EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION (No. 9) 2026

PB 122 of 2026

Authority

This legislative instrument, made under section 85B of the *National Health Act 1953* (the Act), amends the *National Health (Price and Special Patient Contribution) Determination 2022* (PB 98 of 2022) (the Principal Determination).

Subsections 85B(2), (3) and (4) of the Act provide for the Minister to determine, respectively, determined prices, claimed prices and the circumstances in which the Commonwealth will pay a special patient contribution. The Principal Determination contains determinations of these matters.

Variation and revocation

Unless there is an express power to revoke or vary PB 98 of 2022 cited in this instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 98 of 2022.

Purpose

The Act provides for the Minister and the responsible persons to agree a price that is taken to be the appropriate maximum price of a brand of a pharmaceutical item for the purposes of Part VII of the Act (section 85AD). Section 85B of the Act applies if the Minister and the responsible person have been unable to reach an agreement on a price for the *pricing quantity*. Whether or not an agreement is made for the *pricing quantity*, section 85B also applies if the responsible person is dissatisfied with the *proportional ex-manufacturer prices* that will apply to other *pack quantities*.

Subsection 85B(2) provides that the Minister may determine, by reference to the *pricing quantity* of a brand of a pharmaceutical item, an amount that is taken to be the appropriate maximum price of the brand for the purposes of Part VII of the Act. This is termed the 'Determined Price' in this Determination.

Subsection 85B(3) provides that the Minister may determine, by reference to a *pack quantity* of a brand of the pharmaceutical item, an amount that is taken to be the price claimed by the responsible person for the *pack quantity* of the brand, for the purposes of Part VII of the Act. This is termed the 'Claimed Price' in this Determination.

The Determined Price is the *Approved Ex-Manufacturer Price (AEMP)* and is used as the basis for working out the Commonwealth price for the brand of the pharmaceutical item (section 98B of the Act); for *pack quantities* other than the *pricing quantity*, the *proportional ex-manufacturer price (PEMP)* is used as the basis. Approved pharmacists are entitled to receive a payment from the Commonwealth equal to the Commonwealth price less the applicable patient co-payment (section 99 of the Act).

The difference between the responsible person's Commonwealth price for a *pack quantity* (i.e., the price that would be the Commonwealth price if the responsible persons' claimed price had become the *approved ex-manufacturer price* or the *proportional ex-manufacturer price* for that *pack quantity*) and the Commonwealth price for the *pack quantity* is defined in subsection 85B(5) of the Act as the *special patient contribution*. An approved pharmacist

Authorised Version Explanatory Statement registered 29/09/2026 to F2026L01321

may charge a patient an amount equal to the special patient contribution, in addition to any other amount that may be charged (subsection 87(2A) of the Act).

Subsection 85B(4) of the Act provides that the Minister may determine the circumstances in which the Commonwealth is to pay the Special Patient Contribution for a brand. In such cases, the Commonwealth payment to the pharmacist is increased by the amount of the special patient contribution (subsection 99(2AA) of the Act) and the pharmacist may not charge the patient this amount (subsection 87(2A) of the Act).

The purpose of making subsection 85B(4) determinations is to enable patients for whom the base-priced brands (the ones without a special patient contribution) are not suitable, to obtain the higher priced brand (the one with the special patient contribution) without the need to pay the higher price. In such cases the Commonwealth pays the special patient contribution.

This instrument (the Amending Determination) amends the Principal Determination by reinstating the brand premium at a higher price for one brand of one pharmaceutical item on the PBS due to the request by the responsible person.

In addition, this instrument amends the Principal Determination by removing the brand premium for one brand of one pharmaceutical item due to the supply shortage of the premium-free alternative brand on the PBS, and reinstating the brand premium for one brand of one pharmaceutical item due to the resolved shortage of the premium-free alternative brand on the PBS. This is consistent with the department’s policy that pharmaceutical companies are only able to charge brand premiums where there is at least one premium-free brand of the same medicine available on the PBS to allow equitable access to medicines.

This instrument also amends the Principal Determination by removing the brand premiums and claimed prices for two brands of three pharmaceutical items, and adjusting the brand premiums to a lower price for three brands of three pharmaceutical items to maintain their existing claimed prices following approval of the responsible persons' price increase requests.

Furthermore, the instrument amends the Principal Determination by reducing the claimed prices and brand premiums for ten pharmaceutical items due to price disclosure reductions.

The amendments provided by this instrument take effect on 1 October 2026.

Consultation

This Determination affects certain responsible persons with medicines listed on the PBS. Before a pharmaceutical benefit is listed on the PBS, and from time to time thereafter, price negotiations occur between the responsible person and the Minister for the purpose of reaching a price agreement for section 85AD of the Act. If the Minister and the responsible person do not agree on a price, further consultation occurs with the responsible person, and thereafter the Minister determines the price that will be the approved ex-manufacturer price for the brand. The Minister also determines the corresponding price claimed by the responsible persons which is used to calculate the special patient contribution that will apply to the brand.

The responsible person affected by this Determination for reinstating the brand premium at a higher price for tamoxifen made a submission about the claimed price the Minister should determine in relation to their brand. For the following brand, the claimed prices and brand premiums will be reinstated at an increased amount, consistent with the request made by the responsible person:

- Tamoxifen
    - tablet 20 mg (as citrate), Nolvadex-D

For the following brands, the claimed prices are amended to reflect the reduced brand premiums due to the application of subsection 99ADH(3) of the Act as a result of price disclosure:

- Cefuroxime
    - tablet 250 mg (as axetil), Zinnat
- Desvenlafaxine
    - tablet (extended release) 100 mg (as succinate), Pristiq
- Levothyroxine
    - tablet containing 50 micrograms anhydrous levothyroxine sodium, Oroxine
    - tablet containing 75 micrograms anhydrous levothyroxine sodium, Oroxine
    - tablet containing 100 micrograms anhydrous levothyroxine sodium, Oroxine
    - tablet containing 200 micrograms anhydrous levothyroxine sodium, Oroxine
- Olanzapine
    - tablet 7.5 mg, Zyprexa
    - tablet 10 mg, Zyprexa
- Olmesartan with amlodipine
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate), Sevikar 40/5
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate), Sevikar 40/10

For the brand Caduet 5/40, the claimed price and brand premium will be removed due to the shortage of the premium-free alternative brand. The responsible person of this brand agreed to the removal of the brand premium. No additional consultation with experts was undertaken regarding this Determination because consultation with the affected responsible person, which informed the making of this Determination, drew on the knowledge of persons with relevant expertise.

For both strengths of the brand Ventolin Nebules, and the brand Tegretol 200, the responsible person agreed to remove the claimed price following approval of their AEMP increase requests. As a result, no brand premium will be charged to patients.

For the brands Tegretol 100, Cosopt and Indocid, the brand premiums have been adjusted to a lower price at the request of the responsible persons to maintain the existing claimed prices following approval of the requested AEMP increases.

For the Plendil ER brand of felodipine, tablet 2.5 mg (extended release), its brand premium was removed on 1 June 2026 at the department's request due to the shortage of the premium-free alternative brands available on the PBS. As the shortage of the premium-free alternative brands has resolved, the responsible person has been notified that the brand premium will be reinstated on 1 October 2026.

A provision by description of the Determination is contained in the Attachment.

This Determination commences on 1 October 2026.

This Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

Authorised Version Explanatory Statement registered 29/09/2026 to F2026L01321

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION (No. 9) 2026*

(PB 122 of 2026)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination (No. 9) 2026* and may also be cited as PB 122 of 2026.

Section 2 Commencement

This section provides that the Determination commences on 1 October 2026.

Section 3 Authority

This section states that this instrument is made under section 85B of the *National Health Act 1953.*

Section 4 Schedules

Section 4 provides that each instrument is specified in a Schedule to the instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the instrument has effect according to its terms.

Schedule 1 Amendments

Amendment of the *National Health (Price and Special Patient Contribution) Determination 2022* (PB 98 of 2022).

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 October 2026. These changes are detailed in the summary of changes below.

Authorised Version Explanatory Statement registered 29/09/2026 to F2026L01321

SUMMARY OF CHANGES
SCHEDULE 1

Brands reinstated with increased brand premiums

- Tamoxifen
    - tablet 20 mg (as citrate), Nolvadex-D

Brands with reduced brand premiums

- Carbamazepine
    - tablet 100 mg, Tegretol 100
- Cefuroxime
    - tablet 250 mg (as axetil), Zinnat
- Desvenlafaxine
    - tablet (extended release) 100 mg (as succinate), Pristiq
- Dorzolamide with timolol
    - eye drops containing dorzolamide 20 mg (as hydrochloride) with timolol 5 mg (as maleate) per mL, 5 mL, Cosopt
- Indometacin
    - capsule 25 mg, Indocid
- Levothyroxine
    - tablet containing 50 micrograms anhydrous levothyroxine sodium, Oroxine
    - tablet containing 75 micrograms anhydrous levothyroxine sodium, Oroxine
    - tablet containing 100 micrograms anhydrous levothyroxine sodium, Oroxine
    - tablet containing 200 micrograms anhydrous levothyroxine sodium, Oroxine
- Olanzapine
    - tablet 7.5 mg, Zyprexa
    - tablet 10 mg, Zyprexa
- Olmesartan with amlodipine
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate), Sevikar 40/5
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate), Sevikar 40/10

Brands with removed brand premiums

- Amlodipine with atorvastatin
    - amlodipine (as besilate) with 40 mg atorvastatin (as calcium), Caduet 5/40
- Carbamazepine
    - tablet 200 mg, Tegretol 200
- Salbutamol
    - nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 20, Ventolin Nebules
    - nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 20, Ventolin Nebules

Brands with reinstated brand premiums

- Felodipine
    - tablet 2.5 mg (extended release), Plendil ER

Authorised Version Explanatory Statement registered 29/09/2026 to F2026L01321

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Price and Special Patient Contribution) Amendment Determination (No. 9) 2026 (PB 122 of 2026)

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

This legislative instrument, made under section 85B of the *National Health Act 1953* (the Act), amends the *National Health (Price and Special Patient Contribution) Determination 2022* (the Principal Determination), which provides for price determinations in relation to brands of pharmaceutical items listed on the Pharmaceutical Benefits Scheme (PBS) for which the Minister and the Responsible Persons have not been able to make a price agreement. It also provides for the circumstances in which the Commonwealth will pay the special patient contribution resulting from these price determinations.

This instrument (the Amending Determination) amends the Principal Determination by reinstating the brand premium at a higher price for one brand of one pharmaceutical item on the PBS due to the request by the responsible person.

In addition, this instrument amends the Principal Determination by removing the brand premium for one brand of one pharmaceutical item due to the supply shortage of the premium-free alternative brand on the PBS, and reinstating the brand premium for one brand of one pharmaceutical item due to the resolved shortage of the premium-free alternative brand on the PBS. This is consistent with the department’s policy that pharmaceutical companies are only able to charge brand premiums where there is at least one premium-free brand of the same medicine available on the PBS to allow equitable access to medicines.

This instrument also amends the Principal Determination removing the brand premiums and claimed prices for two brands of three pharmaceutical items, and adjusting the brand premiums to a lower price for three brands of three pharmaceutical items to maintain their existing claimed prices following approval of the responsible persons' price increase requests.

Furthermore, the instrument amends the Principal Determination by reducing the claimed prices and brand premiums for ten pharmaceutical items due to price disclosure reductions.

The amendments provided by this instrument take effect on 1 October 2026.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines.

The reinstated brand premium and reinstated brand premium at a higher price for a specific brand are unlikely to result in negative financial impact for patient access as premium-free alternatives remain available on the PBS.

Authorised Version Explanatory Statement registered 29/09/2026 to F2026L01321

Eligible Australians may continue to access any one of the remaining brands for these pharmaceutical items at subsidised prices as they are flagged for substitution by pharmacists against brands with a brand premium.

All brands subsidised by the PBS are evaluated by the Therapeutic Goods Administration for quality and safety and determined to be bioequivalent, which means they are clinically equivalent and work in the same way.

The removal of the brand premium and claimed price from Caduet 5/40 was requested by the department due to supply shortage of the premium-free alternative brand. It is longstanding Government policy that pharmaceutical companies are only able to charge brand premiums where there is at least one premium-free brand of that medicine available through the PBS. This allows for continued access for eligible Australians to these remaining PBS listed brands of this medicine at subsidised prices, without the need to pay a premium.

Conclusion

This legislative instrument is compatible with human rights because it advances the protection of human rights.

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

Authorised Version Explanatory Statement registered 29/09/2026 to F2026L01321