

PB 114 of 2025

National Health (Originator Brand) Determination 2025

National Health Act 1953

I, Rebecca Richardson, Assistant Secretary, PBS Listing, Pricing and Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this determination under subsection 99ADB(6B) of the *National Health Act 1953*.

Dated 17 September 2025

REBECCA RICHARDSON Assistant Secretary PBS Listing, Pricing and Policy Branch Technology Assessment and Access Division Department of Health, Disability and Ageing

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Schedule 1—Originator Brand

1 Name

- (1) This instrument is the National Health (Originator Brand) Determination 2025.
- (2) This instrument may also be cited as PB 114 of 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 October 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Note: This table relates only to the provisions of this instrument as originally made.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 Repeal

The National Health (Originator Brand) Determination 2015 (PB 100 of 2015) is repealed.

4 Authority

This instrument is made under subsection 99ADB(6B) of the National Health Act 1953.

5 Definitions

Note: A number of expressions used in this instrument are defined in section 84 of the Act, including the following:

- (a) brand
- (b) exempt item
- (c) pharmaceutical item

In this instrument:

Act means the National Health Act 1953.

6 Originator Brand

- (1) For subsection 99ADB(6B) of the Act, unless subsections (2) or (3) of this section apply, an originator brand specified in column 3 of an item in Schedule 1 is an originator brand for all brands of pharmaceutical item containing the drug specified in column 2 of the same item in Schedule 1.
- (2) Where a manner of administration is specified in column 4 of an item in Schedule 1, an originator brand specified in column 3 of that item in Schedule 1 is an originator brand for all brands of pharmaceutical item containing the drug specified in column 2, with the manner of administration specified in column 4 of the same item in Schedule 1.
- (3) Where a form is specified in column 5 of an item in Schedule 1, an originator brand specified in column 3 of that item in Schedule 1 is an originator brand for all brands of pharmaceutical item containing the drug specified in column 2, with the manner of administration specified in column 4 and the form specified in column 5 of the same item in Schedule 1.

Note: A brand of an exempt item is not an originator brand due to section 99ADA of the Act.