Therapeutic Goods Amendment Regulations 2010 (No. 1)[1]

Select Legislative Instrument 2010 No. 26

I, QUENTIN BRYCE, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following Regulations under the *Therapeutic Goods Act 1989*.

Dated 25 February 2010

QUENTIN BRYCE
Governor-General

By Her Excellency's Command

MARK BUTLER
Parliamentary Secretary for Health

Federal Register of Legislative Instruments F2010L00470

1 Name of Regulations

These Regulations are the *Therapeutic Goods Amendment Regulations 2010 (No. 1)*.

2 Commencement

These Regulations commence on 1 July 2010.

3 Amendment of *Therapeutic Goods Regulations 1990*

Schedule 1 amends the *Therapeutic Goods Regulations 1990*.

4 Definitions for transitional provisions

In regulations 5, 6 and 7:

Act means the *Therapeutic Goods Act 1989*.

in-house IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* as in force on 1 July 2010.

IVD medical device has the same meaning as in the *Therapeutic Goods (Medical Devices) Regulations 2002* as in force on 1 July 2010.

5 Transitional — certain devices

(1) This regulation applies to a diagnostic good for in vitro use that, immediately before 1 July 2010:

(a) was declared not to be a medical device under subsection 41BD (3) of the Act; and

(b) was:

(i) listed or registered under Part 3-2 of the Act; or

(ii) subject to an approval under paragraph 19 (1) (b) of the Act; or

(iii) exempt from listing or registration under Part 3-2 of the Act; or

(iv) a device for which an effective application for listing or registration under Part 3-2 of the Act had been made but not finally determined.

Note For circumstances in which an application under Part 3-2 of the Act is effective, see subsection 23 (2) of the Act.

(2) The listing or registration under Part 3-2 of the Act of a device mentioned in subparagraph (1) (b) (i) or (iv) is taken to be cancelled on:

(a) if no effective application for including the device in the Register under Chapter 4 of the Act has been made before 1 July 2014 — 1 July 2014; or

(b) the day when inclusion of the device in the Register under Chapter 4 of the Act takes effect following an effective application made for the inclusion of the device in the Register under that Chapter.

(3) Despite the amendments made by Schedule 1, a device mentioned in paragraph (1) (b) (iii) that was exempt from the requirements for registration or listing under Part 3-2 of the Act immediately before 1 July 2010 remains exempt until 30 June 2014.

(4) The amendments made by Schedule 1 do not apply to each of the following diagnostic goods for in vitro use that, immediately before 1 July 2010, was declared not to be a medical device under subsection 41BD (3) of the Act, until the exemption that applies to the goods immediately before 1 July 2010 ceases to have effect:

(a) a device that was exempt from listing or registration under Part 3-2 of the Act because item 3 of Schedule 5A to the *Therapeutic Goods Regulations 1990* applies to it;

(b) a device mentioned in subparagraph (1) (b) (ii);

(c) a device for which an application under paragraph 19 (1) (b) of the Act had been made but not finally determined.

(5) For subparagraph (1) (b) (iv) and paragraph (4) (c), an application is finally determined at the first time both the following conditions are met:

(a) a decision has been made whether to grant the application;

(b) there is no longer any possibility of a change in the outcome of the decision in terms of the granting of the approval for the import, export or supply, or the listing or registration of the device.

(6) For paragraph (5) (b), the possibility of a discretion being exercised after the period has ended, to extend the period for seeking review by a court or tribunal of the decision or of starting other proceedings (including appeals) arising out of the application, decision or review, is not to be considered.

6 Transitional — in-house IVD medical devices

The amendments made by Schedule 1 apply to an in-house IVD medical device after 30 June 2014.

7 Transitional — other devices

The amendments made by Schedule 1 apply to any good or device that is not mentioned in regulation 5 or 6 after 30 June 2010.

Schedule 1 Amendments

(regulation 3)

[1] Regulation 2, definitions of *active implantable therapeutic device*, *active therapeutic device*, *critical medical device*, *diagnostic goods for in vitro use* and *goods for home use*

omit

[2] Regulation 2, definition of *high level disinfectant*

substitute

high level disinfectant means a disinfectant that kills all microbial pathogens, except bacterial endospores, when used as recommended by its manufacturer.

[3] Regulation 2, definitions of *implantable*, *instrument grade disinfectant*, *non critical medical device* and *semi critical medical device*

omit

[4] Paragraph 3 (3) (d)

omit

(Tas).

insert

(Tas);

[5] After paragraph 3 (3) (d)

insert

(e) *Medicines, Poisons and Therapeutic Goods Act 2008* (ACT).

[6] Subregulation 12 (1AA)

omit

[7] Regulation 12C

omit

[8] Subregulation 15A (1)

omit

Drug Safety And Evaluation Branch'

insert

Office of Prescription Medicines'

[9] Subregulation 16 (2)

omit

[10] Regulation 46A

omit

For

insert

(1) For

[11] After regulation 46A

insert

(2) For paragraph 57 (8) (b) of the Act, the following positions are prescribed:

(a) Chief Regulatory Officer;

(b) Principal Medical Adviser.

[12] Schedule 3, Part 1, item 3, paragraphs (a) to (f)

omit

[13] Schedule 3, Part 1, item 3, paragraph (g)

substitute

(g) devices that are:

(i) articles incorporating tissues, cells or substances of human origin, other than medical devices incorporating stable derivatives of either human blood or human plasma that act on, or are likely to act on, the human body in a way that is ancillary to the device; or

(ii) articles incorporating viable tissues, cells or substances of animal origin

[14] Schedule 3, Part 1, item 3, paragraph (h)

omit

[15] Schedule 3, Part 1, items 4 and 5

omit

[16] Schedule 3, Part 2, items 2 to 5, 7 and 8

omit

[17] Schedule 4, Part 1, item 2, paragraph (a)

substitute

(a) item 3 (g) of Part 1 of Schedule 3 applies; or

[18] Schedule 4, Part 1, item 2, paragraph (b)

substitute

(b) item 1, 2, 3 or 4, paragraph 7 (e) or (q) or item 11 of Schedule 5 applies; or

[19] Schedule 4, Part 1, items 13 to 15

omit

[20] Schedule 5, item 5

omit

[21] Schedule 5, item 7, paragraphs (a) to (d)

omit

[22] Schedule 5, item 7, paragraph (e)

substitute

(e) manufacturing, laboratory and dispensary equipment used in the preparation of therapeutic goods; or

[23] Schedule 5, item 7, paragraphs (f) to (p)

omit

[24] Schedule 5, item 8, subparagraph (f) (i)

omit

items 5 and 6

insert

item 6

[25] Schedule 5, item 8, subparagraph (f) (ii)

omit

Schedule 4; or

insert

Schedule 4;

[26] Schedule 5, item 8, subparagraph (f) (iii)

omit

[27] Schedule 5A, item 7

substitute

7	Therapeutic goods, or parts of therapeutic goods, that form part of a medicine delivery system in which the medicine is supplied in a device that acts as a container	(a) none of the goods, or any part of the goods are separately supplied in Australia; and (b) if the component and kit manufacturer are the same manufacturer and the components are not separately supplied outside the kit by the kit sponsor; and (c) if the kit sponsor or the manufacturer obtains components from other manufacturers and the kit manufacturer's licence covers quality control of those components

[28] Schedule 6, items 3, 3A and 4

omit

[29] Schedule 7, items 3 to 5

substitute

3	therapeutic devices that are not sterile and do not contain or include any sterile component or portion, other than devices mentioned in paragraph (g) of item 3 in Part 1 of Schedule 3

[30] Schedule 7, item 13

substitute

13	disinfectants

[31] Schedule 9, Part 2, after item 2A

insert

2AB	Application fee for the variation of entry of a kind of IVD medical device in the Register because the entry contains incomplete or incorrect information	340

[32] Schedule 10, Part 1, heading

substitute

Part 1 Evaluation by the Office of Prescription Medicines

[33] Schedule 10, Part 1, item 14

omit

Drug Safety and Evaluation Branch

insert

Office of Prescription Medicines

[34] Schedule 10, Part 1, item 16

omit

[35] Schedule 10, Part 2, item 3

omit

Complementary Medicines Section

insert

Office of Complementary Medicines

[36] Schedule 10, Part 3, heading

substitute

Part 3 Evaluation by Office of Non-Prescription Medicines

[37] Schedule 10, Part 3, item 5

omit

Scheduling and Over-the-counter Drug Evaluation Section

insert

Office of Non-Prescription Medicines

[38] Schedule 11

omit

Note

1. All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.* See http://www.frli.gov.au.