

**EXPLANATORY STATEMENT**  
**NATIONAL HEALTH ACT 1953**  
**NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION)**  
**AMENDMENT DETERMINATION (No. 3) 2025**  
**PB 34 of 2025**

**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 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 Amendment Determination) amends the Principal Determination by increasing the brand premium 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 two brands of two pharmaceutical items due to supply shortage of the premium-free alternative brands on the PBS, and reinstating the brand premium for one brand of one pharmaceutical item due to the resolved shortage of a 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 increasing the claimed prices for four brands of seven pharmaceutical items on the PBS to account for the increased AEMP requested by the responsible persons and approved by the delegate. The increase to the claimed prices is necessary to ensure that the brand premiums of the premium brands remain unchanged with the price increases implemented. Moreover, this instrument removes the brand premium for one brand of methylphenidate due to an agreement with the responsible person to approve their price increase request.

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

The amendments provided by this instrument take effect on 1 April 2025.

## **Consultation**

This Determination affects certain responsible person 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 increasing the brand premium for olmesartan with amlodipine made a submission about the claimed price the Minister should determine in relation to their brand. For the following brand, the claimed price and brand premium will be increased for the listing of this brand consistent with the request made by the responsible person:

- Olmesartan with amlodipine
  - tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate), Sevikar 20/5

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:

- Clomipramine
  - tablet containing clomipramine hydrochloride 25 mg, Anafranil 25
- Dabigatran etexilate
  - capsule 110 mg (as mesilate), Pradaxa
  - capsule 150 mg (as mesilate), Pradaxa
- Esomeprazole and clarithromycin and amoxicillin
  - pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate), Nexium Hp7
- Exemestane
  - tablet 25 mg, Aromasin
- Lansoprazole
  - tablet 30 mg (orally disintegrating), Zoton FasTabs
- Levothyroxine
  - tablet containing 50 microgram anhydrous levothyroxine sodium, Oroxine
  - tablet containing 75 microgram anhydrous levothyroxine sodium, Oroxine
  - tablet containing 100 microgram anhydrous levothyroxine sodium, Oroxine
  - tablet containing 200 microgram anhydrous levothyroxine sodium, Oroxine
- Mefenamic acid
  - capsule 250 mg, Ponstan
- Perindopril
  - tablet containing perindopril arginine 10 mg, Coversyl 10mg

The responsible persons of the following brands affected by this Determination each made a submission for a price increase for their respective brand. For the following brands with brand premiums, the claimed prices will be increased to retain the current brand premium for the listing of these brands as a result of the price increase:

- Ezetimibe and rosuvastatin
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium), Rosuzet Composite Pack
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium), Rosuzet Composite Pack
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium), Rosuzet Composite Pack
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium), Rosuzet Composite Pack

- Naproxen
  - tablet containing naproxen sodium 550 mg, Anaprox 550
  - tablet 750 mg (sustained release), Naprosyn SR750
  - tablet 1 g (sustained release), Naprosyn SR1000

For the brand Ritalin 10, the responsible person agreed to remove the claimed price due to an increased AEMP for the pharmaceutical item and as a result, no brand premium will be charged to patients. 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 the brands Dothep 75 and Atozet, the claimed price and brand premium will be removed due to the shortage of the premium-free brands for dosulepin and ezetimibe with atorvastatin respectively. The responsible person of these brands agreed to the removal of the brand premiums. 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 the brand Rivotril, its brand premium was removed on 1 January 2025 at the Department's request due to the shortage of the only premium-free alternative brand available on the PBS. As the shortage of the premium-free alternative brand has resolved, the responsible person has been notified that the brand premium will be reinstated on 1 April 2025.

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

This Determination commences on 1 April 2025.

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

**PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH  
(PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT  
DETERMINATION (No. 3) 2025*  
(PB 34 of 2025)**

**Section 1 Name of Determination**

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination (No. 3) 2025* and may also be cited as PB 34 of 2025.

**Section 2 Commencement**

This section provides that the Determination commences on 1 April 2025.

**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 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 April 2025. These changes are detailed in the summary of changes below.

## **SUMMARY OF CHANGES**

### ***SCHEDULE 1***

#### **Brands with increased brand price premiums**

- Olmesartan with amlodipine
  - tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate), Sevikar 20/5

#### **Brands with reduced brand premiums**

- Clomipramine
  - tablet containing clomipramine hydrochloride 25 mg, Anafranil 25
- Dabigatran etexilate
  - capsule 110 mg (as mesilate), Pradaxa
  - capsule 150 mg (as mesilate), Pradaxa
- Esomeprazole and clarithromycin and amoxicillin
  - pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate), Nexium Hp7
- Exemestane
  - tablet 25 mg, Aromasin
- Lansoprazole
  - tablet 30 mg (orally disintegrating), Zoton FasTabs
- Levothyroxine
  - tablet containing 50 microgram anhydrous levothyroxine sodium, Oroxine
  - tablet containing 75 microgram anhydrous levothyroxine sodium, Oroxine
  - tablet containing 100 microgram anhydrous levothyroxine sodium, Oroxine
  - tablet containing 200 microgram anhydrous levothyroxine sodium, Oroxine
- Mefenamic acid
  - capsule 250 mg, Ponstan
- Perindopril
  - tablet containing perindopril arginine 10 mg, Coversyl 10mg

#### **Brands with increased claimed prices to maintain the current brand premiums due to increased determined price**

- Ezetimibe and rosuvastatin
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium), Rosuzet Composite Pack
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium), Rosuzet Composite Pack
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium), Rosuzet Composite Pack
  - pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium), Rosuzet Composite Pack
- Naproxen
  - tablet containing naproxen sodium 550 mg, Anaprox 550
  - tablet 750 mg (sustained release), Naprosyn SR750
  - tablet 1 g (sustained release), Naprosyn SR1000

**Brands with removed brand premiums**

- Dosulepin
  - tablet containing dosulepin hydrochloride 75 mg, Dothep 75
- Ezetimibe with atorvastatin
  - tablet 10 mg-20 mg, Atozet
- Methylphenidate
  - tablet containing methylphenidate hydrochloride 10 mg, Ritalin 10

**Brands with reinstated brand premiums**

- Clonazepam
  - tablet 500 micrograms, Rivotril

## 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. 3) 2025 (PB 34 of 2025)**

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 Amendment Determination) amends the Principal Determination by increasing the brand premium of one brand of a pharmaceutical item as requested by the responsible person, removing the brand premium for two brands of two pharmaceutical items due to supply shortage of the premium-free alternative brands on the PBS, and reinstating the brand premium for one brand of one pharmaceutical item due to the resolved shortage of a premium-free alternative brand on the PBS. This instrument also amends the Principal Determination by increasing the claimed prices for four brands of seven pharmaceutical items on the PBS, such that the brand premiums remain unchanged with the increased AEMPs implemented as requested by the responsible persons and approved by the delegate. Moreover, this instrument removes the brand premium for one brand of methylphenidate due to an agreement with the responsible person to approve their price increase request.

Additionally, this instrument amends the Principal Determination by reducing the claimed price and brand premiums for twelve pharmaceutical items due to price disclosure reductions.

These changes take effect on 1 April 2025.

#### **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 increased brand premium for a specific brand is unlikely to result in negative financial impact for patient access as premium-free alternatives remain available on the PBS.

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.

The removal of the brand premium and claimed price from the brands Atozet and Dothep 75 was requested consistent with the longstanding Government policy that pharmaceutical companies are only able to charge brand price 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.

It is longstanding Government policy that pharmaceutical companies are only able to charge brand price premiums where there is at least one premium-free brand of that medicine available through the PBS. Changes to brand price premiums will not limit patient access to healthcare with the availability of premium-free brands on the PBS.

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. Removing items with brand price premiums will not result in negative financial impact for patients, therefore ensuring their rights to social security are maintained. The recommendatory role of the Pharmaceutical Benefits Advisory Committee ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

## **Conclusion**

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

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