



# **National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024**

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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 20 June 2024

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 2024*.

## 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 2024.	1 July 2024

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 “212,790”, substitute “214,435”.

#### 2 Subsection 7(2)

Omit “430”, substitute “455”.

#### 3 Subsection 8(4)

Omit “117,390”, substitute “118,305”.

#### 4 Subsection 8(4)

Omit “430”, substitute “455”.

#### 5 Subsection 12(4)

Omit “430”, substitute “455”.

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

Omit “15,440”, substitute “16,410”.

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

Omit “20,980”, substitute “22,290”.

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

Repeal the table, substitute:

<b>Fees and deposits for providing submission services</b>			
	<b>Column 1</b>	<b>Column 2</b>	<b>Column 3</b>
<b>Item</b>	<b>Evaluation categories of submissions</b>	<b>Fee (\$)</b>	<b>Deposit (\$)</b>
1	Category 1	264,595	455
2	Category 2	206,435	455
3	Category 3	45,155	455
4	Category 4	35,405	455
5	Committee Secretariat category	12,785	455
6	New brand or new oral form of existing pharmaceutical item category	6,830	0
7	Standard re-entry pathway category	204,245	455
8	Early re-entry pathway category	43,785	455
9	Early resolution pathway category	43,935	455
10	Facilitated resolution pathway category	280,175	72,440

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

Omit “430”, substitute “455”.

**10 Subsection 35(6)**

Omit “430”, substitute “455”.

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

Omit “140,280”, substitute “148,955”.

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

Omit “111,200”, substitute “118,005”.

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

Omit “73,780”, substitute “78,215”.

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

Omit “20,050”, substitute “21,345”.

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

Omit “12,430”, substitute “13,225”.

**16 Subsection 41(2)**

Omit “430”, substitute “455”.

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

Omit “131,640”, substitute “139,975”.

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

Omit “102,560”, substitute “109,025”.

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

Omit “65,140”, substitute “69,235”.

**20 Subsection 51(5)**

Omit “430”, substitute “455”.

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

Omit “4,980”, substitute “5,300”.

**22 Subsection 56(1) (table item 2)**

Omit “1,990”, substitute “2,060”.

**23 Subsection 56(1) (table item 3)**

Omit “10,820”, substitute “11,230”.

**24 Subsection 56(1) (table item 4)**

Omit “6,910”, substitute “7,350”.

**25 Subsection 56(1) (table item 5)**

Omit “4,880”, substitute “5,190”.

**26 Subsection 60(2)**

Omit “8,640”, substitute “8,980”.

**27 In the appropriate position in Part 9**

Insert:

**Division 4—Amendments made by the National Health  
(Pharmaceuticals and Vaccines—Cost Recovery)  
Amendment (Fees) Regulations 2024**

**87 Application provision for the *National Health (Pharmaceuticals and  
Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024***

- (1) The amendments of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2024* 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 2024;
  - (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 2024.
- (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.