



National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) 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 20 February 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 (Administrative Arrangements) 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 March 2025.	1 March 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 41(2)

Omit “subsections 49(3) and 51(2) (about refunds excluding deposits)”, substitute “subsection 51(2) (about a refund excluding a deposit)”.

2 Subsection 41(3)

After “purposes of”, insert “subsection 49(3) (about a refund excluding a deposit) and”.

3 At the end of subsection 41(3)

Add:

; and (d) the fee prescribed by item 4 or 5 of the table in subsection (1) of this section includes a deposit of \$455.

4 Subsection 49(3)

Omit “deposit referred to in subsection 41(2)”, substitute “relevant deposit referred to in subsection 41(3)”.

5 Paragraphs 51(2)(b), (3)(b) and (4)(b)

Omit “10 business days”, substitute “30 business days”.

6 Section 66 (at the end of the paragraph beginning “The Secretary may”)

Add:

The Secretary may seek further information from the person who made the request to assist the Secretary to decide whether to waive the fee.

7 At the end of section 68

Add:

(5) The Secretary may, by written notice given to the person who made the request, seek further information from the person to assist the Secretary to decide under subsection (1) whether to waive one or more fees.

8 At the end of section 69

Add:

(5) The Secretary may, by written notice given to the person who made the request, seek further information from the person to assist the Secretary to decide under subsection (1) whether to waive the fee.

9 At the end of Part 9

Add:

**Division 5—Amendments made by the National Health
(Pharmaceuticals and Vaccines—Cost Recovery)
Amendment (Administrative Arrangements)
Regulations 2025**

88 Definitions for this Division

In this Division:

amending regulations means the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025*.

commencement day means the day the amending regulations commence.

89 Application provision for the *National Health (Pharmaceuticals and Vaccines—Cost Recovery) Amendment (Administrative Arrangements) Regulations 2025*

- (1) The amendments of sections 41 and 49 made by the amending regulations apply in relation to the refund of a fee amount paid for the provision of pricing services in response to a proposed pricing application for which a notice of intent is given on or after the commencement day.
- (2) The amendments of section 51 made by the amending regulations apply in relation to the withdrawal of:
 - (a) a notice of intent (in relation to a proposed pricing application) that is given on or after the commencement day; or
 - (b) a pricing application that is received by the Department on or after the commencement day.
- (3) The amendment of section 68 made by the amending regulations applies in relation to a request to waive a fee that is made in:
 - (a) an ATAGI application, submission or pricing application that is received by the Department on or after the commencement day; or
 - (b) a notice of intent (in relation to a proposed ATAGI application, submission or pricing application) that is given on or after the commencement day.
- (4) The amendment of section 69 made by the amending regulations applies in relation to a request to waive a fee that is included in a list management application that is received by the Department on or after the commencement day.