



National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2025

I, the Honourable Sam Mostyn AC, Governor-General of the Commonwealth of Australia, acting with the advice of the Federal Executive Council, make the following regulations.

Dated 6 March 2025

Sam Mostyn AC
Governor-General

By Her 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 2025*.

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 2025.	1 July 2025

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 “\$214,435”, substitute “\$220,795”.

2 Subsection 7(2)

Omit “\$455”, substitute “\$465”.

3 Subsection 8(4)

Omit “\$118,305”, substitute “\$121,775”.

4 Subsection 8(4)

Omit “\$455”, substitute “\$465”.

5 Subsection 12(4)

Omit “\$455”, substitute “\$465”.

6 Section 14 (table item 1, column headed “Fee (\$)”)

Omit “16,410”, substitute “16,690”.

7 Section 14 (table item 2, column headed “Fee (\$)”)

Omit “22,290”, substitute “22,710”.

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	270,315	465
2	Category 2	210,805	465
3	Category 3	46,215	465
4	Category 4	36,015	465
5	Committee Secretariat category	12,945	465
6	New brand or new oral form of existing pharmaceutical item category	6,930	0
7	Standard re-entry pathway category	208,465	465
8	Early re-entry pathway category	44,715	465
9	Early resolution pathway category	44,875	465
10	Facilitated resolution pathway category	288,145	74,250

9 Subsection 22(2) (note 4)

Omit “\$455”, substitute “\$465”.

10 Subsection 35(6)

Omit “\$455”, substitute “\$465”.

11 Subsection 35(8)

Omit “\$72,440”, substitute “\$74,250”.

12 Subsection 41(1) (table item 1, column 2)

Omit “148,955”, substitute “151,365”.

13 Subsection 41(1) (table item 2, column 2)

Omit “118,005”, substitute “119,975”.

14 Subsection 41(1) (table item 3, column 2)

Omit “78,215”, substitute “79,515”.

15 Subsection 41(1) (table item 4, column 2)

Omit “21,345”, substitute “21,665”.

16 Subsection 41(1) (table item 5, column 2)

Omit “13,225”, substitute “13,415”.

17 Subsection 41(2)

Omit “\$455”, substitute “\$465”.

18 Paragraph 41(3)(a)

Omit “\$139,975”, substitute “\$142,165”.

19 Paragraph 41(3)(b)

Omit “\$109,025”, substitute “\$110,775”.

20 Paragraph 41(3)(c)

Omit “\$69,235”, substitute “\$70,315”.

21 Paragraph 41(3)(d)

Omit “\$455”, substitute “\$465”.

22 Subsection 51(5)

Omit “\$455”, substitute “\$465”.

23 Subsection 56(1) (table item 1, column 2)

Omit “5,300”, substitute “5,370”.

24 Subsection 56(1) (table item 2, column 2)

Omit “2,060”, substitute “2,110”.

25 Subsection 56(1) (table item 3, column 2)

Omit “11,230”, substitute “11,510”.

26 Subsection 56(1) (table item 4, column 2)

Omit “7,350”, substitute “7,470”.

27 Subsection 56(1) (table item 5, column 2)

Omit “5,190”, substitute “5,270”.

28 Subsection 60(2)

Omit “\$8,980”, substitute “\$9,200”.

29 At the end of Part 9

Add:

**Division 6—Amendments made by the National Health
(Pharmaceuticals and Vaccines—Cost Recovery)
Amendment (Fees) Regulations 2025**

**90 Application provision for the *National Health (Pharmaceuticals and
Vaccines—Cost Recovery) Amendment (Fees) Regulations 2025***

- (1) The amendments of this instrument made by the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Fees) Regulations 2025* 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 2025;
 - (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 2025.

- (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.