



# **National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023**

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I, General the Honourable David Hurley AC DSC (Retd), Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 19 June 2023

David Hurley  
Governor-General

By His Excellency's Command

Mark Butler  
Minister for Health and Aged Care

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## 1 Name

This instrument is the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023*.

## 2 Commencement

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

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 July 2023.	1 July 2023

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

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

## 3 Authority

This instrument is made under the *National Health Act 1953*.

## 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

## Schedule 1—Amendments

### *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Regulations 2022*

#### 1 Subsection 7(2)

Omit “177,830”, substitute “212,790”.

#### 2 Subsection 7(2)

Omit “420”, substitute “430”.

#### 3 Subsection 8(4)

Omit “101,520”, substitute “117,390”.

#### 4 Subsection 8(4)

Omit “420”, substitute “430”.

#### 5 Subsection 12(4)

Omit “420”, substitute “430”.

#### 6 Section 14 (table item 1)

Omit “14,980”, substitute “15,440”.

#### 7 Section 14 (table item 2)

Omit “20,360”, substitute “20,980”.

#### 8 Subsection 22(2) (table)

Repeal the table, substitute:

Fees and deposits for providing submission services			
	Column 1	Column 2	Column 3
Item	Evaluation categories of submissions	Fee (\$)	Deposit (\$)
1	Category 1	252,540	430
2	Category 2	197,930	430
3	Category 3	42,890	430
4	Category 4	33,370	430
5	Committee Secretariat category	11,990	430
6	New brand or new oral form of existing pharmaceutical item category	6,410	0
7	Standard re-entry pathway category	195,820	430
8	Early re-entry pathway category	41,470	430
9	Early resolution pathway category	41,620	430
10	Facilitated resolution pathway category	269,450	72,440

**9 Subsection 22(2) (note 4)**

Omit “420”, substitute “430”.

**10 Subsection 35(6)**

Omit “420”, substitute “430”.

**11 Subsection 41(1) (table item 1)**

Omit “135,690”, substitute “140,280”.

**12 Subsection 41(1) (table item 2)**

Omit “107,480”, substitute “111,200”.

**13 Subsection 41(1) (table item 3)**

Omit “71,110”, substitute “73,780”.

**14 Subsection 41(1) (table item 4)**

Omit “19,070”, substitute “20,050”.

**15 Subsection 41(1) (table item 5)**

Omit “11,650”, substitute “12,430”.

**16 Subsection 41(2)**

Omit “420”, substitute “430”.

**17 Paragraph 41(3)(a)**

Omit “127,895”, substitute “131,640”.

**18 Paragraph 41(3)(b)**

Omit “99,685”, substitute “102,560”.

**19 Paragraph 41(3)(c)**

Omit “63,315”, substitute “65,140”.

**20 Subsection 51(5)**

Omit “420”, substitute “430”.

**21 Subsection 56(1) (table)**

Repeal the table, substitute:

<b>Fees for providing list management services</b>		
	<b>Column 1</b>	<b>Column 2</b>
<b>Item</b>	<b>Powers of Minister under the Act</b>	<b>Fee (\$)</b>
1	Power under: (a) subsection 85AD(1) (about price agreements) of the Act; or (b) section 85B (about price determinations) of the Act; relating to a listed brand of a pharmaceutical item if subsection (2) of this section applies	4,980

<b>Fees for providing list management services</b>		
<b>Column 1</b>		<b>Column 2</b>
<b>Item</b>	<b>Powers of Minister under the Act</b>	<b>Fee (\$)</b>
2	Power under subsection 85E(1) of the Act (as affected by subsection 33(3) of the <i>Acts Interpretation Act 1901</i> ) to vary a deed entered into under subsection 85E(1) of the Act	1,990
3	Power under subsection 85E(1) of the Act to enter into a deed with a person replacing an expired deed entered into with the person under that subsection	10,820
4	Power under any of the following provisions of the Act (relating to pricing): (a) subsection 99ACB(6A); (b) subsection 99ACBA(1); (c) subsection 99ACC(5C); (d) subsection 99ACD(7A); (e) subsection 99ACEA(1); (f) subsection 99ACF(3); (g) subsection 99ACR(6); (h) subsection 99ADHB(6)	6,910
5	Power under subsection 99AEKC(2) of the Act to determine an applicable quantity of a brand of a pharmaceutical item	4,880

**22 Subsection 60(2)**

Omit “8,215”, substitute “8,640”.

**23 At the end of Part 9**

Add:

**Division 3—Amendments made by the National Health  
(Pharmaceuticals and Vaccines—Cost Recovery)  
Amendment (Fees) Regulations 2023**

**86 Application provision for the *National Health (Pharmaceuticals and  
Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023***

- (1) The amendments of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2023* apply in relation to the following:
  - (a) if a notice of intent in relation to an application or a submission for the provision of services is not required—an application or a submission (including a remade application or submission) that is received by the Department on or after 1 July 2023;
  - (b) in any other case—an application or a submission (including a remade application or submission) for the provision of services, for which a notice of intent is given on or after 1 July 2023.
- (2) In this section:
 

*services* means any of the following:

  - (a) ATAGI advice;



- (b) the service of the Department holding a pre-submission meeting with a person;
- (c) submission services;
- (d) pricing services;
- (e) list management services.