12 Insert:

43A Subsection 42DL(1)

43B Subsection 42DLA(1)

43C Subsection 42DM(1)

43D Subsection 42DW(1)

13 **47 Subsection 60(1) (at the end of paragraph (l) of the**
14 **definition of *initial decision*)**

15 Add “or subsection 42DV(1) or (2)”.

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48 Application and saving provisions—therapeutic goods

- 1
- 2 (1) Subsections 21B(4) and 22(2), (3) and (5A) of the *Therapeutic Goods*
3 *Act 1989*, as added or inserted by this Part, apply in relation to
4 advertisements occurring on or after the commencement of this item.
- 5 (2) Despite the amendments made by this Part, paragraph 30(1)(f) of the
6 *Therapeutic Goods Act 1989*, as in force immediately before the
7 commencement of this item, continues to apply on and after that
8 commencement in relation to a direction or requirement referred to in
9 that paragraph that was given or made before that commencement.
- 10 (3) Paragraph 30(1)(fb) of the *Therapeutic Goods Act 1989*, as substituted
11 by this Part, applies in relation to a breach occurring on or after the
12 commencement of this item.
- 13 (4) Subsection 30(1AA) of the *Therapeutic Goods Act 1989*, as inserted by
14 this Part, applies in relation to a breach occurring on or after the
15 commencement of this item.
- 16 (5) Despite the amendments made by this Part, paragraph 30(1A)(c) and
17 subsection 30(1B) of the *Therapeutic Goods Act 1989*, as in force
18 immediately before the commencement of this item, continue to apply
19 on and after that commencement in relation to a breach occurring before
20 that commencement.

49 Application and saving provisions—biologicals

- 21
- 22 (1) Subsections 32BJ(2A), (2B) and (3A) and section 32BL of the
23 *Therapeutic Goods Act 1989*, as inserted or added by this Part, apply in
24 relation to advertisements occurring on or after the commencement of
25 this item.
- 26 (2) Despite the amendments made by this Part, paragraph 32GA(1)(i) of the
27 *Therapeutic Goods Act 1989*, as in force immediately before the
28 commencement of this item, continues to apply on and after that
29 commencement in relation to a direction or requirement referred to in
30 that paragraph that was given or made before that commencement.
- 31 (3) Despite the amendments made by this Part, paragraph 32GA(1)(j) of the
32 *Therapeutic Goods Act 1989*, as in force immediately before the
33 commencement of this item, continues to apply on and after that

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Schedule 6 Advertising

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1 commencement in relation to a breach occurring before that
2 commencement.

3 (4) Paragraph 32GA(1)(k) of the *Therapeutic Goods Act 1989*, as
4 substituted by this Part, applies in relation to a breach occurring on or
5 after the commencement of this item.

6 **50 Application and saving provisions—medical devices**

7 (1) Despite the amendments made by this Part, paragraph 41GL(g) of the
8 *Therapeutic Goods Act 1989*, as in force immediately before the
9 commencement of this item, continues to apply on and after that
10 commencement in relation to a direction or requirement referred to in
11 that paragraph that was given or made before that commencement.

12 (2) The amendment of paragraph 41GL(h) of the *Therapeutic Goods Act*
13 *1989* made by this Part applies in relation to a breach occurring on or
14 after the commencement of this item.

15 (3) Paragraph 41GN(1)(k) of the *Therapeutic Goods Act 1989*, as added by
16 this Part, applies in relation to non-compliance occurring on or after the
17 commencement of this item.

18 (4) Sections 41ML and 41MLB of the *Therapeutic Goods Act 1989*, as
19 substituted or inserted by this Part, apply in relation to advertisements
20 occurring on or after the commencement of this item.

21 **51 Application and saving provisions—advertising and** 22 **generic information**

23 (1) The substitution of subsection 42DKB(1) of the *Therapeutic Goods Act*
24 *1989* made by this Part applies in relation to:

- 25 (a) an advertisement first-mentioned in that subsection that
26 occurs on or after the commencement of this item; and
27 (b) an advertisement first-mentioned in that subsection that
28 occurs in the 60 days ending at the end of the day before the
29 commencement of this item, where no notice had been given
30 under subsection 42DKB(1) of that Act in relation to the
31 advertisement before that commencement.

32 (2) The repeal and substitution of subsection 42DKB(1) of the *Therapeutic*
33 *Goods Act 1989* made by this Part does not affect the validity of a

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Advertising **Schedule 6**
Enforcement **Part 1**

- 1 notice given under that subsection before the commencement of this
2 item.
- 3 (3) Subsection 42DKB(3) of the *Therapeutic Goods Act 1989*, as added by
4 this Part, applies in relation to a notice given on or after the
5 commencement of this item.
- 6 (4) The substitution of section 42DL of the *Therapeutic Goods Act 1989*
7 made by this Part applies in relation to advertisements occurring on or
8 after the commencement of this item.
- 9 (5) Section 42DL of the *Therapeutic Goods Act 1989*, as in force
10 immediately before the commencement of this item, continues to apply
11 on and after that commencement in relation to:
- 12 (a) an advertisement published or broadcast before that
13 commencement; and
- 14 (b) an advertisement published or broadcast on or after that
15 commencement, where a notice was given under
16 section 42DKB of that Act before that commencement.
- 17 (6) Sections 42DLA and 42DLC of the *Therapeutic Goods Act 1989*, as
18 substituted by this Part, apply in relation to notices given under
19 section 42DKB of that Act on or after the commencement of this item.
- 20 (7) Sections 42DLB, 42DM and 42DMA of the *Therapeutic Goods Act*
21 *1989*, as substituted by this Part, apply in relation to advertisements
22 occurring on or after the commencement of this item.
- 23 (8) Section 42DM of the *Therapeutic Goods Act 1989*, as in force
24 immediately before the commencement of this item, continues to apply
25 on and after that commencement in relation to publications or
26 broadcasts occurring before that commencement.
- 27 (9) Sections 42DP and 42DQ of the *Therapeutic Goods Act 1989*, as
28 substituted by this Part, apply in relation to the dissemination of generic
29 information about therapeutic goods occurring on or after the
30 commencement of this item.
- 31 (10) Section 42DP of the *Therapeutic Goods Act 1989*, as in force
32 immediately before the commencement of this item, continues to apply
33 on and after that commencement in relation to publications or
34 broadcasts occurring before that commencement.
-

EXPOSURE DRAFT

Schedule 6 Advertising

Part 1 Enforcement

- 1 (11) Divisions 5, 6 and 7 of Part 5-1 of the *Therapeutic Goods Act 1989*, as
2 added by this Part, apply in relation to:
- 3 (a) advertisements occurring before, on or after the
4 commencement of this item; and
- 5 (b) the dissemination of generic information about therapeutic
6 goods occurring before, on or after the commencement of
7 this item.

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Advertising **Schedule 6**
Removal of requirement for advertisements to be approved **Part 2**

1 **Part 2—Removal of requirement for advertisements**
2 **to be approved**

3 ***Broadcasting Services Act 1992***

4 **52 Clause 6 of Schedule 2**

5 Repeal the clause.

6 **53 Paragraph 7(1)(j) of Schedule 2**

7 Omit “, 5 and 6”, substitute “and 5”.

8 **54 Paragraph 8(1)(i) of Schedule 2**

9 Omit “, 5 and 6”, substitute “and 5”.

10 **55 Paragraph 9(1)(i) of Schedule 2**

11 Omit “, 5 and 6”, substitute “and 5”.

12 **56 Paragraph 11(1)(d) of Schedule 2**

13 Omit “, 5 and 6”, substitute “and 5”.

14 **57 Paragraph 24(1)(a) of Schedule 6**

15 Omit “, 5 and 6”, substitute “and 5”.

16 **58 Subclause 24(4) of Schedule 6**

17 Omit “, 5 and 6”, substitute “and 5”.

18 ***Therapeutic Goods Act 1989***

19 **59 Section 42B**

20 Repeal the following definitions:

- 21 (a) definition of *approval number*;
- 22 (b) definition of *approved advertisement*;
- 23 (c) definition of *broadcaster*;
- 24 (d) definition of *broadcast media*;
- 25 (e) definition of *mainstream media*;

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Schedule 6 Advertising

Part 2 Removal of requirement for advertisements to be approved

- 1 (f) definition of *publisher*;
2 (g) definition of *publishing*;
3 (h) definition of *specified media*;
4 (i) definition of *visual broadcast media*.

5 **60 Division 2 of Part 5-1**

6 Repeal the Division.

7 **61 Section 42DA**

8 Repeal the section, substitute:

9 **42DA Simplified outline of this Division**

10 Representations in advertisements about therapeutic goods may be
11 restricted representations, required representations or prohibited
12 representations. The offences and civil penalties in Division 3A
13 refer to these 3 kinds of representations.

14 **62 Paragraph 42DF(4)(a)**

15 Repeal the paragraph.

16 **63 Division 3A of Part 5-1 (heading)**

17 Repeal the heading, substitute:

18 **Division 3A—Advertising offences and civil penalties**

19 **64 Section 42DKA**

20 Repeal the section.

21 **65 Saving provisions**

- 22 (1) Despite the amendments made by this Part, Divisions 1 and 2 of
23 Part 5-1 of the *Therapeutic Goods Act 1989*, and the *Therapeutic Goods*
24 *Regulations 1990*, as in force immediately before the commencement of
25 this item, continue to apply on and after that commencement in relation
26 to advertisements published or broadcast before that commencement.

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Advertising **Schedule 6**
Removal of requirement for advertisements to be approved **Part 2**

- 1 (2) Despite the amendments made by this Part, clauses 6, 7, 8, 9 and 11 of
2 Schedule 2 to the *Broadcasting Services Act 1992*, as in force
3 immediately before the commencement of this item, continue to apply
4 on and after that commencement in relation to advertisements relating
5 to therapeutic goods that were broadcast before that commencement.
- 6 (3) Despite the amendments made by this Part, clause 24 of Schedule 6 to
7 the *Broadcasting Services Act 1992*, as in force immediately before the
8 commencement of this item, continues to apply on and after that
9 commencement in relation to advertisements relating to therapeutic
10 goods that were provided on a datacasting service before that
11 commencement.

EXPOSURE DRAFT

Schedule 7 Enforcement

1 **Schedule 7—Enforcement**
2

3 ***Therapeutic Goods Act 1989***

4 **1 Subsection 3(1)**

5 Insert:

6 *Federal Circuit Court* means the Federal Circuit Court of
7 Australia.

8 **2 Section 5A**

9 Omit “subsections 21A(1), (2) and (4)”, substitute “subsections 21A(1),
10 (4) and (4A)”.

11 **3 Section 5A**

12 After “22A,”, insert “32DO,”.

13 **4 Subparagraph 9G(1)(d)(i)**

14 Omit “or will result in,”, substitute “will result in, or is likely to result
15 in,”.

16 **5 Subparagraph 9G(1)(d)(ii)**

17 Omit “would result in”, substitute “would result in, or would be likely
18 to result in,”.

19 **6 Subsections 9G(2) and (3)**

20 Repeal the subsections.

21 **7 At the end of section 9G**

22 Add:

- 23 (5) A person commits an offence if:
24 (a) the person makes a statement; and
25 (b) the statement is made in or in connection with a request
26 under section 9D for the variation of an entry in the Register
27 in relation to therapeutic goods; and
28 (c) the statement is false or misleading in a material particular.
-

1 Penalty: 100 penalty units.

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

3 **8 Paragraph 14(1)(c)**

4 After “to the goods”, insert “(other than by reason of a matter relating to
5 labelling or packaging)”.

6 **9 Subparagraph 14(1)(d)(i)**

7 Omit “or will result in,”, substitute “will result in, or is likely to result
8 in,”.

9 **10 Subparagraph 14(1)(d)(ii)**

10 Omit “would result in”, substitute “would result in, or would be likely
11 to result in,”.

12 **11 Paragraph 14(1)(e)**

13 Omit “or would result,”, substitute “is likely to result, would result, or
14 would be likely to result,”.

15 **12 Subsections 14(2) and (3)**

16 Repeal the subsections.

17 **13 At the end of paragraph 14(4)(c)**

18 Add “(other than by reason of a matter relating to labelling or
19 packaging)”.

20 **14 After subsection 14(4)**

21 Insert:

22 (4A) A person commits an offence if:

- 23 (a) the person imports therapeutic goods into Australia; and
24 (b) the goods are imported without the consent in writing of the
25 Secretary; and
26 (c) the goods do not conform with a standard applicable to the
27 goods (other than by reason of a matter relating to labelling
28 or packaging).

29 Penalty: 100 penalty units.

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Schedule 7 Enforcement

1 (4B) An offence against subsection (4A) is an offence of strict liability.

2 **15 Subsection 14(5)**

3 Repeal the subsection.

4 **16 Before subsection 14(5A)**

5 Insert:

6 *Exception*

7 **17 Subsection 14(5A)**

8 Omit “Subsection (1), (2) or (4)”, substitute “Subsection (1), (4) or
9 (4A)”.

10 **18 Subparagraph 14(6)(d)(i)**

11 Omit “or will result in,” substitute “will result in, or is likely to result
12 in,”.

13 **19 Subparagraph 14(6)(d)(ii)**

14 Omit “would result in”, substitute “would result in, or would be likely
15 to result in,”.

16 **20 Paragraph 14(6)(e)**

17 Omit “or would result,” substitute “is likely to result, would result, or
18 would be likely to result,”.

19 **21 Subsections 14(7) and (8)**

20 Repeal the subsections.

21 **22 After subsection 14(9)**

22 Insert:

23 (9AA) A person commits an offence if:

24 (a) the person supplies therapeutic goods for use in Australia;
25 and

26 (b) the goods are supplied without the consent in writing of the
27 Secretary; and

1 (c) the goods do not conform with a standard applicable to the
2 goods.

3 Penalty: 100 penalty units.

4 (9AB) An offence against subsection (9AA) is an offence of strict
5 liability.

6 **23 Subsection 14(9A)**

7 Omit “Subsection (6), (7) or (9)”, substitute “Subsection (6), (9) or
8 (9AA)”.

9 **24 Subparagraph 14(10)(d)(i)**

10 Omit “or will result in”, substitute “will result in, or is likely to result
11 in”.

12 **25 Subparagraph 14(10)(d)(ii)**

13 Omit “would result in”, substitute “would result in, or would be likely
14 to result in”.

15 **26 Paragraph 14(10)(e)**

16 Omit “or would result”, substitute “is likely to result, would result, or
17 would be likely to result”.

18 **27 Subsections 14(11) and (12)**

19 Repeal the subsections.

20 **28 After subsection 14(13)**

21 Insert:

22 (13AA) A person commits an offence if:

- 23 (a) the person exports therapeutic goods from Australia; and
24 (b) the goods are exported without the consent in writing of the
25 Secretary; and
26 (c) the goods do not conform with a standard applicable to the
27 goods (other than a standard relating to the labelling of the
28 goods for supply in Australia).

29 Penalty: 100 penalty units.

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Schedule 7 Enforcement

1 (13AB) An offence against subsection (13AA) is an offence of strict
2 liability.

3 **29 Subsection 14(13A)**

4 Omit “Subsection (10), (11) or (13)”, substitute “Subsection (10), (13)
5 or (13AA)”.

6 **30 Paragraph 14B(a)**

7 Omit “subsection 14(1), (2), (4), (10), (11) or (13)”, substitute
8 “subsection 14(1), (4), (4A), (10), (13) or (13AA)”.

9 **31 Paragraph 15(2)(c)**

10 Omit “or will result in,”, substitute “will result in, or is likely to result
11 in,”.

12 **32 Subsections 15(3) and (4)**

13 Repeal the subsections.

14 **33 At the end of section 15**

15 Add:

16 (6) A person commits an offence if:

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

18 (b) the act or omission breaches a condition of a consent.

19 Penalty: 100 penalty units.

20 (7) An offence against subsection (6) is an offence of strict liability.

21 **34 Subparagraph 19B(1)(c)(i)**

22 Omit “or will result in,”, substitute “will result in, or is likely to result
23 in,”.

24 **35 Subparagraph 19B(1)(c)(ii)**

25 Omit “would result in”, substitute “would result in, or would be likely
26 to result in,”.

27 **36 Subsections 19B(2) and (3)**

28 Repeal the subsections.

1 **37 After subsection 19B(4)**

2 Insert:

3 (4A) A person commits an offence if:

4 (a) the person:

5 (i) imports into Australia therapeutic goods for use in
6 humans; or

7 (ii) exports from Australia therapeutic goods for use in
8 humans; or

9 (iii) manufactures in Australia therapeutic goods for use in
10 humans; or

11 (iv) supplies in Australia therapeutic goods for use in
12 humans; and

13 (b) none of the following subparagraphs applies in relation to the
14 goods:

15 (i) the goods are registered goods or listed goods in relation
16 to the person;

17 (ii) the goods are exempt goods;

18 (iii) the goods are exempt under section 18A;

19 (iv) the goods are the subject of an approval or authority
20 under section 19;

21 (v) the goods are the subject of an approval under
22 section 19A.

23 Penalty: 100 penalty units.

24 (4B) An offence against subsection (4A) is an offence of strict liability.

25 **38 Subsection 19B(5)**

26 Omit “subsection (1), (2) or (4)”, substitute “subsection (1), (4) or
27 (4A)”.

28 **39 Paragraph 19B(6)(a)**

29 Omit “or will not,”, substitute “will not, or is not likely to,”.

30 **40 Paragraph 19B(6)(b)**

31 Omit “would not”, substitute “would not, or would not be likely to,”.

EXPOSURE DRAFT

Schedule 7 Enforcement

1 **41 Paragraph 19B(7)(a)**

2 Omit “subsection (1), (2) or (4)”, substitute “subsection (1), (4) or
3 (4A)”.

4 **42 After subsection 20(1B)**

5 Insert:

6 (1BA) A person commits an offence if:

7 (a) the person is the sponsor of therapeutic goods for use in
8 humans; and

9 (b) the person:

10 (i) imports the goods into Australia; or

11 (ii) exports the goods from Australia; or

12 (iii) manufactures the goods in Australia; or

13 (iv) supplies the goods in Australia; and

14 (c) the person has not, at the time of the importation, export,
15 manufacture or supply, properly notified to the Secretary
16 either or both of the following:

17 (i) the manufacturer of the goods;

18 (ii) premises used in the manufacture of the goods.

19 Penalty: 100 penalty units.

20 (1BB) An offence against subsection (1BA) is an offence of strict
21 liability.

22 **43 Subsection 20(1C)**

23 Omit “paragraph (1B)(c)”, substitute “paragraphs (1B)(c) and
24 (1BA)(c)”.

25 **44 Subparagraph 21A(1)(d)(i)**

26 Omit “or will result in,”, substitute “will result in, or is likely to result
27 in,”.

28 **45 Subparagraph 21A(1)(d)(ii)**

29 Omit “would result in”, substitute “would result in, or would be likely
30 to result in,”.

1 **46 Subsections 21A(2) and (3)**

2 Repeal the subsections.

3 **47 After subsection 21A(4)**

4 Insert:

5 (4A) A person commits an offence if:

- 6 (a) the person makes a statement; and
7 (b) the statement is made in or in connection with a certification
8 of any matter under subsection 26A(2) or 26AB(2); and
9 (c) the statement is false or misleading in a material particular.

10 Penalty: 100 penalty units.

11 (4B) An offence against subsection (4A) is an offence of strict liability.

12 **48 Paragraph 21A(5)(d)**

13 Omit “or will result in,”, substitute “will result in, or is likely to result
14 in,”.

15 **49 Subsections 21A(6) and (7)**

16 Repeal the subsections.

17 **50 After subsection 21A(8)**

18 Insert:

19 (8A) A person commits an offence if:

- 20 (a) therapeutic goods are registered or listed in relation to the
21 person; and
22 (b) the person does an act or omits to do an act; and
23 (c) the act or omission breaches a condition of the registration or
24 listing of the goods.

25 Penalty: 100 penalty units.

26 (8B) An offence against subsection (8A) is an offence of strict liability.

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1 **51 Subparagraph 21A(9)(d)(i)**

2 Omit “or will result in,”, substitute “will result in, or is likely to result
3 in,”.

4 **52 Subparagraph 21A(9)(d)(ii)**

5 Omit “would result in”, substitute “would result in, or would be likely
6 to result in,”.

7 **53 Paragraph 21A(9)(e)**

8 Omit “or would result,”, substitute “is likely to result, would result, or
9 would be likely to result,”.

10 **54 Subsection 21A(9) (note)**

11 Repeal the note.

12 **55 Subsections 21A(10) and (11)**

13 Repeal the subsections, substitute:

14 (9A) A person commits an offence if:

- 15 (a) the Secretary has authorised, under subsection 19(5), the
16 person to supply therapeutic goods; and
17 (b) the person supplies those goods; and
18 (c) any of the following applies:
19 (i) the supply is not in accordance with the authority;
20 (ii) the supply is not in accordance with the conditions to
21 which the authority is subject;
22 (iii) the supply is not in accordance with regulations made
23 for the purpose of subsection 19(7).

24 Penalty: 500 penalty units.

25 (10) A person commits an offence if:

- 26 (a) the Secretary has authorised, under subsection 19(5), the
27 person to supply therapeutic goods; and
28 (b) the person supplies those goods; and
29 (c) any of the following applies:
30 (i) the supply is not in accordance with the authority;
-

- 1 (ii) the supply is not in accordance with the conditions to
2 which the authority is subject;
3 (iii) the supply is not in accordance with regulations made
4 for the purpose of subsection 19(7).

5 Penalty: 100 penalty units.

6 (11) An offence against subsection (10) is an offence of strict liability.

7 **56 Subparagraph 21A(11A)(e)(i)**

8 Omit “or will result in,” substitute “will result in, or is likely to result
9 in.”.

10 **57 Subparagraph 21A(11A)(e)(ii)**

11 Omit “would result in,” substitute “would result in, or would be likely
12 to result in.”.

13 **58 Paragraph 21A(11A)(f)**

14 Omit “or would result,” substitute “is likely to result, would result, or
15 would be likely to result.”.

16 **59 Subsection 21A(11B)**

17 Repeal the subsection.

18 **60 After subsection 21A(11C)**

19 Insert:

20 (11D) A person commits an offence if:

- 21 (a) the person is a health practitioner; and
22 (b) the person is included in a class of health practitioners
23 specified in subsection 19(7A) rules; and
24 (c) the person supplies:
25 (i) therapeutic goods specified in those rules; or
26 (ii) therapeutic goods included in a class of therapeutic
27 goods specified in those rules; and
28 (d) any of the following applies:
29 (i) the supply is not in accordance with those rules;
30 (ii) the supply is not in the circumstances specified in those
31 rules;
-

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1 (iii) the supply is not in accordance with the conditions
2 specified in those rules.

3 Penalty: 100 penalty units.

4 (11E) An offence against subsection (11D) is an offence of strict liability.

5 **61 Subparagraphs 21A(12)(e)(i) and (ii)**

6 Omit “or will result in,” substitute “will result in, or is likely to result
7 in,”.

8 **62 Subsection 21A(12) (note)**

9 Repeal the note.

10 **63 Subsections 21A(13) and (14)**

11 Repeal the subsections, substitute:

12 (12A) A person commits an offence if:

- 13 (a) the person uses therapeutic goods; and
14 (b) the goods are used:
15 (i) in the treatment of another person; or
16 (ii) solely for experimental purposes in humans; and
17 (c) the goods are not:
18 (i) exempt goods; or
19 (ii) listed goods; or
20 (iii) registered goods; or
21 (iv) goods exempt under section 18A; or
22 (v) goods that are the subject of an approval under
23 section 19A; and
24 (d) the goods are not used in accordance with:
25 (i) an approval or authority under section 19; or
26 (ii) a condition applicable under regulations made for the
27 purposes of subsection 19(4A).

28 Penalty: 500 penalty units.

29 (13) A person commits an offence if:

- 30 (a) the person uses therapeutic goods; and
31 (b) the goods are used:
-

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- 1 (i) in the treatment of another person; or
2 (ii) solely for experimental purposes in humans; and
3 (c) the goods are not:
4 (i) exempt goods; or
5 (ii) listed goods; or
6 (iii) registered goods; or
7 (iv) goods exempt under section 18A; or
8 (v) goods that are the subject of an approval under
9 section 19A; and
10 (d) the goods are not used in accordance with:
11 (i) an approval or authority under section 19; or
12 (ii) a condition applicable under regulations made for the
13 purposes of subsection 19(4A).

14 Penalty: 100 penalty units.

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

16 **64 Subsections 22(7A) and (8)**

17 Repeal the subsections.

18 **65 Subparagraph 22A(1)(d)(i)**

19 Omit “or will result in,” substitute “will result in, or is likely to result
20 in,”.

21 **66 Subparagraph 22A(1)(d)(ii)**

22 Omit “would result in”, substitute “would result in, or would be likely
23 to result in,”.

24 **67 Subsections 22A(2) and (3)**

25 Repeal the subsections.

26 **68 At the end of section 22A**

27 Add:

- 28 (5) A person commits an offence if:
29 (a) the person makes a statement; and

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1 (b) the statement is made in or in connection with an application
2 for registration of therapeutic goods; and

3 (c) the statement is false or misleading in a material particular.

4 Penalty: 100 penalty units.

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

69 Subsection 30EA(1) (table item 5)

7 Omit “subsection 19B(1), (2) or (4)”, substitute “subsection 19B(1), (4)
8 or (4A)”.

70 Paragraph 30EC(1)(c)

10 Omit “or will result in,” substitute “will result in, or is likely to result
11 in,”.

71 Subsections 30EC(2) and (3)

12 Repeal the subsections.

72 At the end of section 30EC

14 Add:

16 (5) A person commits an offence if:

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

18 (b) the act or omission breaches a requirement imposed on the
19 person under section 30EA.

20 Penalty: 100 penalty units.

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

73 Subparagraph 30F(4B)(d)(i)

22 Omit “or will result in,” substitute “will result in, or is likely to result
23 in,”.
24

74 Subparagraph 30F(4B)(d)(ii)

25 Omit “would result in”, substitute “would result in, or would be likely
26 to result in,”.
27

1 **75 Paragraph 30F(4B)(e)**

2 Omit “or would result,” substitute “is likely to result, would result, or
3 would be likely to result.”

4 **76 Subsections 30F(4C) and (4D)**

5 Repeal the subsections.

6 **77 Subsection 30F(6)**

7 Repeal the subsection, substitute:

8 (6) A person commits an offence if:

- 9 (a) the Secretary gives a notice to the person under
10 subsection (2); and
11 (b) the notice specifies a particular requirement mentioned in
12 subsection (3); and
13 (c) the person fails to comply with that requirement.

14 Penalty: 100 penalty units.

15 (6A) An offence against subsection (6) is an offence of strict liability.

16 **78 After subsection 31(4A)**

17 Insert:

18 (4B) A person commits an offence if:

- 19 (a) either:
20 (i) the person is given a notice under subsection (1) and the
21 person is covered by paragraph (1)(ab) or (ac); or
22 (ii) the person is given a notice under subsection (2) and the
23 person is covered by paragraph (2)(ab) or (ac); and
24 (b) the person fails to comply with the notice.

25 Penalty: 100 penalty units.

26 **79 Subsection 31(5)**

27 Omit “under subsection (4)”, substitute “against subsection (4B)”.

28 **80 After subsection 31(5)**

29 Insert:

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1 (5AA) Subsection (4B) does not apply if the person has a reasonable
2 excuse.

3 Note: A defendant bears an evidential burden in relation to the matter in
4 subsection (5AA): see subsection 13.3(3) of the *Criminal Code*.

5 **81 Subparagraph 31(5A)(d)(i)**

6 Omit “or will result in,” substitute “will result in, or is likely to result
7 in,”.

8 **82 Subparagraph 31(5A)(d)(ii)**

9 Omit “would result in,” substitute “would result in, or would be likely
10 to result in,”.

11 **83 Subsections 31(5B) to (6)**

12 Repeal the subsections, substitute:

13 (6) A person commits an offence if:

- 14 (a) the person is given a notice under this section in relation to
15 therapeutic goods; and
16 (b) the person gives information or a document in compliance or
17 purported compliance with the notice; and
18 (c) the information or document is false or misleading in a
19 material particular.

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

22 (7) A person commits an offence if:

- 23 (a) the person is given a notice under this section in relation to
24 therapeutic goods; and
25 (b) the person gives information or a document in compliance or
26 purported compliance with the notice; and
27 (c) the information or document is false or misleading in a
28 material particular.

29 Penalty: 100 penalty units.

30 (8) An offence against subsection (7) is an offence of strict liability.

1 **84 Section 31C (heading)**

2 Repeal the heading, substitute:

3 **31C Criminal offences for failing to give information or documents**
4 **sought under section 31A, 31AA, 31B or 31BA**

5 **85 Section 31C**

6 Before “A”, insert “(1)”.

7 **86 Section 31C (note)**

8 Repeal the note.

9 **87 At the end of section 31C**

10 Add:

11 (2) A person commits an offence if:

12 (a) the person is given a notice under section 31A, 31AA, 31B or
13 31BA; and

14 (b) the person fails to comply with the notice.

15 Penalty: 100 penalty units.

16 (3) An offence against subsection (2) is an offence of strict liability.

17 **88 After subsection 31D(1)**

18 Insert:

19 (1A) A person to whom a notice is given under section 31A, 31AA, 31B
20 or 31BA commits an offence if:

21 (a) the person gives information to the Secretary in compliance
22 or purported compliance with the notice; and

23 (b) the information:

24 (i) is false or misleading; or

25 (ii) omits any matter or thing without which the information
26 is misleading.

27 Penalty: 100 penalty units.

28 (1B) An offence against subsection (1A) is an offence of strict liability.

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1 **89 Subsection 31D(2)**

2 After “Subsection (1)”, insert “or (1A)”.

3 **90 Subsection 31D(2)**

4 After “subparagraph (1)(b)(i)”, insert “or (1A)(b)(i)”.

5 **91 Subsection 31D(2) (note)**

6 Repeal the note, substitute:

7 Note: A defendant bears an evidential burden in relation to the matter in
8 subsection (2); see subsection 13.3(3) of the *Criminal Code*.

9 **92 Subsection 31D(3)**

10 After “Subsection (1)”, insert “or (1A)”.

11 **93 Subsection 31D(3)**

12 After “subparagraph (1)(b)(ii)”, insert “or (1A)(b)(ii)”.

13 **94 Subsection 31D(3) (note)**

14 Repeal the note, substitute:

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

17 **95 After subsection 31E(1)**

18 Insert:

19 (1A) A person commits an offence if:

- 20 (a) the person produces a document to the Secretary; and
21 (b) the document is false or misleading; and
22 (c) the document is produced in compliance or purported
23 compliance with a notice given under section 31A, 31AA,
24 31B or 31BA.

25 Penalty: 100 penalty units.

26 (1B) An offence against subsection (1A) is an offence of strict liability.

27 **96 Subsection 31E(2)**

28 After “Subsection (1)”, insert “or (1A)”.

1 **97 Subsection 31E(2) (note)**

2 Repeal the note, substitute:

3 Note: A defendant bears an evidential burden in relation to the matter in
4 subsection (2): see subsection 13.3(3) of the *Criminal Code*.

5 **98 Subsection 31E(3)**

6 After “Subsection (1)”, insert “or (1A)”.

7 **99 Subsection 31E(3) (note)**

8 Repeal the note, substitute:

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

11 **100 Subsection 31F(1)**

12 After “section”, insert “31,”.

13 **101 Paragraph 31F(2)(d)**

14 After “of,”, insert “subsection 31(5A), (6) or (7) or”.

15 **102 Paragraph 31F(2)(e)**

16 Repeal the paragraph, substitute:

17 (e) civil proceedings, except proceedings under section 42Y for a
18 contravention of section 31AAA.

19 **103 Subparagraph 32BA(1)(c)(i)**

20 Omit “or will result in,”, substitute “will result in, or is likely to result
21 in,”.

22 **104 Subparagraph 32BA(1)(c)(ii)**

23 Omit “would result in”, substitute “would result in, or would be likely
24 to result in,”.

25 **105 Subsections 32BA(2) and (3)**

26 Repeal the subsections.

27 **106 After subsection 32BA(4)**

28 Insert:

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- 1 (4A) A person commits an offence if:
2 (a) the person imports into Australia a biological for use in
3 humans; and
4 (b) none of the following subparagraphs applies:
5 (i) the biological is included in the Register in relation to
6 the person;
7 (ii) the person is exempt under subsection 32CA(1) in
8 relation to the biological or the biological is exempt
9 under subsection 32CA(2);
10 (iii) the biological is exempt under section 32CB;
11 (iv) the biological is the subject of an approval under
12 subsection 32CK(1) that is held by the person, being an
13 approval covering the importation into Australia of the
14 biological;
15 (v) the biological is the subject of an approval under
16 subsection 32CO(1), (1A) or (2) that is held by the
17 person.

18 Penalty: 100 penalty units.

19 (4B) An offence against subsection (4A) is an offence of strict liability.

20 **107 Subsection 32BA(5)**

21 Omit “Subsection (1), (2) or (4)”, substitute “Subsection (1), (4) or
22 (4A)”.

23 **108 Paragraph 32BA(6)(a)**

24 Omit “or will not,”, substitute “will not, or is not likely to,”.

25 **109 Paragraph 32BA(6)(b)**

26 Omit “would not”, substitute “would not, or would not be likely to,”.

27 **110 Subparagraph 32BB(1)(c)(i)**

28 Omit “or will result in,”, substitute “will result in, or is likely to result
29 in,”.

30 **111 Subparagraph 32BB(1)(c)(ii)**

31 Omit “would result in”, substitute “would result in, or would be likely
32 to result in,”.

1 **112 Subsections 32BB(2) and (3)**

2 Repeal the subsections.

3 **113 After subsection 32BB(4)**

4 Insert:

5 (4A) A person commits an offence if:

6 (a) the person exports from Australia a biological for use in
7 humans; and

8 (b) none of the following subparagraphs applies:

9 (i) the biological is included in the Register in relation to
10 the person;

11 (ii) the person is exempt under subsection 32CA(1) in
12 relation to the biological or the biological is exempt
13 under subsection 32CA(2);

14 (iii) the biological is exempt under section 32CB;

15 (iv) the biological is the subject of an approval under
16 subsection 32CK(1) that is held by the person, being an
17 approval covering the exportation from Australia of the
18 biological.

19 Penalty: 100 penalty units.

20 (4B) An offence against subsection (4A) is an offence of strict liability.

21 **114 Subsection 32BB(5)**

22 Omit “Subsection (1), (2) or (4)”, substitute “Subsection (1), (4) or
23 (4A)”.

24 **115 Paragraph 32BB(6)(a)**

25 Omit “or will not,”, substitute “will not, or is not likely to,”.

26 **116 Paragraph 32BB(6)(b)**

27 Omit “would not”, substitute “would not, or would not be likely to,”.

28 **117 After section 32BB**

29 Insert:

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1 **32BBA Treating biologicals as prohibited imports or exports**

2 If:

3 (a) the importation or exportation of a biological is an offence
4 under subsection 32BA(1), (4) or (4A) or 32BB(1), (4) or
5 (4A); and

6 (b) the Secretary notifies the Comptroller-General of Customs in
7 writing that the Secretary wishes the *Customs Act 1901* to
8 apply to that importation or exportation;

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

12 (c) prohibited imports within the meaning of that Act; or

13 (d) prohibited exports within the meaning of that Act;

14 as the case requires.

15 **118 Subparagraph 32BC(1)(c)(i)**

16 Omit “or will result in,” substitute “will result in, or is likely to result
17 in,”.

18 **119 Subparagraph 32BC(1)(c)(ii)**

19 Omit “would result in”, substitute “would result in, or would be likely
20 to result in,”.

21 **120 Subsections 32BC(2) and (3)**

22 Repeal the subsections.

23 **121 After subsection 32BC(4)**

24 Insert:

25 (4A) A person commits an offence if:

26 (a) the person manufactures in Australia a biological for use in
27 humans; and

28 (b) none of the following subparagraphs applies:

29 (i) the biological is included in the Register in relation to
30 the person;

- 1 (ii) the person is exempt under subsection 32CA(1) in
2 relation to the biological or the biological is exempt
3 under subsection 32CA(2);
4 (iii) the biological is exempt under section 32CB.

5 Penalty: 100 penalty units.

6 (4B) An offence against subsection (4A) is an offence of strict liability.

7 **122 Subsection 32BC(5)**

8 Omit “Subsection (1), (2) or (4)”, substitute “Subsection (1), (4) or
9 (4A)”.

10 **123 Paragraph 32BC(6)(a)**

11 Omit “or will not,”, substitute “will not, or is not likely to,”.

12 **124 Paragraph 32BC(6)(b)**

13 Omit “would not”, substitute “would not, or would not be likely to,”.

14 **125 Subparagraph 32BD(1)(c)(i)**

15 Omit “or will result in,”, substitute “will result in, or is likely to result
16 in,”.

17 **126 Subparagraph 32BD(1)(c)(ii)**

18 Omit “would result in”, substitute “would result in, or would be likely
19 to result in,”.

20 **127 Subsections 32BD(2) and (3)**

21 Repeal the subsections.

22 **128 After subsection 32BD(4)**

23 Insert:

24 (4A) A person commits an offence if:

- 25 (a) the person supplies in Australia a biological for use in
26 humans; and
27 (b) none of the following subparagraphs applies:
28 (i) the biological is included in the Register in relation to
29 the person;
-

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- 1 (ii) the person is exempt under subsection 32CA(1) in
2 relation to the biological or the biological is exempt
3 under subsection 32CA(2);
4 (iii) the biological is exempt under section 32CB;
5 (iv) the biological is the subject of an approval under
6 subsection 32CK(1) that is held by the person, being an
7 approval covering the supply in Australia of the
8 biological;
9 (v) the biological is the subject of an authority under
10 subsection 32CM(1) or (7A) that covers the supply of
11 the biological by the person;
12 (vi) the biological is the subject of an approval under
13 subsection 32CO(1), (1A) or (2) that is held by the
14 person, being an approval covering the supply in
15 Australia of the biological.

16 Penalty: 100 penalty units.

17 (4B) An offence against subsection (4A) is an offence of strict liability.

18 **129 Subsection 32BD(5)**

19 Omit “Subsection (1), (2) or (4)”, substitute “Subsection (1), (4) or
20 (4A)”.

21 **130 Paragraph 32BD(6)(a)**

22 Omit “or will not,”, substitute “will not, or is not likely to,”.

23 **131 Paragraph 32BD(6)(b)**

24 Omit “would not”, substitute “would not, or would not be likely to,”.

25 **132 At the end of section 32BF**

26 Add:

27 *Application of the Customs Act 1901*

28 (7) If:

- 29 (a) the importation or exportation of a biological contravenes
30 subsection (1) or (2); and

- 1 (b) the Secretary notifies the Comptroller-General of Customs in
2 writing that the Secretary wishes the *Customs Act 1901* to
3 apply to that importation or exportation;
4 the *Customs Act 1901* has effect as if the biological included in that
5 importation or exportation were goods described as forfeited to the
6 Crown under section 229 of that Act because they were:
7 (c) prohibited imports within the meaning of that Act; or
8 (d) prohibited exports within the meaning of that Act;
9 as the case requires.

10 **133 Section 32BG (heading)**

11 Repeal the heading, substitute:

12 **32BG Criminal offences and civil penalty relating to a failure to**
13 **notify the Secretary about manufacturing**

14 **134 Subsection 32BG(1) (heading)**

15 Repeal the heading, substitute:

16 *Criminal offences*

17 **135 After subsection 32BG(1)**

18 Insert:

- 19 (1A) A person commits an offence if:
20 (a) the person:
21 (i) imports a biological into Australia for use in humans; or
22 (ii) exports a biological from Australia for use in humans;
23 or
24 (iii) manufactures a biological in Australia for use in
25 humans; or
26 (iv) supplies a biological in Australia for use in humans; and
27 (b) the person is the sponsor of the biological; and
28 (c) the person is not exempt under subsection 32CA(1) in
29 relation to the biological and the biological is not exempt
30 under subsection 32CA(2); and

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- 1 (d) the person has not, at or before the time of the importation,
2 exportation, manufacture or supply, properly notified to the
3 Secretary either or both of the following:
4 (i) the manufacturer of the biological;
5 (ii) the premises used in the manufacture of the biological.

6 Penalty: 100 penalty units.

7 (1B) An offence against subsection (1A) is an offence of strict liability.

8 **136 Subparagraphs 32BI(1)(d)(i) and (ii)**

9 Omit “or will result in,”, substitute “will result in, or is likely to result
10 in,”.

11 **137 Subsections 32BI(2) and (3)**

12 Repeal the subsections.

13 **138 Subsection 32BI(4) (penalty)**

14 Repeal the penalty, substitute:

15 Penalty: 500 penalty units.

16 **139 At the end of section 32BI**

17 Add:

- 18 (5) A person commits an offence if:
19 (a) the person uses a biological; and
20 (b) the biological is used:
21 (i) in the treatment of another person; or
22 (ii) solely for experimental purposes in humans; and
23 (c) none of the following subparagraphs applies:
24 (i) the biological is included in the Register;
25 (ii) the person is exempt under subsection 32CA(1) in
26 relation to the biological or the biological is exempt
27 under subsection 32CA(2);
28 (iii) the biological is exempt under section 32CB;
29 (iv) the biological is the subject of an approval under
30 subsection 32CO(1), (1A) or (2);

- 1 (v) the person uses the biological in accordance with an
2 approval under subsection 32CK(1);
3 (vi) the person uses the biological in accordance with a
4 condition applicable under regulations made for the
5 purposes of section 32CL;
6 (vii) the person uses the biological in accordance with an
7 authority under subsection 32CM(1) or (7A).

8 Penalty: 100 penalty units.

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

10 **140 Subparagraph 32CJ(6)(d)(i)**

11 Omit “or will result in,” substitute “will result in, or is likely to result
12 in.”

13 **141 Subparagraph 32CJ(6)(d)(ii)**

14 Omit “would result in”, substitute “would result in, or would be likely
15 to result in.”

16 **142 Paragraph 32CJ(6)(e)**

17 Omit “or would result,” substitute “is likely to result, would result, or
18 would be likely to result.”

19 **143 Subsections 32CJ(7) and (8)**

20 Repeal the subsections, substitute:

- 21 (7) A person commits an offence if:
22 (a) the Secretary gives a notice to the person under
23 subsection (2); and
24 (b) the notice specifies a particular requirement mentioned in
25 subsection (3); and
26 (c) the person fails to comply with that requirement.

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

29 **144 Subsection 32CJ(9) (penalty)**

30 Repeal the penalty, substitute:

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1 Penalty: 100 penalty units.

2 **145 Subparagraph 32CN(1)(d)(i)**

3 Omit “or will result in,” substitute “will result in, or is likely to result
4 in,”.

5 **146 Subparagraph 32CN(1)(d)(ii)**

6 Omit “would result in,” substitute “would result in, or would be likely
7 to result in,”.

8 **147 Paragraph 32CN(1)(e)**

9 Omit “or would result,” substitute “is likely to result, would result, or
10 would be likely to result,”.

11 **148 Subsections 32CN(2) and (3)**

12 Repeal the subsections.

13 **149 After subsection 32CN(4)**

14 Insert:

15 (4A) A person commits an offence if:

- 16 (a) the Secretary has authorised, under subsection 32CM(1), the
17 person to supply a biological; and
18 (b) the person supplies the biological; and
19 (c) any of the following applies:
20 (i) the supply is not in accordance with the authority;
21 (ii) the supply is not in accordance with the conditions to
22 which the authority is subject;
23 (iii) the supply is not in accordance with regulations made
24 for the purpose of subsection 32CM(6).

25 Penalty: 100 penalty units.

26 (4B) An offence against subsection (4A) is an offence of strict liability.

27 **150 Subparagraph 32CN(5)(e)(i)**

28 Omit “or will result in,” substitute “will result in, or is likely to result
29 in,”.

1 **151 Subparagraph 32CN(5)(e)(ii)**

2 Omit “would result in”, substitute “would result in, or would be likely
3 to result in,”.

4 **152 Paragraph 32CN(5)(f)**

5 Omit “or would result,”, substitute “is likely to result, would result, or
6 would be likely to result,”.

7 **153 Subsection 32CN(6)**

8 Repeal the subsection.

9 **154 Subsection 32CN(7) (penalty)**

10 Repeal the penalty, substitute:

11 Penalty: 500 penalty units.

12 **155 At the end of section 32CN**

13 Add:

14 (8) A person commits an offence if:

15 (a) the person is a health practitioner; and

16 (b) the person is included in a class of health practitioners
17 specified in subsection 32CM(7A) rules; and

18 (c) the person supplies a biological specified in those rules; and

19 (d) any of the following applies:

20 (i) the supply is not in accordance with those rules;

21 (ii) the supply is not in the circumstances specified in those
22 rules;

23 (iii) the supply is not in accordance with the conditions
24 specified in those rules.

25 Penalty: 100 penalty units.

26 (9) An offence against subsection (8) is an offence of strict liability.

27 **156 Subparagraph 32DO(1)(d)(i)**

28 Omit “or will result in,”, substitute “will result in, or is likely to result
29 in,”.

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1 **157 Subparagraph 32DO(1)(d)(ii)**

2 Omit “would result in”, substitute “would result in, or would be likely
3 to result in,”.

4 **158 Subsections 32DO(2) and (3)**

5 Repeal the subsections.

6 **159 Subsection 32DO(4) (penalty)**

7 Repeal the penalty, substitute:

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

10 **160 At the end of section 32DO**

11 Add:

12 (5) A person commits an offence if:

- 13 (a) the person makes a statement; and
14 (b) the statement is made in, or in connection with, an
15 application for inclusion of a biological in the Register; and
16 (c) the statement is false or misleading in a material particular.

17 Penalty: 100 penalty units.

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

19 **161 Paragraph 32EF(1)(d)**

20 Omit “or will result in,”, substitute “will result in, or is likely to result
21 in,”.

22 **162 Subsections 32EF(2) and (3)**

23 Repeal the subsections.

24 **163 Subsection 32EF(4) (penalty)**

25 Repeal the penalty, substitute:

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

1 **164 At the end of section 32EF**

2 Add:

3 (5) A person commits an offence if:

4 (a) a biological is included in the Register in relation to the
5 person; and

6 (b) the person does an act or omits to do an act; and

7 (c) the act or omission breaches a condition of the inclusion of
8 the biological in the Register.

9 Penalty: 100 penalty units.

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

11 **165 Paragraph 32HC(1)(c)**

12 Omit “or will result in,” substitute “will result in, or is likely to result
13 in,”.

14 **166 Subsections 32HC(2) and (3)**

15 Repeal the subsections.

16 **167 Subsection 32HC(4) (penalty)**

17 Repeal the penalty, substitute:

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

20 **168 At the end of section 32HC**

21 Add:

22 (5) A person commits an offence if:

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

24 (b) the act or omission breaches a requirement imposed on the
25 person under section 32HA.

26 Penalty: 100 penalty units.

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

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1 **169 After subsection 32JB(1A)**

2 Insert:

3 (1B) A person commits an offence if:

- 4 (a) the person is given a notice under section 32JA; and
5 (b) the person is covered by paragraph 32JA(1)(b) or (c); and
6 (c) the person fails to comply with the notice.

7 Penalty: 100 penalty units.

8 (1C) An offence against subsection (1B) is an offence of strict liability.

9 (1D) Subsection (1B) does not apply if the person has a reasonable
10 excuse.

11 Note: A defendant bears an evidential burden in relation to the matter in
12 subsection (1D): see subsection 13.3(3) of the *Criminal Code*.

13 **170 Subparagraph 32JB(2)(d)(i)**

14 Omit “or will result in,” substitute “will result in, or is likely to result
15 in,”.

16 **171 Subparagraph 32JB(2)(d)(ii)**

17 Omit “would result in”, substitute “would result in, or would be likely
18 to result in,”.

19 **172 Subsections 32JB(3) and (4)**

20 Repeal the subsections.

21 **173 Subsection 32JB(5) (penalty)**

22 Repeal the penalty, substitute:

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

25 **174 At the end of section 32JB**

26 Add:

27 (6) A person commits an offence if:

- 28 (a) the person is given a notice under section 32JA; and
-

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- 1 (b) the person gives information or produces a document in
2 compliance or purported compliance with the notice; and
3 (c) the information or document is false or misleading in a
4 material particular.

5 Penalty: 100 penalty units.

6 (7) An offence against subsection (6) is an offence of strict liability.

7 **175 Paragraph 32JD(2)(d)**

8 Omit “(2), (3) or (5)”, substitute “(1B), (2), (5) or (6)”.

9 **176 After subsection 32JI(1)**

10 Insert:

11 (1A) A person commits an offence if:

12 (a) the person is given a notice under section 32JE, 32JF, 32JG
13 or 32JH; and

14 (b) the person fails to comply with the notice.

15 Penalty: 100 penalty units.

16 (1B) An offence against subsection (1A) is an offence of strict liability.

17 **177 Subsection 31JI(2) (penalty)**

18 Repeal the penalty, substitute:

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

21 **178 At the end of section 32JI**

22 Add:

23 (3) A person commits an offence if:

24 (a) the person is given a notice under section 32JE, 32JF, 32JG
25 or 32JH; and

26 (b) the person gives information or produces a document in
27 compliance or purported compliance with the notice; and

28 (c) the information or document is false or misleading in a
29 material particular.

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1 Penalty: 100 penalty units.

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

3 **179 Paragraph 32JK(2)(d)**

4 Omit “subsection 32JI(1) or (2)”, substitute “subsection 32JI(1), (1A),
5 (2) or (3)”.

6 **180 Subparagraph 35(1)(d)(i)**

7 Omit “or will result in,”, substitute “will result in, or is likely to result
8 in,”.

9 **181 Subparagraph 35(1)(d)(ii)**

10 Omit “would result in”, substitute “would result in, or would be likely
11 to result in,”.

12 **182 Paragraph 35(1)(e)**

13 Omit “or would result,”, substitute “is likely to result, would result, or
14 would be likely to result,”.

15 **183 Subsections 35(2) and (3)**

16 Repeal the subsections.

17 **184 After subsection 35(4)**

18 Insert:

19 (4A) A person commits an offence if:

20 (a) the person, at premises in Australia, carries out a step in the
21 manufacture of therapeutic goods (other than goods exempt
22 under section 18A or 32CB); and

23 (b) the goods are for supply for use in humans; and

24 (c) none of the following applies:

25 (i) the goods are exempt goods;

26 (ii) the person is an exempt person in relation to the
27 manufacture of the goods;

28 (iii) the person is the holder of a licence that is in force that
29 authorises the carrying out of that step in relation to the
30 goods at those premises.

1 Penalty: 100 penalty units.

2 (4B) An offence against subsection (4A) is an offence of strict liability.

3 **185 Subparagraph 35(5)(e)(i)**

4 Omit “or will result in,” substitute “will result in, or is likely to result
5 in,”.

6 **186 Subparagraph 35(5)(e)(ii)**

7 Omit “would result in,” substitute “would result in, or would be likely
8 to result in,”.

9 **187 Paragraph 35(5)(f)**

10 Omit “or would result,” substitute “is likely to result, would result, or
11 would be likely to result,”.

12 **188 Subsections 35(6), (7) and (8)**

13 Repeal the subsections.

14 **189 Subsection 35(10)**

15 Repeal the subsection, substitute:

16 (10) A person commits an offence if:

17 (a) the person, at premises in Australia, carries out a step in the
18 manufacture of therapeutic goods; and

19 (b) the goods are for supply for use in humans; and

20 (c) the goods are exempt under section 18A or 32CB; and

21 (d) the person is not the holder of a licence that:

22 (i) is in force; and

23 (ii) authorises the carrying out of that step in relation to the
24 goods at those premises.

25 Penalty: 100 penalty units.

26 (11) An offence against subsection (10) is an offence of strict liability.

27 **190 Paragraph 35B(1)(d)**

28 Omit “or will result in,” substitute “will result in, or is likely to result
29 in,”.

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1 **191 Subsections 35B(2) and (3)**

2 Repeal the subsections.

3 **192 At the end of section 35B**

4 Add:

5 (5) A person commits an offence if:

6 (a) the person holds a licence; and

7 (b) the person does an act or omits to do an act; and

8 (c) the act or omission breaches a condition of the licence.

9 Penalty: 100 penalty units.

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

11 **193 Subparagraph 41E1(1)(d)(i)**

12 Omit “or will result in”, substitute “will result in, or is likely to result
13 in”.

14 **194 Subparagraph 41E1(1)(d)(ii)**

15 Omit “would result in”, substitute “would result in, or would be likely
16 to result in”.

17 **195 Subsections 41E1(2) and (3)**

18 Repeal the subsections.

19 **196 At the end of section 41E1**

20 Add:

21 (5) A person commits an offence if:

22 (a) the person makes a statement (whether orally, in a document
23 or in any other way); and

24 (b) the statement is in or in connection with an application for a
25 conformity assessment certificate; and

26 (c) the statement is false or misleading in a material particular.

27 Penalty: 100 penalty units.

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

1 **197 Division 2 of Part 4-4 (note after heading)**

2 Omit “(6) and (8)”, substitute “(8) and (8A)”.

3 **198 Subparagraph 41FE(1)(d)(i)**

4 Omit “or will result in”, substitute “will result in, or is likely to result
5 in”.

6 **199 Subparagraph 41FE(1)(d)(ii)**

7 Omit “would result in”, substitute “would result in, or would be likely
8 to result in”.

9 **200 Subsections 41FE(2) and (3)**

10 Repeal the subsections.

11 **201 At the end of section 41FE**

12 Add:

13 (5) A person commits an offence if:

14 (a) the person makes a statement (whether orally, in a document
15 or in any other way); and

16 (b) the statement is false or misleading in a material particular;
17 and

18 (c) the statement is in or in connection with:

19 (i) an application for including a kind of medical device in
20 the Register under this Chapter; or

21 (ii) a certification or purported certification under
22 section 41FD.

23 Penalty: 100 penalty units.

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

25 **202 Division 2 of Part 4-5 (note after heading)**

26 Omit “(2) and (4)”, substitute “(4) and (4A)”.

27 **203 After subsection 41JB(3A)**

28 Insert:

29 (3B) A person commits an offence if:

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- 1 (a) the person is given a notice under section 41JA; and
2 (b) the person is covered by paragraph 41JA(1)(b), (ba), (d) or
3 (da) or subsection 41JA(1E); and
4 (d) the person fails to comply with the notice.

5 Penalty: 100 penalty units.

6 (3C) An offence against subsection (3B) is an offence of strict liability.

7 (3D) Subsection (3B) does not apply if the person has a reasonable
8 excuse.

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

11 **204 Subparagraph 41JB(4)(d)(i)**

12 Omit “or will result in,” substitute “will result in, or is likely to result
13 in,”.

14 **205 Subparagraph 41JB(4)(d)(ii)**

15 Omit “would result in,” substitute “would result in, or would be likely
16 to result in,”.

17 **206 Subsections 41JB(5) and (6)**

18 Repeal the subsections.

19 **207 At the end of section 41JB**

20 Add:

- 21 (8) A person commits an offence if:
22 (a) the person is given a notice under section 41JA; and
23 (b) the person gives information in purported compliance with
24 the notice; and
25 (c) the information is false or misleading in a material particular.

26 Penalty: 100 penalty units.

27 (9) An offence against subsection (8) is an offence of strict liability.

28 **208 Paragraph 41JC(2)(d)**

29 Omit “(5) or (7)”, substitute “(7) or (8)”.

1 **209 Section 41JG**

2 Before “A”, insert “(1)”.

3 **210 Section 41JG (note)**

4 Repeal the note.

5 **211 At the end of section 41JG**

6 Add:

7 (2) A person commits an offence if:

8 (a) the person is given a notice under section 41JCA, 41JD,
9 41JE, 41JF or 41JFA; and

10 (b) the person fails to comply with the notice.

11 Penalty: 100 penalty units.

12 (3) An offence against subsection (2) is an offence of strict liability.

13 **212 Section 41JH**

14 Before “A”, insert “(1)”.

15 **213 At the end of section 41JH**

16 Add:

17 (2) A person to whom a notice is given under section 41JCA, 41JD,
18 41JE, 41JF or 41JFA commits an offence if:

19 (a) the person gives information to the Secretary; and

20 (b) the information:

21 (i) is false or misleading; or

22 (ii) omits any matter or thing without which the information
23 is misleading; and

24 (c) the information is given in compliance or purported
25 compliance with the notice.

26 Penalty: 100 penalty units.

27 (3) An offence against subsection (2) is an offence of strict liability.

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1 (4) Subsection (1) or (2) does not apply as a result of
2 subparagraph (1)(b)(i) or (2)(b)(i) if the information is not false or
3 misleading in a material particular.

4 Note: A defendant bears an evidential burden in relation to the matter in
5 subsection (4): see subsection 13.3(3) of the *Criminal Code*.

6 (5) Subsection (1) or (2) does not apply as a result of
7 subparagraph (1)(b)(ii) or (2)(b)(ii) if the information did not omit
8 any matter or thing without which the information is misleading in
9 a material particular.

10 Note: A defendant bears an evidential burden in relation to the matter in
11 subsection (5): see subsection 13.3(3) of the *Criminal Code*.

12 **214 After subsection 41JI(1)**

13 Insert:

14 (1A) A person commits an offence if:

- 15 (a) the person produces a document to the Secretary; and
16 (b) the document is false or misleading; and
17 (c) the document is produced in compliance or purported
18 compliance with a notice given under section 41JCA, 41JD,
19 41JE, 41JF or 41JFA.

20 Penalty: 100 penalty units.

21 (1B) An offence against subsection (1A) is an offence of strict liability.

22 (1C) Subsection (1) or (1A) does not apply if the document is not false
23 or misleading in a material particular.

24 Note: A defendant bears an evidential burden in relation to the matter in
25 subsection (1C): see subsection 13.3(3) of the *Criminal Code*.

26 **215 Subsection 41JI(2)**

27 After “Subsection (1)”, insert “or (1A)”.

28 **216 Paragraph 41KC(1)(c)**

29 Omit “or will result in,”, substitute “will result in, or is likely to result
30 in,”.

1 **217 Subsections 41KC(2) and (3)**

2 Repeal the subsections.

3 **218 At the end of section 41KC**

4 Add:

5 (5) A person commits an offence if:

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

7 (b) the act or omission breaches a requirement imposed on the
8 person under section 41KA.

9 Penalty: 100 penalty units.

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

11 **219 Subparagraph 41MA(1)(d)(i)**

12 Omit “or will result in,” substitute “will result in, or is likely to result
13 in,”.

14 **220 Subparagraph 41MA(1)(d)(ii)**

15 Omit “would result in”, substitute “would result in, or would be likely
16 to result in,”.

17 **221 Paragraph 41MA(1)(e)**

18 Omit “or would result,” substitute “is likely to result, would result, or
19 would be likely to result,”.

20 **222 Subsections 41MA(2) and (3)**

21 Repeal the subsections.

22 **223 After subsection 41MA(4)**

23 Insert:

24 (4A) A person commits an offence if:

25 (a) the person imports a medical device into Australia; and

26 (b) the medical device does not comply with the essential
27 principles relating to matters other than the labelling of the
28 device; and

29 (c) the Secretary has not consented to the importation; and

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1 (d) the device is not of a kind covered by an exemption in force
2 under section 41GS.

3 Penalty: 100 penalty units.

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

5 **224 Subparagraph 41MA(5)(d)(i)**

6 Omit “or will result in,” substitute “will result in, or is likely to result
7 in,”.

8 **225 Subparagraph 41MA(5)(d)(ii)**

9 Omit “would result in,” substitute “would result in, or would be likely
10 to result in,”.

11 **226 Paragraph 41MA(5)(e)**

12 Omit “or would result,” substitute “is likely to result, would result, or
13 would be likely to result,”.

14 **227 Subsections 41MA(6) and (7)**

15 Repeal the subsections.

16 **228 After subsection 41MA(8)**

17 Insert:

18 (8A) A person commits an offence if:

- 19 (a) the person supplies a medical device for use in Australia; and
20 (b) the medical device does not comply with the essential
21 principles; and
22 (c) the Secretary has not consented to the supply; and
23 (d) the device is not of a kind covered by an exemption in force
24 under section 41GS.

25 Penalty: 100 penalty units.

26 (8B) An offence against subsection (8A) is an offence of strict liability.

27 **229 Paragraph 41MA(9)(b)**

28 After “principles”, insert “relating to matters other than the labelling of
29 the device for supply in Australia”.

1 **230 Subparagraph 41MA(9)(d)(i)**

2 Omit “or will result in,”, substitute “will result in, or is likely to result
3 in,”.

4 **231 Subparagraph 41MA(9)(d)(ii)**

5 Omit “would result in”, substitute “would result in, or would be likely
6 to result in,”.

7 **232 Paragraph 41MA(9)(e)**

8 Omit “or would result,”, substitute “is likely to result, would result, or
9 would be likely to result,”.

10 **233 Subsections 41MA(10) and (11)**

11 Repeal the subsections.

12 **234 Paragraph 41MA(12)(b)**

13 After “principles”, insert “relating to matters other than the labelling of
14 the device for supply in Australia”.

15 **235 Subsection 41MA(13)**

16 Repeal the subsection, substitute:

17 (13) A person commits an offence if:

- 18 (a) the person exports a medical device from Australia; and
19 (b) the medical device does not comply with the essential
20 principles relating to matters other than the labelling of the
21 device for supply in Australia; and
22 (c) the Secretary has not consented to the exportation; and
23 (d) the device is not of a kind covered by an exemption in force
24 under section 41GS.

25 Penalty: 100 penalty units.

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

27 **236 Paragraph 41MAA(3)(b)**

28 After “principles”, insert “relating to matters other than the labelling of
29 the device for supply in Australia”.

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1 **237 Paragraph 41MC(2)(c)**

2 Omit “has resulted, or will result in,” substitute “has resulted in, will
3 result in, or is likely to result in.”

4 **238 Subsections 41MC(3) and (4)**

5 Repeal the subsections.

6 **239 At the end of section 41MC**

7 Add:

8 (6) A person commits an offence if:

- 9 (a) the person does an act or omits to do an act; and
10 (b) the act or omission breaches a condition of a consent.

11 Penalty: 100 penalty units.

12 (7) An offence against subsection (6) is an offence of strict liability.

13 **240 Paragraph 41MD(a)**

14 Omit “subsection 41MA(1), (2), (4), (9), (10) or (12)”, substitute
15 “subsection 41MA(1), (4), (4A), (9), (12) or (13)”.

16 **241 Subparagraph 41ME(1)(d)(i)**

17 Omit “or will result in,” substitute “will result in, or is likely to result
18 in.”

19 **242 Subparagraph 41ME(1)(d)(ii)**

20 Omit “would result in”, substitute “would result in, or would be likely
21 to result in.”

22 **243 Paragraph 41ME(1)(e)**

23 Omit “or would result,” substitute “is likely to result, would result, or
24 would be likely to result.”

25 **244 Subsections 41ME(2) and (3)**

26 Repeal the subsections.

1 **245 After subsection 41ME(4)**

2 Insert:

3 (4A) A person commits an offence if:

- 4 (a) the person manufactures a medical device; and
5 (b) the person supplies the device in Australia; and
6 (c) the conformity assessment procedures have not been applied
7 to the device; and
8 (d) the device is not of a kind covered by an exemption in force
9 under section 41GS.

10 Penalty: 100 penalty units.

11 (4B) An offence against subsection (4A) is an offence of strict liability.

12 **246 Subparagraph 41ME(5)(d)(i)**

13 Omit “or will result in,” substitute “will result in, or is likely to result
14 in,”.

15 **247 Subparagraph 41ME(5)(d)(ii)**

16 Omit “would result in,” substitute “would result in, or would be likely
17 to result in,”.

18 **248 Paragraph 41ME(5)(e)**

19 Omit “or would result,” substitute “is likely to result, would result, or
20 would be likely to result,”.

21 **249 Subsections 41ME(6) and (7)**

22 Repeal the subsections.

23 **250 At the end of section 41ME**

24 Add:

25 (9) A person commits an offence if:

- 26 (a) the person manufactures a medical device; and
27 (b) the person exports the device from Australia; and
28 (c) the conformity assessment procedures have not been applied
29 to the device; and
-

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1 (d) the device is not of a kind covered by an exemption in force
2 under section 41GS.

3 Penalty: 100 penalty units.

4 (10) An offence against subsection (9) is an offence of strict liability.

5 **251 Subparagraph 41MF(1)(c)(i)**

6 Omit “or will result in,” substitute “will result in, or is likely to result
7 in,”.

8 **252 Subparagraph 41MF(1)(c)(ii)**

9 Omit “would result in,” substitute “would result in, or would be likely
10 to result in,”.

11 **253 Paragraph 41MF(1)(d)**

12 Omit “or would result,” substitute “is likely to result, would result, or
13 would be likely to result,”.

14 **254 Subparagraph 41MF(3)(c)(i)**

15 Omit “or will result in,” substitute “will result in, or is likely to result
16 in,”.

17 **255 Subparagraph 41MF(3)(c)(ii)**

18 Omit “would result in,” substitute “would result in, or would be likely
19 to result in,”.

20 **256 Paragraph 41MF(3)(d)**

21 Omit “or would result,” substitute “is likely to result, would result, or
22 would be likely to result,”.

23 **257 Subparagraph 41MI(1)(c)(i)**

24 Omit “or will result in,” substitute “will result in, or is likely to result
25 in,”.

26 **258 Subparagraph 41MI(1)(c)(ii)**

27 Omit “would result in,” substitute “would result in, or would be likely
28 to result in,”.

1 **259 Subsections 41MI(2) and (3)**

2 Repeal the subsections.

3 **260 Subsection 41MI(5)**

4 Repeal the subsection, substitute:

5 (5) A person commits an offence if:

6 (a) the person:

- 7 (i) imports a medical device into Australia; or
- 8 (ii) exports a medical device from Australia; or
- 9 (iii) supplies a medical device in Australia; or
- 10 (iv) manufactures a medical device in Australia; and

11 (b) none of the following subparagraphs applies in relation to the
12 device:

- 13 (i) the device is of a kind included in the Register in
14 relation to the person;
- 15 (ii) the device is of a kind covered by an exemption in force
16 under section 41GS;
- 17 (iii) the device is an exempt device;
- 18 (iv) the device is the subject of an approval under
19 section 41HB or an authority under section 41HC;
- 20 (v) the device is the subject of an approval under
21 subsection 41HD(1), (1A) or (2) that is held by the
22 person.

23 Penalty: 100 penalty units.

24 (5A) An offence against subsection (5) is an offence of strict liability.

25 **261 Subsection 41MI(6)**

26 Omit “(2) or (4)”, substitute “(4) or (5)”.

27 **262 Paragraph 41MI(7)(a)**

28 Omit “or will not,”, substitute “will not, or is not likely to,”.

29 **263 Paragraph 41MI(7)(b)**

30 Omit “would not”, substitute “would not, or would not be likely to,”.

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1 **264 Paragraph 41MJ(a)**

2 Omit “(2) or (4)”, substitute “(4) or (5)”.

3 **265 Paragraph 41MN(1)(d)**

4 Omit “or will result in,”, substitute “will result in, or is likely to result
5 in,”.

6 **266 Subsections 41MN(2) and (3)**

7 Repeal the subsections.

8 **267 After subsection 41MN(4)**

9 Insert:

10 (4A) A person commits an offence if:

11 (a) a kind of medical device is included in the Register in
12 relation to the person; and

13 (b) the person does an act or omits to do an act; and

14 (c) the act or omission breaches a condition of the inclusion of
15 the kind of device in the Register.

16 Penalty: 100 penalty units.

17 (4B) An offence against subsection (4A) is an offence of strict liability.

18 **268 Paragraph 41MN(5)(d)**

19 Omit “or will result in,”, substitute “will result in, or is likely to result
20 in,”.

21 **269 Subsections 41MN(6) and (7)**

22 Repeal the subsections.

23 **270 After subsection 41MN(8)**

24 Insert:

25 (8A) A person commits an offence if:

26 (a) a conformity assessment certificate is issued in respect of the
27 person; and

28 (b) the person does an act or omits to do an act; and

1 (c) the act or omission breaches a condition of the conformity
2 assessment certificate.

3 Penalty: 100 penalty units.

4 (8B) An offence against subsection (8A) is an offence of strict liability.

5 **271 Subparagraph 41MO(1)(c)(i)**

6 Omit “or will result in,” substitute “will result in, or is likely to result
7 in,”.

8 **272 Subparagraph 41MO(1)(c)(ii)**

9 Omit “would result in”, substitute “would result in, or would be likely
10 to result in,”.

11 **273 Paragraph 41MO(1)(d)**

12 Omit “or would result,” substitute “is likely to result, would result, or
13 would be likely to result,”.

14 **274 Subsections 41MO(2) and (3)**

15 Repeal the subsections.

16 **275 After subsection 41MO(4)**

17 Insert:

18 (4AA) A person commits an offence if:

19 (a) the person has been granted an authority under
20 subsection 41HC(1) relating to a specified kind of medical
21 device; and

22 (b) the person supplies a medical device of that kind:

23 (i) otherwise than in accordance with the authority; or

24 (ii) otherwise than in accordance with any conditions to
25 which the authority is subject; or

26 (iii) otherwise than in accordance with any regulations made
27 for the purpose of subsection 41HC(5).

28 Penalty: 100 penalty units.

29 (4AB) An offence against subsection (4AA) is an offence of strict
30 liability.

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1 **276 Subparagraph 41MO(4A)(e)(i)**

2 Omit “or will result in,” substitute “will result in, or is likely to result
3 in,”.

4 **277 Subparagraph 41MO(4A)(e)(ii)**

5 Omit “would result in,” substitute “would result in, or would be likely
6 to result in,”.

7 **278 Paragraph 41MO(4A)(f)**

8 Omit “or would result,” substitute “is likely to result, would result, or
9 would be likely to result,”.

10 **279 Subsection 41MO(4B)**

11 Repeal the subsection.

12 **280 After subsection 41MO(4C)**

13 Insert:

14 (4D) A person commits an offence if:

- 15 (a) the person is a health practitioner; and
16 (b) the person is included in a class of health practitioners
17 specified in subsection 41HC(6) rules; and
18 (c) the person supplies a medical device of a kind specified in
19 those rules; and
20 (d) any of the following applies:
21 (i) the supply is not in accordance with those rules;
22 (ii) the supply is not in the circumstances specified in those
23 rules;
24 (iii) the supply is not in accordance with the conditions
25 specified in those rules.

26 Penalty: 100 penalty units.

27 (4E) An offence against subsection (4D) is an offence of strict liability.

28 **281 Subparagraph 41MO(5)(c)(i)**

29 Omit “or will result in,” substitute “will result in, or is likely to result
30 in,”.

1 **282 Subparagraph 41MO(5)(c)(ii)**

2 Omit “would result in”, substitute “would result in, or would be likely
3 to result in,”.

4 **283 Subsections 41MO(6) and (7)**

5 Repeal the subsections.

6 **284 At the end of section 41MO**

7 Add:

8 (9) A person commits an offence if:

9 (a) the person has been granted an approval under section 41HB
10 relating to a specified medical device or specified kind of
11 medical device; and

12 (b) the person uses a medical device of that kind:

13 (i) in the treatment of another person; or

14 (ii) solely for experimental purposes in humans;
15 otherwise than in accordance with the approval.

16 Penalty: 100 penalty units.

17 (10) An offence against subsection (9) is an offence of strict liability.

18 **285 Subparagraph 42V(6)(b)(i)**

19 Omit “or will result in,”, substitute “will result in, or is likely to result
20 in,”.

21 **286 Subparagraph 42V(6)(b)(ii)**

22 Omit “would result in”, substitute “would result in, or would be likely
23 to result in,”.

24 **287 Paragraph 42V(6)(c)**

25 Omit “or would result,”, substitute “is likely to result, would result, or
26 would be likely to result,”.

27 **288 Subsections 42V(6A) and (6B)**

28 Repeal the subsections.

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1 **289 After subsection 42V(6C)**

2 Insert:

3 (6D) A person commits an offence if the person fails to comply with a
4 requirement under subsection (1) in relation to a supply of
5 therapeutic goods.

6 Penalty: 100 penalty units.

7 (6E) An offence against subsection (6D) is an offence of strict liability.

8 **290 After section 42YC**

9 Insert:

10 **42YCA Continuing contraventions of civil penalty provisions**

11 (1) If an act or thing is required under a civil penalty provision to be
12 done:

13 (a) within a particular period; or

14 (b) before a particular time;

15 then the obligation to do that act or thing continues until the act or
16 thing is done (even if the period has expired or the time has
17 passed).

18 (2) A person who contravenes a civil penalty provision that requires an
19 act or thing to be done:

20 (a) within a particular period; or

21 (b) before a particular time;

22 commits a separate contravention of that provision in respect of
23 each day during which the contravention occurs (including the day
24 the order under subsection 42Y(2) is made or any later day).

25 **291 Part 5A-2**

26 Repeal the Part, substitute:

1 **Part 5A-2—Infringement notices**
2

3 **42YJ Simplified outline of this Part**

4 The Secretary can give a person an infringement notice for a
5 contravention of a provision of this Act or the regulations that is an
6 offence of strict liability or for a contravention of a civil penalty
7 provision.

8 The person can choose to pay an amount as an alternative to having
9 court proceedings brought against the person for the contravention.
10 If the person does not choose to pay the amount, proceedings can
11 be brought against the person in relation to the contravention.

12 **42YK When an infringement notice may be given**

- 13 (1) If the Secretary reasonably believes that a person has contravened:
14 (a) a provision of this Act or the regulations that is an offence of
15 strict liability; or
16 (b) a civil penalty provision;
17 the Secretary may give to the person an infringement notice for the
18 alleged contravention.
- 19 (2) The infringement notice must be given within 12 months after the
20 day on which the contravention is alleged to have taken place.
- 21 (3) A single infringement notice must relate only to a single
22 contravention of a single provision unless subsection (4) applies.
- 23 (4) The Secretary may give a person a single infringement notice
24 relating to multiple contraventions of a single provision if:
25 (a) the provision requires the person to do a thing within a
26 particular period or before a particular time; and
27 (b) the person fails or refuses to do that thing within that period
28 or before that time; and
29 (c) the failure or refusal occurs on more than 1 day; and
30 (d) each contravention is constituted by the failure or refusal on
31 one of those days.

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1 Note: For continuing offences, see subsection 4K(2) of the *Crimes Act 1914*.
2 For continuing contraventions of civil penalty provisions, see
3 section 42YCA of this Act.

4 **42YKA Matters to be included in an infringement notice**

- 5 (1) An infringement notice must:
- 6 (a) be identified by a unique number; and
 - 7 (b) state the day on which it is given; and
 - 8 (c) state the name of the person to whom the notice is given; and
 - 9 (d) state the name and contact details of the person who gave the
10 notice; and
 - 11 (e) give brief details of the alleged contravention, or each alleged
12 contravention, to which the notice relates, including:
 - 13 (i) the provision that was allegedly contravened; and
 - 14 (ii) the maximum penalty that a court could impose for each
15 contravention, if the provision were contravened; and
 - 16 (iii) the time (if known) and day of, and the place of, each
17 alleged contravention; and
 - 18 (f) state the amount that is payable under the notice; and
 - 19 (g) give an explanation of how payment of the amount is to be
20 made; and
 - 21 (h) state that, if the person to whom the notice is given pays the
22 amount within 28 days after the day the notice is given, then
23 (unless the notice is withdrawn):
 - 24 (i) if the provision is an offence of strict liability—the
25 person will not be liable to be prosecuted in a court for
26 the alleged contravention; or
 - 27 (ii) if the provision is a civil penalty provision—
28 proceedings seeking an order under subsection 42Y(2)
29 will not be brought in relation to the alleged
30 contravention; and
 - 31 (i) state that payment of the amount is not an admission of guilt
32 or liability; and
 - 33 (j) state that the person may apply to the Secretary to have the
34 period in which to pay the amount extended; and
 - 35 (k) state that the person may choose not to pay the amount and, if
36 the person does so:

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- 1 (i) if the provision is an offence of strict liability—the
2 person may be prosecuted in a court for the alleged
3 contravention; or
4 (ii) if the provision is a civil penalty provision—
5 proceedings seeking an order under subsection 42Y(2)
6 may be brought in relation to the alleged contravention;
7 and
8 (l) set out how the notice can be withdrawn; and
9 (m) state that if the notice is withdrawn:
10 (i) if the provision is an offence of strict liability—the
11 person may be prosecuted in a court for the alleged
12 contravention; or
13 (ii) if the provision is a civil penalty provision—
14 proceedings seeking an order under subsection 42Y(2)
15 may be brought in relation to the alleged contravention;
16 and
17 (n) state that the person may make written representations to the
18 Secretary seeking the withdrawal of the notice.
- 19 (2) If the notice relates to only one alleged contravention of the
20 provision by the person, the amount to be stated in the notice for
21 the purposes of paragraph (1)(f) is the lesser of:
22 (a) one-fifth of the maximum penalty that a court could impose
23 on the person for that contravention; and
24 (b) 12 penalty units where the person is an individual, or 60
25 penalty units where the person is a body corporate.
- 26 (3) If the notice relates to more than one alleged contravention of the
27 provision by the person, the amount to be stated in the notice for
28 the purposes of paragraph (1)(f) is the lesser of:
29 (a) one-fifth of the amount worked out by adding together the
30 maximum penalty that a court could impose on the person for
31 each alleged contravention; and
32 (b) either:
33 (i) if the person is an individual—the number of penalty
34 units worked out by multiplying the number of alleged
35 contraventions by 12; or

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- 1 (ii) if the person is a body corporate—the number of
2 penalty units worked out by multiplying the number of
3 alleged contraventions by 60.

4 Note: Under section 42YK, a single infringement notice may only deal with
5 multiple contraventions if they are contraventions of a single provision
6 continuing over a period.

7 **42YKB Extension of time to pay amount**

- 8 (1) A person to whom an infringement notice has been given may
9 apply to the Secretary for an extension of the period referred to in
10 paragraph 42YKA(1)(h).
- 11 (2) If the application is made before the end of that period, the
12 Secretary may, in writing, extend that period. The Secretary may
13 do so before or after the end of that period.
- 14 (3) If the Secretary extends that period, a reference in this Part, or in a
15 notice or other instrument under this Part, to the period referred to
16 in paragraph 42YKA(1)(h) is taken to be a reference to that period
17 so extended.
- 18 (4) If the Secretary does not extend that period, a reference in this Part,
19 or in a notice or other instrument under this Part, to the period
20 referred to in paragraph 42YKA(1)(h) is taken to be a reference to
21 the period that ends on the later of the following days:
22 (a) the day that is the last day of the period referred to in
23 paragraph 42YKA(1)(h);
24 (b) the day that is 7 days after the day the person was given
25 notice of the Secretary's decision not to extend.
- 26 (5) The Secretary may extend the period more than once under
27 subsection (2).

28 **42YKC Withdrawal of an infringement notice**

29 *Representations seeking withdrawal of notice*

- 30 (1) A person to whom an infringement notice has been given may
31 make written representations to the Secretary seeking the
32 withdrawal of the notice.

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1 *Withdrawal of notice*

- 2 (2) The Secretary may withdraw an infringement notice given to a
3 person (whether or not the person has made written representations
4 seeking the withdrawal).
- 5 (3) When deciding whether or not to withdraw an infringement notice
6 (the ***relevant infringement notice***), the Secretary:
- 7 (a) must take into account any written representations seeking
8 the withdrawal that were given by the person to the
9 Secretary; and
- 10 (b) may take into account the following:
- 11 (i) whether a court has previously imposed a penalty on the
12 person for a contravention of a provision of this Act or
13 the regulations that is an offence of strict liability or for
14 a contravention of a civil penalty provision;
- 15 (ii) the circumstances of the alleged contravention;
- 16 (iii) whether the person has paid an amount, stated in an
17 earlier infringement notice, for a contravention of a
18 provision of this Act or the regulations that is an offence
19 of strict liability or for a contravention of a civil penalty
20 provision if the contravention is constituted by conduct
21 that is the same, or substantially the same, as the
22 conduct alleged to constitute the contravention in the
23 relevant infringement notice;
- 24 (iv) any other matter the Secretary considers relevant.

25 *Notice of withdrawal*

- 26 (4) Notice of the withdrawal of the infringement notice must be given
27 to the person. The withdrawal notice must state:
- 28 (a) the person's name and address; and
- 29 (b) the day the infringement notice was given; and
- 30 (c) the identifying number of the infringement notice; and
- 31 (d) that the infringement notice is withdrawn; and
- 32 (e) that:
- 33 (i) if the provision is an offence of strict liability—the
34 person may be prosecuted in a court for the alleged
35 contravention; or

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- 1 (ii) if the provision is a civil penalty provision—
2 proceedings seeking an order under subsection 42Y(2)
3 may be brought in relation to the alleged contravention.

4 *Refund of amount if infringement notice withdrawn*

- 5 (5) If:
6 (a) the Secretary withdraws the infringement notice; and
7 (b) the person has already paid the amount stated in the notice;
8 the Commonwealth must refund to the person an amount equal to
9 the amount paid.

10 **42YKD Effect of payment of amount**

- 11 (1) If the person to whom an infringement notice for an alleged
12 contravention of a provision is given pays the amount stated in the
13 notice before the end of the period referred to in
14 paragraph 42YKA(1)(h):
15 (a) any liability of the person for the alleged contravention is
16 discharged; and
17 (b) if the provision is an offence of strict liability—the person
18 may not be prosecuted in a court for the alleged
19 contravention; and
20 (c) if the provision is a civil penalty provision—proceedings
21 seeking an order under subsection 42Y(2) may not be
22 brought in relation to the alleged contravention; and
23 (d) the person is not regarded as having admitted guilt or liability
24 for the alleged contravention; and
25 (e) if the provision is an offence of strict liability—the person is
26 not regarded as having been convicted of the alleged offence.
- 27 (2) Subsection (1) does not apply if the notice has been withdrawn.

28 **42YKE Effect of this Part**

- 29 This Part does not:
30 (a) require an infringement notice to be given to a person for an
31 alleged contravention of a provision of this Act or the
32 regulations that is an offence of strict liability or an alleged
33 contravention of a civil penalty provision; or
-

- 1 (b) affect the liability of a person for an alleged contravention of
2 a provision of this Act or the regulations that is an offence of
3 strict liability or an alleged contravention of a civil penalty
4 provision if:
5 (i) the person does not comply with an infringement notice
6 given to the person for the contravention; or
7 (ii) an infringement notice is not given to the person for the
8 contravention; or
9 (iii) an infringement notice is given to the person for the
10 contravention and is subsequently withdrawn; or
11 (c) prevent the giving of 2 or more infringement notices to a
12 person for an alleged contravention of a provision of this Act
13 or the regulations that is an offence of strict liability or an
14 alleged contravention of a civil penalty provision; or
15 (d) limit a court's discretion to determine the amount of a
16 penalty to be imposed on a person who is found to have
17 contravened a provision of this Act or the regulations that is
18 an offence of strict liability or to have contravened a civil
19 penalty provision.

20 **292 At the end of Chapter 5A**

21 Add:

22 **Part 5A-4—Injunctions**
23

24 **42YM Simplified outline of this Part**

25 The Secretary can seek injunctions from the Federal Court or
26 Federal Circuit Court to restrain a person from contravening this
27 Act or the regulations, or to compel compliance with this Act or
28 the regulations.

29 Interim injunctions are also available.

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1 **42YN Grant of injunctions**

2 *Restraining injunctions*

- 3 (1) If a person has engaged, is engaging or is proposing to engage, in
4 conduct in contravention of this Act or the regulations, the Federal
5 Court or Federal Circuit Court may, on application by the
6 Secretary, grant an injunction:
7 (a) restraining the person from engaging in the conduct; and
8 (b) if, in the court's opinion, it is desirable to do so—requiring
9 the person to do a thing.

10 *Performance injunctions*

- 11 (2) If:
12 (a) a person has refused or failed, or is refusing or failing, or is
13 proposing to refuse or fail, to do a thing; and
14 (b) the refusal or failure was, is or would be a contravention of
15 this Act or the regulations;
16 the Federal Court or Federal Circuit Court may, on application by
17 the Secretary, grant an injunction requiring the person to do that
18 thing.

19 **42YO Interim injunctions**

20 *Grant of interim injunctions*

- 21 (1) Before deciding an application for an injunction under
22 section 42YN, the Federal Court or Federal Circuit Court may
23 grant an interim injunction:
24 (a) restraining a person from engaging in conduct; or
25 (b) requiring a person to do a thing.

26 *No undertakings as to damages*

- 27 (2) The Federal Court or Federal Circuit Court must not require the
28 Secretary to give an undertaking as to damages as a condition of
29 granting an interim injunction.

1 **42YP Discharging or varying injunctions**

2 The Federal Court or Federal Circuit Court may discharge or vary
3 an injunction granted by that court under this Part.

4 **42YQ Certain limits on granting injunctions not to apply**

5 *Restraining injunctions*

6 (1) The power of the Federal Court or Federal Circuit Court under this
7 Part to grant an injunction restraining a person from engaging in
8 conduct may be exercised:

- 9 (a) whether or not it appears to the court that the person intends
10 to engage again, or to continue to engage, in conduct of that
11 kind; and
12 (b) whether or not the person has previously engaged in conduct
13 of that kind; and
14 (c) whether or not there is an imminent danger of substantial
15 damage to any other person if the person engages in conduct
16 of that kind.

17 *Performance injunctions*

18 (2) The power of the Federal Court or Federal Circuit Court under this
19 Part to grant an injunction requiring a person to do a thing may be
20 exercised:

- 21 (a) whether or not it appears to the court that the person intends
22 to refuse or fail again, or to continue to refuse or fail, to do
23 that thing; and
24 (b) whether or not the person has previously refused or failed to
25 do that thing; and
26 (c) whether or not there is an imminent danger of substantial
27 damage to any other person if the person refuses or fails to do
28 that thing.

29 **42YR Other powers of court unaffected**

30 The powers conferred on the Federal Court or Federal Circuit
31 Court under this Part are in addition to, and not instead of, any

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1 other powers of the court, whether conferred by this Act or
2 otherwise.

3 **293 Section 46 (heading)**

4 Repeal the heading, substitute:

5 **46 Searches to monitor compliance with Act or regulations**

6 **294 At the end of paragraph 46(1)(b)**

7 Add “and section 48BA”.

8 **295 After paragraph 46A(1)(a)**

9 Insert:

10 (aa) examine or observe any activity conducted on the premises;

11 **296 At the end of subsection 46A(1)**

12 Add:

13 ; (e) take extracts from or make copies of any such book, record
14 or document.

15 **297 Paragraph 47(1)(b)**

16 Omit “and subsection 48(1)”, substitute “, subsection 48(1) and
17 section 48C”.

18 **298 After paragraph 48(1)(a)**

19 Insert:

20 (aa) to examine or observe any activity conducted on the
21 premises;

22 **299 After section 48A**

23 Insert:

24 **48AA Completing execution of warrant under section 50 after** 25 **temporary cessation**

26 (1) This section applies if an authorised person who is executing a
27 warrant under section 50 in relation to premises temporarily ceases
28 its execution and leaves the premises.

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- 1 (2) The authorised person may complete the execution of the warrant
2 if:
3 (a) the warrant is still in force; and
4 (b) the authorised person is absent from the premises:
5 (i) for not more than 1 hour; or
6 (ii) if there is an emergency situation, for not more than 12
7 hours or such longer period as allowed by a magistrate
8 under subsection (5); or
9 (iii) for a longer period if the occupier of the premises
10 consents in writing.

11 *Application for extension in emergency situation*

- 12 (3) An authorised person may apply to a magistrate for an extension of
13 the 12-hour period mentioned in subparagraph (2)(b)(ii) if:
14 (a) there is an emergency situation; and
15 (b) the authorised person believes on reasonable grounds that the
16 authorised person will not be able to return to the premises
17 within that period.
- 18 (4) If it is practicable to do so, before making the application, the
19 authorised person must give notice to the occupier of the premises
20 of his or her intention to apply for an extension.

21 *Extension in emergency situation*

- 22 (5) A magistrate may extend the period during which the authorised
23 person may be away from the premises if:
24 (a) an application is made under subsection (3); and
25 (b) the magistrate is satisfied, by information on oath or
26 affirmation, that there are exceptional circumstances that
27 justify the extension; and
28 (c) the extension would not result in the period ending after the
29 warrant ceases to be in force.

30 **300 After section 48B**

31 Insert:

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1 **48BA Use of electronic equipment at premises for monitoring**
2 **compliance with Act or regulations**

- 3 (1) An authorised person may operate electronic equipment at the
4 premises to see whether information relevant to determining
5 whether this Act or the regulations have been complied with is
6 accessible by doing so.
- 7 (2) If the authorised person, after operating the equipment, finds that
8 information relevant to determining whether this Act or the
9 regulations have been complied with is accessible by doing so, he
10 or she may:
- 11 (a) operate electronic equipment on the premises to put the
12 information in documentary form and remove the documents
13 so produced from the premises; or
- 14 (b) operate electronic equipment on the premises to transfer the
15 information to a disk, tape or other storage device that:
- 16 (i) is brought to the premises for the exercise of the power;
17 or
- 18 (ii) is on the premises and the use of which for that purpose
19 has been agreed in writing by the occupier of the
20 premises;
- 21 and remove the disk, tape or other storage device from the
22 premises.
- 23 (3) An authorised person may operate electronic equipment as
24 mentioned in subsection (1) or (2) only if the authorised person
25 believes on reasonable grounds that the operation of the equipment
26 can be carried out without damage to the equipment.

27 Note: For compensation for damage to electronic equipment, see
28 section 48D.

- 29 (4) If the authorised person believes on reasonable grounds that:
- 30 (a) information relevant to determining whether this Act or the
31 regulations have been complied with may be accessible by
32 operating electronic equipment at the premises; and
- 33 (b) expert assistance is required to operate the equipment; and

- 1 (c) if he or she does not take action under this subsection, the
2 information may be destroyed, altered or otherwise interfered
3 with;
4 he or she may do whatever is necessary to secure the equipment,
5 whether by locking it up, placing a guard or otherwise.
- 6 (5) The authorised person must give notice to the occupier of the
7 premises of his or her intention to secure equipment and of the fact
8 that the equipment may be secured for up to 24 hours.
- 9 (6) The equipment may be secured:
10 (a) for a period not exceeding 24 hours; or
11 (b) until the equipment has been operated by the expert;
12 whichever happens first.
- 13 (7) The authorised person may apply to a magistrate for an extension
14 of the 24-hour period if the authorised person believes on
15 reasonable grounds that the equipment needs to be secured for
16 longer than that period.
- 17 (8) The authorised person must give notice to the occupier of the
18 premises of his or her intention to apply for an extension, and the
19 occupier is entitled to be heard in relation to the application.
- 20 (9) The 24-hour period may be extended more than once.

21 **301 Section 48C (heading)**

22 Repeal the heading, substitute:

23 **48C Use of electronic equipment at premises relating to offences and** 24 **civil penalty provisions**

25 **302 Subsection 48C(1)**

26 Omit “The”, substitute “An”.

27 **303 Subsection 48C(1)**

28 Omit “if he or she believes on reasonable grounds that the operation of
29 the equipment can be carried out without damage to the equipment”.

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1 **304 Subsection 48C(2)**

2 Repeal the subsection, substitute:

- 3 (2) If the authorised person, after operating the equipment, finds that
4 evidential material in respect of an offence against this Act, in
5 respect of a contravention of a civil penalty provision or in respect
6 of both is accessible by doing so, he or she may:
- 7 (a) seize the equipment and any disk, tape or other associated
8 device; or
 - 9 (b) operate electronic equipment on the premises to put the
10 evidential material in documentary form and remove the
11 documents so produced from the premises; or
 - 12 (c) operate electronic equipment on the premises to transfer the
13 evidential material to a disk, tape or other storage device that:
 - 14 (i) is brought to the premises for the exercise of the power;
15 or
 - 16 (ii) is on the premises and the use of which for that purpose
17 has been agreed in writing by the occupier of the
18 premises;
- 19 and remove the disk, tape or other storage device from the
20 premises.

- 21 (2A) An authorised person may operate electronic equipment as
22 mentioned in subsection (1) or (2) only if the authorised person
23 believes on reasonable grounds that the operation of the equipment
24 can be carried out without damage to the equipment.

25 Note: For compensation for damage to electronic equipment, see
26 section 48D.

27 **305 Paragraph 48C(3)(a)**

28 Omit “copy”, substitute “transfer”.

29 **306 Subsection 48C(7)**

30 Repeal the subsection, substitute:

- 31 (7) The authorised person may apply to a magistrate for an extension
32 of the 24-hour period if the authorised person believes on
33 reasonable grounds that the equipment needs to be secured for
34 longer than that period.
-

1 **307 At the end of section 48C**

2 Add:

3 (9) The 24-hour period may be extended more than once.

4 **308 Paragraph 48D(1)(a)**

5 After “section”, insert “48BA or”.

6 **309 Subsection 48E(2)**

7 Repeal the subsection, substitute:

8 (2) Subsection (1) does not apply if possession of the document, film,
9 computer file, thing or information by the occupier could constitute
10 an offence against a law of the Commonwealth or contravention of
11 a civil penalty provision.

12 **310 After section 48F**

13 Insert:

14 **48FA Responsibility to provide facilities and assistance**

15 (1) The occupier of premises to which a warrant relates, or another
16 person who apparently represents the occupier, must provide an
17 authorised person executing the warrant with all reasonable
18 facilities and assistance for the effective exercise of the authorised
19 person’s powers.

20 (2) A person commits an offence if:

- 21 (a) the person is subject to subsection (1); and
22 (b) the person fails to comply with that subsection.

23 Penalty for contravention of this subsection:30 penalty units.

24 **311 Subparagraph 49(4)(a)(ii)**

25 After “subsection 48(1)”, insert “and section 48BA”.

26 **312 Subparagraph 50(4)(b)(ii)**

27 After “48(1)”, insert “and section 48C”.

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1 **313 Section 51A (heading)**

2 Repeal the heading, substitute:

3 **51A Inspections for purposes of Mutual Recognition Convention**

4 **314 Section 53A (table items 8 and 9)**

5 Repeal the items, substitute:

8	subsection 21A(9)	subsection 21A(9A)
9	subsection 21A(12)	subsection 21A(12A)

6 **315 Section 53A (before table item 13F)**

7 Insert:

13EB	subsection 32CJ(6)	subsection 32CJ(7)
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8 **316 After paragraph 54(3)(a)**

9 Insert:

10 (aa) makes an order under section 19B of the *Crimes Act 1914* in
11 respect of a person charged with an offence against this Act;
12 or

13 **317 Section 54BA (table items 1 to 4)**

14 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)

15 **318 Section 54BA (table item 6)**

16 Repeal the item, substitute:

6 Subsection 22A(1)

17 **319 Section 54BA (table items 9 to 11)**

18 Repeal the items, substitute:

9 Subsection 30EC(1)

10 Subsection 30F(4B)

11 Subsection 31(5A)

1 **320 Section 54BA (table items 14 to 17)**

2 Repeal the items, substitute:

14 Subsection 32BA(1)

15 Subsection 32BB(1)

16 Subsection 32BC(1)

17 Subsection 32BD(1)

3 **321 Section 54BA (table items 19 and 20)**

4 Repeal the items, substitute:

19 Subsection 32CJ(6)

20 Subsection 32DO(1)

5 **322 Section 54BA (table items 23 to 25)**

6 Repeal the items, substitute:

23 Subsection 32EF(1)

24 Subsection 32HC(1)

25 Subsection 32JB(2)

7 **323 Section 54BA (table item 27)**

8 Repeal the item, substitute:

27 Subsection 35(1) or (5)

27AA Subsection 35B(1)

9 **324 Section 54BA (table items 28 to 31)**

10 Repeal the items, substitute:

28 Subsection 41EI(1)

29 Subsection 41FE(1)

30 Subsection 41JB(4)

31 Subsection 41JH(1)

11 **325 Section 54BA (table items 33 to 36)**

12 Repeal the items, substitute:

33 Subsection 41KC(1)

EXPOSURE DRAFT

Schedule 7 Enforcement

34 Subsection 41MA(1), (5) or (9)

35 Subsection 41MC(2)

36 Subsection 41ME(1) or (5)

1 **326 Section 54BA (table item 39)**

2 Repeal the item, substitute:

39 Subsection 41MI(1)

3 **327 Section 54BA (table item 40)**

4 Repeal the item, substitute:

40 Subsection 41MN(1), (5) or (10)

5 **328 Section 54BA (table item 46)**

6 Repeal the item, substitute:

46 Subsection 42V(6)

7 **329 Application provision—application of the *Criminal Code***

8 The amendments of section 5A of the *Therapeutic Goods Act 1989*
9 made by this Schedule apply in relation to offences committed on or
10 after the commencement of this item.

11 **330 Application provision—Register**

12 The amendments of section 9G of the *Therapeutic Goods Act 1989*
13 made by this Schedule apply in relation to statements made on or after
14 the commencement of this item.

15 **331 Application provisions—therapeutic goods**

16 (1) The amendments of section 14 of the *Therapeutic Goods Act 1989*
17 made by this Schedule apply in relation to therapeutic goods imported,
18 exported or supplied on or after the commencement of this item.

19 (2) The amendment of section 14B of the *Therapeutic Goods Act 1989*
20 made by this Schedule applies in relation to goods imported or exported
21 on or after the commencement of this item.

22 (3) The amendments of section 15 of the *Therapeutic Goods Act 1989*
23 made by this Schedule apply in relation to acts or omissions occurring
24 on or after the commencement of this item.

EXPOSURE DRAFT

Enforcement **Schedule 7**

-
- 1 (4) The amendments of section 19B of the *Therapeutic Goods Act 1989*
2 made by this Schedule apply in relation to therapeutic goods imported,
3 exported, manufactured or supplied on or after the commencement of
4 this item.
- 5 (5) Subsection 20(1BA) of the *Therapeutic Goods Act 1989*, as inserted by
6 this Schedule, applies in relation to therapeutic goods imported,
7 exported, manufactured or supplied on or after the commencement of
8 this item.
- 9 (6) The amendments of subsection 21A(1), the repeal of
10 subsections 21A(2) and (3) and the insertion of subsections 21A(4A)
11 and (4B) of the *Therapeutic Goods Act 1989* made by this Schedule
12 apply in relation to statements made on or after the commencement of
13 this item.
- 14 (7) The amendment of subsection 21A(5), the repeal of subsections 21A(6)
15 and (7) and the insertion of subsections 21A(8A) and (8B) of the
16 *Therapeutic Goods Act 1989* made by this Schedule apply in relation to
17 acts or omissions occurring on or after the commencement of this item.
- 18 (8) The amendments of subsections 21A(9) and (11A), the substitution of
19 subsections 21A(9A), (10) and (11), the repeal of subsections 21A(11B)
20 and 22(7A) and the insertion of subsections 21A(11D) and (11E) of the
21 *Therapeutic Goods Act 1989* made by this Schedule apply in relation to
22 therapeutic goods supplied on or after the commencement of this item.
- 23 (9) The amendment of subsection 21A(12), the substitution of
24 subsections 21A(12A), (13) and (14) and the repeal of subsection 22(8)
25 of the *Therapeutic Goods Act 1989* made by this Schedule apply in
26 relation to the use of therapeutic goods on or after the commencement
27 of this item.
- 28 (10) The amendments of section 22A of the *Therapeutic Goods Act 1989*
29 made by this Schedule apply in relation to statements made on or after
30 the commencement of this item.
- 31 (11) The amendment of section 30EA of the *Therapeutic Goods Act 1989*
32 made by this Schedule applies in relation to goods supplied on or after
33 the commencement of this item.

EXPOSURE DRAFT

Schedule 7 Enforcement

- 1 (12) The amendments of section 30EC of the *Therapeutic Goods Act 1989*
2 made by this Schedule apply in relation to acts or omissions occurring
3 on or after the commencement of this item.
- 4 (13) The amendments of section 30F of the *Therapeutic Goods Act 1989*
5 made by this Schedule apply in relation to notices given on or after the
6 commencement of this item.
- 7 (14) The amendments of section 31 of the *Therapeutic Goods Act 1989*
8 made by this Schedule apply in relation to notices given on or after the
9 commencement of this item.
- 10 (15) Subsections 31C(2) and (3) of the *Therapeutic Goods Act 1989*, as
11 added by this Schedule, apply in relation to notices given on or after the
12 commencement of this item.
- 13 (16) The amendments of sections 31D and 31E of the *Therapeutic Goods*
14 *Act 1989* made by this Schedule apply in relation to notices given under
15 section 31A, 31AA, 31B or 31BA of that Act on or after the
16 commencement of this item.
- 17 (17) The amendments of section 31F of the *Therapeutic Goods Act 1989*
18 made by this Schedule apply in relation to notices given under
19 section 31, 31A, 31AA, 31B or 31BA of that Act on or after the
20 commencement of this item.

21 **332 Application provisions—biologicals**

- 22 (1) The amendments of section 32BA of the *Therapeutic Goods Act 1989*
23 made by this Schedule apply in relation to biologicals imported on or
24 after the commencement of this item.
- 25 (2) The amendments of section 32BB of the *Therapeutic Goods Act 1989*
26 made by this Schedule apply in relation to biologicals exported on or
27 after the commencement of this item.
- 28 (3) Section 32BBA and subsection 32BF(7) of the *Therapeutic Goods Act*
29 *1989*, as inserted or added by this Schedule, apply in relation to
30 biologicals imported or exported on or after the commencement of this
31 item.

EXPOSURE DRAFT

Enforcement **Schedule 7**

- 1 (4) The amendments of section 32BC of the *Therapeutic Goods Act 1989*
2 made by this Schedule apply in relation to biologicals manufactured on
3 or after the commencement of this item.
- 4 (5) The amendments of section 32BD of the *Therapeutic Goods Act 1989*
5 made by this Schedule apply in relation to biologicals supplied on or
6 after the commencement of this item.
- 7 (6) Subsections 32BG(1A) and (1B) of the *Therapeutic Goods Act 1989*, as
8 inserted by this Schedule, apply in relation to biologicals imported,
9 exported, manufactured or supplied on or after the commencement of
10 this item.
- 11 (7) The amendments of section 32BI of the *Therapeutic Goods Act 1989*
12 made by this Schedule apply in relation to the use of biologicals on or
13 after the commencement of this item.
- 14 (8) The amendments of section 32CJ of the *Therapeutic Goods Act 1989*
15 made by this Schedule apply in relation to notices given on or after the
16 commencement of this item.
- 17 (9) The amendments of section 32CN of the *Therapeutic Goods Act 1989*
18 made by this Schedule apply in relation to biologicals supplied on or
19 after the commencement of this item.
- 20 (10) The amendments of section 32DO of the *Therapeutic Goods Act 1989*
21 made by this Schedule apply in relation to statements made on or after
22 the commencement of this item.
- 23 (11) The amendments of sections 32EF and 32HC of the *Therapeutic Goods*
24 *Act 1989* made by this Schedule apply in relation to acts or omissions
25 occurring on or after the commencement of this item.
- 26 (12) The amendments of sections 32JB and 32JD of the *Therapeutic Goods*
27 *Act 1989* made by this Schedule apply in relation to notices given under
28 section 32JA of that Act on or after the commencement of this item.
- 29 (13) The amendments of sections 32JI and 32JK of the *Therapeutic Goods*
30 *Act 1989* made by this Schedule apply in relation to notices given under
31 section 32JE, 32JF, 32JG or 32JH of that Act on or after the
32 commencement of this item.
-

EXPOSURE DRAFT

1 **333 Application provisions—manufacturing of therapeutic**
2 **goods**

- 3 (1) The amendments of section 35 of the *Therapeutic Goods Act 1989*
4 made by this Schedule apply in relation to steps in the manufacture of
5 therapeutic goods that are carried out on or after the commencement of
6 this item.
- 7 (2) The amendments of section 35B of the *Therapeutic Goods Act 1989*
8 made by this Schedule apply in relation to acts or omissions occurring
9 on or after the commencement of this item.

10 **334 Application provisions—medical devices**

- 11 (1) The amendments of sections 41EI and 41FE of the *Therapeutic Goods*
12 *Act 1989* made by this Schedule apply in relation to statements made on
13 or after the commencement of this item.
- 14 (2) The amendments of sections 41JB and 41JC of the *Therapeutic Goods*
15 *Act 1989* made by this Schedule apply in relation to notices given under
16 section 41JA of that Act on or after the commencement of this item.
- 17 (3) The amendments of sections 41JG, 41JH and 41JI of the *Therapeutic*
18 *Goods Act 1989* made by this Schedule apply in relation to notices
19 given under section 41JCA, 41JD, 41JE, 41JF or 41JFA of that Act on
20 or after the commencement of this item.
- 21 (4) The amendments of section 41KC of the *Therapeutic Goods Act 1989*
22 made by this Schedule apply in relation to acts or omissions occurring
23 on or after the commencement of this item.
- 24 (5) The amendments of sections 41MA and 41MAA of the *Therapeutic*
25 *Goods Act 1989* made by this Schedule apply in relation to medical
26 devices imported, supplied or exported on or after the commencement
27 of this item.
- 28 (6) The amendments of section 41MC of the *Therapeutic Goods Act 1989*
29 made by this Schedule apply in relation to acts or omissions occurring
30 on or after the commencement of this item.
- 31 (7) The amendments of sections 41MD and 41MJ of the *Therapeutic Goods*
32 *Act 1989* made by this Schedule apply in relation to medical devices
33 imported or exported on or after the commencement of this item.

EXPOSURE DRAFT

Enforcement **Schedule 7**

- 1 (8) The amendments of section 41ME of the *Therapeutic Goods Act 1989*
2 made by this Schedule apply in relation to medical devices
3 manufactured on or after the commencement of this item.
- 4 (9) The amendments of section 41MF of the *Therapeutic Goods Act 1989*
5 made by this Schedule apply in relation to medical devices supplied or
6 exported on or after the commencement of this item.
- 7 (10) The amendments of section 41MI of the *Therapeutic Goods Act 1989*
8 made by this Schedule apply in relation to medical devices imported,
9 exported, supplied or manufactured on or after the commencement of
10 this item.
- 11 (11) The amendments of section 41MN of the *Therapeutic Goods Act 1989*
12 made by this Schedule apply in relation to acts or omissions occurring
13 on or after the commencement of this item.
- 14 (12) The amendments of subsections 41MO(1) and (4A), the repeal of
15 subsections 41MO(2), (3) and (4B) and the insertion of
16 subsections 41MO(4AA), (4AB), (4D) and (4E) of the *Therapeutic*
17 *Goods Act 1989* made by this Schedule apply in relation to a medical
18 device supplied on or after the commencement of this item.
- 19 (13) The amendments of subsection 41MO(5), the repeal of
20 subsections 41MO(6) and (7) and the addition of subsections 41MO(9)
21 and (10) of the *Therapeutic Goods Act 1989* made by this Schedule
22 apply in relation to use of a medical device on or after the
23 commencement of this item.

24 **335 Application provision—product tampering**

25 The amendments of section 42V of the *Therapeutic Goods Act 1989*
26 made by this Schedule apply in relation to requirements imposed on or
27 after the commencement of this item.

28 **336 Application provision—civil penalties**

29 Section 42YCA of the *Therapeutic Goods Act 1989*, as inserted by this
30 Schedule, applies in relation to an act or thing required to be done
31 within a particular period, or before a particular time, where the period
32 ends, or the time occurs, on or after the commencement of this item.

EXPOSURE DRAFT

1 **337 Application and saving provisions—infringement notices**

2 (1) Part 5A-2 of the *Therapeutic Goods Act 1989*, as substituted by this
3 Schedule, applies in relation to an alleged contravention of a provision
4 of that Act or the regulations under that Act that is an offence of strict
5 liability, or an alleged contravention of a civil penalty provision,
6 occurring on or after the commencement of this item.

7 (2) Part 5A-2 of the *Therapeutic Goods Act 1989*, and the *Therapeutic*
8 *Goods Regulations 1990*, as in force immediately before the
9 commencement of this item, continue to apply on and after that
10 commencement in relation to:

11 (a) an alleged commission of an offence occurring before that
12 commencement; and

13 (b) an alleged contravention of a civil penalty provision
14 occurring before that commencement.

15 **338 Application provision—injunctions**

16 Part 5A-4 of the *Therapeutic Goods Act 1989*, as added by this
17 Schedule, applies in relation to contraventions occurring, or proposed to
18 occur, on or after the commencement of this item.

19 **339 Application and saving provisions—entry, searches and**
20 **warrants**

21 (1) The amendments of sections 46, 46A, 48, 48C, 48D and 48E of the
22 *Therapeutic Goods Act 1989* made by this Schedule apply in relation to
23 entries to premises on or after the commencement of this item.

24 (2) Section 48AA of the *Therapeutic Goods Act 1989*, as inserted by this
25 Schedule, applies in relation to warrants issued under section 50, or
26 signed under section 51, of that Act on or after the commencement of
27 this item.

28 (3) Section 48BA of the *Therapeutic Goods Act 1989*, as inserted by this
29 Schedule, applies in relation to entries to premises on or after the
30 commencement of this item.

31 (4) The repeal and substitution of subsection 48C(2) of the *Therapeutic*
32 *Goods Act 1989* made by this Schedule does not affect the validity of

1 anything done under that subsection before the commencement of this
2 item.

3 (5) Section 48FA of the *Therapeutic Goods Act 1989*, as inserted by this
4 Schedule, applies in relation to warrants issued under section 49 or 50,
5 or signed under section 51, of that Act on or after the commencement of
6 this item.

7 (6) The amendment of section 49 of the *Therapeutic Goods Act 1989* made
8 by this Schedule applies in relation to applications for a warrant made
9 on or after the commencement of this item.

10 **340 Application provision—offences and forfeiture**

11 Paragraph 54(3)(aa) of the *Therapeutic Goods Act 1989*, as inserted by
12 this Schedule, applies in relation to an order referred to in that
13 paragraph that is made on or after the commencement of this item
14 (whether the person was charged with the offence before, on or after
15 that commencement).

16 **341 Saving provision—personal liability of an executive 17 officer of a body corporate**

18 Despite the amendments made by this Schedule, the table in
19 section 54BA of the *Therapeutic Goods Act 1989*, as in force
20 immediately before the commencement of this item, continues to apply
21 on and after that commencement in relation to the application of
22 section 54B of that Act on or after that commencement in relation to
23 offences committed by bodies corporate before that commencement.

EXPOSURE DRAFT

Schedule 8 Record-keeping etc.

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)”.

EXPOSURE DRAFT

Record-keeping etc. **Schedule 8**

1 **6 Application provision**

2 The amendments made by this Schedule apply in relation to biologicals
3 included in the Register before, on or after the commencement of this
4 item.

EXPOSURE DRAFT

Schedule 9 Other amendments

1 **Schedule 9—Other amendments**
2

3 ***Therapeutic Goods Act 1989***

4 **1 After subsection 19(1)**

5 Insert:

6 (1AA) An approval for use of the kind referred to in paragraph (1)(a) must
7 not be granted to a person unless the person is a health practitioner.

8 **2 Paragraph 19(2)(a)**

9 After “be”, insert “in a form (if any) approved, in writing, by the
10 Secretary and be”.

11 **3 After subsection 19(5)**

12 Insert:

13 (5AA) An application for an authority under subsection (5) must be in a
14 form (if any) approved, in writing, by the Secretary.

15 **4 Subsection 22(6)**

16 Repeal the subsection, substitute:

17 (6) A person commits an offence if:

- 18 (a) the person claims, by any means, that the person or another
19 person can arrange the supply of therapeutic goods; and
20 (b) none of the following subparagraphs applies in relation to the
21 goods:
22 (i) the goods are registered goods or listed goods;
23 (ii) the goods are exempt goods;
24 (iii) the goods are exempt under section 18A;
25 (iv) the goods are the subject of an approval or authority
26 under section 19 that covers the supply of the goods by
27 the person or other person;
28 (v) the goods are the subject of an approval under
29 section 19A that covers the supply of the goods by the
30 person or other person.
-

1 Penalty: 60 penalty units.

2 **5 At the end of subsection 28(5)**

3 Add:

4 ; and (h) deliver a reasonable number of samples of the subject goods
5 if the Secretary so requests:

6 (i) within the period specified in the request (which must
7 include at least 10 working days); and

8 (ii) in accordance with any other requirements specified in
9 the request.

10 **6 Subsection 28(5A)**

11 Repeal the subsection.

12 **7 Paragraph 29D(1)(b)**

13 Omit “or (fb)”, substitute “, (fb) or (g)”.

14 **8 Subsection 30(3)**

15 Omit “otherwise than as a result of a failure to pay the annual
16 registration or listing charge”.

17 **9 Subparagraph 32BH(b)(v)**

18 Omit “that is held”, substitute “or (7A) that covers the supply of the
19 biological”.

20 **10 Subparagraph 32BI(1)(c)(vii)**

21 After “subsection 32CM(1)”, insert “or (7A)”.

22 **11 At the end of subparagraph 32BI(4)(c)(vii)**

23 Add “or (7A)”.

24 **12 Subparagraph 32BJ(4)(b)(i)**

25 Omit “in relation to the person”.

26 **13 Subparagraph 32BJ(4)(b)(ii)**

27 After “person”, insert “or other person”.

EXPOSURE DRAFT

Schedule 9 Other amendments

1 **14 Subparagraph 32BJ(4)(b)(iv)**

2 After “person”, insert “or other person”.

3 **15 Subparagraph 32BJ(4)(b)(v)**

4 Omit “that is held by the person”, substitute “or (7A) that covers the
5 supply of the biological by the person or other person”.

6 **16 Subparagraph 32BJ(4)(b)(vi)**

7 After “person”, insert “or other person”.

8 **17 Paragraph 32BK(2)(e)**

9 After “subsection 32CM(1)”, insert “or (7A)”.

10 **18 After subsection 32CK(1)**

11 Insert:

12 (1A) An approval for use of the kind referred to in paragraph (1)(d) must
13 not be granted to a person unless the person is a health practitioner.

14 **19 After paragraph 32CK(3)(a)**

15 Insert:

16 (aa) be in a form (if any) approved, in writing, by the Secretary;
17 and

18 **20 After subsection 32CM(1)**

19 Insert:

20 (1A) An application for an authority under subsection (1) must be in a
21 form (if any) approved, in writing, by the Secretary.

22 **21 Paragraph 32FA(1)(b)**

23 Omit “or (d)”, substitute “, (d) or (g)”.

24 **22 Subsection 32HA(1) (table items 3, 4 and 5)**

25 After “subsection 32CM(1)”, insert “or (7A)”.

26 **23 After subsection 40B(9)**

27 Insert:

EXPOSURE DRAFT

Other amendments **Schedule 9**

1

Removal of manufacturing sites

2

(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.

3

4

5

(9B) An application under subsection (9A) must:

6

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

7

8

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

9

10

(c) be accompanied by the prescribed application fee.

11

(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.

12

13

14

15

(9D) A variation under subsection (9C) takes effect on the day specified in the notice.

16

17

24 Subsection 40B(10)

18

Omit “or (6)”, substitute “, (6) or (9A)”.

19

25 Paragraph 40B(10)(b)

20

Before “to allow”, insert “for an application under subsection (1) or (6)—”.

21

22

26 Subsection 40B(11)

23

Omit “or (7)(a)”, substitute “, (7)(a) or (9B)(a)”.

24

27 At the end of section 41EC

25

Add:

26

(6) The Secretary may, by written notice given to the applicant, require the applicant:

27

28

(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

29

30

EXPOSURE DRAFT

Schedule 9 Other amendments

1 than 14 days after the day the notice is given, specified in the
2 notice; and

3 (b) to do so in a manner specified in the notice.

4 **28 Paragraph 41EG(b)**

5 After “by the Secretary”, insert “under subsection 41EC(6)”.

6 **29 After subsection 41FI(1)**

7 Insert:

8 (1A) In auditing the application, the Secretary may, by written notice
9 given to the applicant, require the applicant:

10 (a) to deliver to the office to which the application was made a
11 reasonable number of samples of the kind of medical device
12 to which the application relates within the period, of not less
13 than 14 days after the day the notice is given, specified in the
14 notice; and

15 (b) to do so in a manner specified in the notice.

16 **30 Paragraph 41FK(b)**

17 After “by the Secretary”, insert “under subsection 41FI(1A)”.

18 **31 Paragraph 41GA(1)(b)**

19 Omit “or (d)”, substitute “, (d) or (f)”.

20 **32 After subsection 41HB(1)**

21 Insert:

22 (1A) An approval for use of the kind referred to in paragraph (1)(d) must
23 not be granted to a person unless the person is a health practitioner.

24 **33 Subsection 41HB(4)**

25 After “be”, insert “in a form (if any) approved, in writing, by the
26 Secretary and be”.

27 **34 After subsection 41HC(1)**

28 Insert:

1 (1A) An application for an authority under subsection (1) must be in a
2 form (if any) approved, in writing, by the Secretary.

3 **35 Section 41MM**

4 Repeal the section, substitute:

5 **41MM Claims about arranging supplies of medical devices**

6 A person commits an offence if:

- 7 (a) the person claims, by any means, that the person or another
8 person can arrange the supply of a medical device; and
9 (b) none of the following subparagraphs applies in relation to the
10 device:
11 (i) the device is of a kind included in the Register;
12 (ii) the device is of a kind covered by an exemption in force
13 under section 41GS;
14 (iii) the device is an exempt device;
15 (iv) the device is the subject of an approval under
16 section 41HB or an authority under section 41HC that
17 covers the supply of the device by the person or other
18 person;
19 (v) the device is the subject of an approval under
20 subsection 41HD(1), (1A) or (2) that covers the supply
21 of the device by the person or other person.

22 Penalty: 60 penalty units.

23 **36 Subparagraph 46A(4)(a)(i)**

24 Omit “section 19”, substitute “subsection 19(1) or (5)”.

25 **37 Subparagraph 46A(4)(a)(ia)**

26 Omit “section 41HB or 41HC”, substitute “subsection 41HB(1) or
27 41HC(1)”.

28 **38 Application provisions—therapeutic goods**

29 (1) Subsection 19(1AA) of the *Therapeutic Goods Act 1989*, as inserted by
30 this Schedule, applies in relation to approvals granted on or after the
31 commencement of this item.

EXPOSURE DRAFT

Schedule 9 Other amendments

- 1 (2) The amendment of paragraph 19(2)(a) of the *Therapeutic Goods Act*
2 *1989* made by this Schedule applies in relation to applications made on
3 or after the commencement of this item.
- 4 (3) Subsection 19(5AA) of the *Therapeutic Goods Act 1989*, as inserted by
5 this Schedule, applies in relation to applications made on or after the
6 commencement of this item.
- 7 (4) The repeal and substitution of subsection 22(6) of the *Therapeutic*
8 *Goods Act 1989* made by this Schedule applies in relation to claims
9 made on or after the commencement of this item.
- 10 (5) The amendment of subsection 28(5) of the *Therapeutic Goods Act 1989*
11 made by this Schedule applies in relation to the registration or listing of
12 therapeutic goods before, on or after the commencement of this item.
- 13 (6) The *Therapeutic Goods Act 1989*, as in force immediately before the
14 commencement of this item, continues to apply on and after that
15 commencement in relation to a request referred to in subsection 28(5A)
16 of that Act that was made before that commencement.
- 17 (7) The amendment of paragraph 29D(1)(b) of the *Therapeutic Goods Act*
18 *1989* made by this Schedule applies in relation to suspensions made on
19 or after the commencement of this item (whether the therapeutic goods
20 were included in the Register before, on or after that commencement).

21 **39 Application provisions—biologicals**

- 22 (1) The amendment of subparagraph 32BH(b)(v) of the *Therapeutic Goods*
23 *Act 1989* made by this Schedule applies in relation to supplies of a
24 biological occurring on or after the commencement of this item.
- 25 (2) The amendments of section 32BI of the *Therapeutic Goods Act 1989*
26 made by this Schedule apply in relation to uses of a biological on or
27 after the commencement of this item.
- 28 (3) The amendments of section 32BJ of the *Therapeutic Goods Act 1989*
29 made by this Schedule apply in relation to claims made on or after the
30 commencement of this item.
- 31 (4) The amendment of paragraph 32BK(2)(e) of the *Therapeutic Goods Act*
32 *1989* made by this Schedule applies in relation to representations made
33 on or after the commencement of this item.

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Other amendments **Schedule 9**

- 1 (5) Subsection 32CK(1A) of the *Therapeutic Goods Act 1989*, as inserted
2 by this Schedule, applies in relation to approvals granted on or after the
3 commencement of this item.
- 4 (6) The amendment of subsection 32CK(3) of the *Therapeutic Goods Act*
5 *1989* made by this Schedule applies in relation to applications made on
6 or after the commencement of this item.
- 7 (7) Subsection 32CM(1A) of the *Therapeutic Goods Act 1989*, as inserted
8 by this Schedule, applies in relation to applications made on or after the
9 commencement of this item.
- 10 (8) The amendment of paragraph 32FA(1)(b) of the *Therapeutic Goods Act*
11 *1989* made by this Schedule applies in relation to suspensions made on
12 or after the commencement of this item (whether the biological was
13 included in the Register before, on or after that commencement).
- 14 (9) The amendment of subsection 32HA(1) of the *Therapeutic Goods Act*
15 *1989* made by this Schedule applies in relation to supplies of a
16 biological occurring on or after the commencement of this item.

17 **40 Application provisions—medical devices**

- 18 (1) The amendments of sections 41EC and 41EG of the *Therapeutic Goods*
19 *Act 1989* made by this Schedule apply in relation to:
20 (a) an application for a conformity assessment certificate that is
21 made on or after the commencement of this item; and
22 (b) an application for a conformity assessment certificate that
23 was pending immediately before the commencement of this
24 item.
- 25 (2) The amendments of sections 41FI and 41FK of the *Therapeutic Goods*
26 *Act 1989* made by this Schedule apply in relation to:
27 (a) an application for a kind of medical device to be included in
28 the Register that is made on or after the commencement of
29 this item; and
30 (b) an application for a kind of medical device to be included in
31 the Register that was pending immediately before the
32 commencement of this item.
- 33 (3) The amendment of paragraph 41GA(1)(b) of the *Therapeutic Goods Act*
34 *1989* made by this Schedule applies in relation to suspensions made on
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Schedule 9 Other amendments

- 1 or after the commencement of this item (whether the kind of medical
2 device was included in the Register before, on or after that
3 commencement).
- 4 (4) Subsection 41HB(1A) of the *Therapeutic Goods Act 1989*, as inserted
5 by this Schedule, applies in relation to approvals granted on or after the
6 commencement of this item.
- 7 (5) The amendment of subsection 41HB(4) of the *Therapeutic Goods Act*
8 *1989* made by this Schedule applies in relation to applications made on
9 or after the commencement of this item.
- 10 (6) Subsection 41HC(1A) of the *Therapeutic Goods Act 1989*, as inserted
11 by this Schedule, applies in relation to applications made on or after the
12 commencement of this item.
- 13 (7) The repeal and substitution of section 41MM of the *Therapeutic Goods*
14 *Act 1989* made by this Schedule applies in relation to claims made on or
15 after the commencement of this item.