



# National Health (Pharmaceuticals and Vaccines — Cost Recovery) Amendment Regulations 2010 (No. 1)<sup>1</sup>

## Select Legislative Instrument 2010 No. 294

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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 *National Health Act 1953*.

Dated 24 November 2010

QUENTIN BRYCE  
Governor-General

By Her Excellency's Command

NICOLA ROXON  
Minister for Health and Ageing

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**1 Name of Regulations**

These Regulations are the *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Amendment Regulations 2010 (No. 1)*.

**2 Commencement**

These Regulations commence on the day on which Schedule 6 to the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010* commences.

**3 Amendment of *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2009***

Schedule 1 amends the *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2009*.

**4 Transitional**

The amendments made by Schedule 1 apply to an application under Part 2 of the *National Health (Pharmaceuticals and Vaccines — Cost Recovery) Regulations 2009* made on or after the commencement of these Regulations.

**Schedule 1 Amendments**

(regulation 3)

**[1] Subparagraph 2.4 (1) (a) (i)**

*omit*

2.12

*insert*

2.5A

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**[2] Paragraph 2.4 (2) (a)**

*omit*

drug, special pharmaceutical product

*insert*

drug

**[3] Subparagraph 2.7 (2) (a) (i)**

*omit*

2.9, 2.11 or 2.14

*insert*

2.9 or 2.11

**[4] Subregulation 2.8 (1)**

*omit*

2.12

*insert*

2.5A

**[5] Subparagraph 2.8 (2) (b) (i)**

*omit*

drug, special pharmaceutical product

*insert*

drug

**[6] Regulation 2.9**

*omit*

or 3.2

**[7] Paragraph 2.12 (1) (a)**

*omit*  
or 2.13

**[8] Subregulation 2.12 (2)**

*omit*  
2.12  
*insert*  
2.5A

**[9] Paragraph 2.12 (2) (a)**

*omit*  
drug, a special pharmaceutical product  
*insert*  
drug

**[10] Regulation 2.13**

*omit*  
or 3.2

**[11] Regulation 2.14**

*omit*  
or 3.2

**[12] Paragraph 2.16 (2) (b)**

*omit*  
or 3.2

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**[13] Subparagraph 3.1 (b) (iii)**

*omit*

Act; or

*insert*

Act.

**[14] Subparagraph 3.1 (b) (iv), including the note**

*substitute*

*Note* There are no fees payable under these Regulations for price agreements and determinations being made as a result of applications in the *new brand of existing pharmaceutical item* evaluation category.

**[15] Paragraph 3.3 (1) (b)**

*omit*

drug, a special pharmaceutical product

*insert*

drug

**[16] Subparagraph 3.3 (2) (a) (ii)**

*omit*

**[17] Paragraph 3.3 (3) (a)**

*omit*

drug, a special pharmaceutical product

*insert*

drug

**[18] Subparagraph 3.4 (b) (i)**

*omit*

drug, special pharmaceutical product, or

*insert*

drug or a

**[19] Paragraph 3.6 (a)**

*omit*

drug, a special pharmaceutical product

*insert*

drug

**[20] Subparagraph 3.8 (1) (a) (i)**

*omit*

3.1 (b) (i), (iii) or (iv)

*insert*

3.1 (b) (i) or (iii)

**[21] Paragraph 4.3 (1) (b)**

*omit*

85 (2A)

*insert*

85 (7)

**[22] Regulation 4.3, note**

*substitute*

*Note* See the Independent Review (PBS) website at <http://www.independentreviewpbs.gov.au>.

**[23] Paragraph 5.1 (1) (h)***omit*

85 (2AA)

*insert*

101 (4AAA)

**[24] Paragraph 5.1 (1) (i)***omit*

85 (2A)

*insert*

101 (4AAA)

**[25] Schedule 1, items 2.1 and 2.2***after*

Act

*insert*

and, if applicable, subsection 85 (2A) of the Act

**[26] Schedule 1, items 2.3 and 2.4***omit*

85 (2A)

*insert*

85 (7) or paragraph 85 (8) (b)

**[27] Schedule 1, item 2.5***substitute*

2.5 To determine, or vary a determination about:

- (a) a form of a listed drug under subsection 85 (3) of the Act;  
or
- (b) the manner of administration of a form of a listed drug under subsection 85 (5) of the Act

2.5A To determine, or vary a determination, that a pharmaceutical benefit (other than a pharmaceutical benefit that has a drug covered by subsection 85 (2A) of the Act) can only be supplied under special arrangements under section 100 of the Act

**[28] Schedule 1, item 2.8**

*after*

93

*insert*

or 93AA

**[29] Schedule 1, item 2.9**

*substitute*

2.9 To make or vary a special arrangement under section 100 of the Act to provide for the supply of pharmaceutical benefits

**[30] Schedule 1, items 2.10 and 2.11**

*omit*

special pharmaceutical product

*insert*

pharmaceutical benefit

**[31] Schedule 1, items 2.12, 2.13 and 2.14**

*omit*

**[32] Schedule 1, after item 2.16**

*insert*

2.17 To revoke or vary a declaration under subsection 85 (2A) of the Act so that a listed drug is generally available for supply under Part VII of the Act rather than available only under special arrangements under section 100 of the Act



**[33] Schedule 1, Part 3 heading**

*substitute*

**Part 3 Existing pharmaceutical items**

**[34] Schedule 1, item 3.2**

*omit*

**[35] Schedule 2, item 1**

*omit*

or a special pharmaceutical product

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**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>.