EXPLANATORY STATEMENT

*NATIONAL HEALTH ACT 1953*

*NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION (No. 7) 2025*

*PB 92 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 (Determination) amends the Principal Determination by introducing the brand premium for two brands of six pharmaceutical items and increasing the brand premium for nine brands of six pharmaceutical items on the PBS due to the request by the responsible persons. In addition, this instrument amends the Principal Determination by reinstating the brand premium for two brands of two pharmaceutical items due to the resolved shortage of the premium-free alternative brands on the PBS, and by removing the brand premium from one brand of one pharmaceutical item due to the supply shortage of the only 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 alternative brand of the same medicine available on the PBS to allow equitable access to medicines.

**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 persons affected by this Determination for introducing the brand premium for gabapentin and pantoprazole each made a submission about the claimed price the Minister should determine in relation to their brands. For the following brands, the claimed price and brand premium will be introduced, consistent with the request made by the responsible persons:

* Gabapentin
	+ capsule 100 mg, Neurontin
	+ capsule 300 mg, Neurontin
	+ capsule 400 mg, Neurontin
	+ tablet 600 mg, Neurontin
* Pantoprazole
	+ tablet (enteric coated) 20 mg (as sodium sesquihydrate), Somac
	+ tablet (enteric coated) 40 mg (as sodium sesquihydrate), Somac

The responsible persons affected by this Determination for increasing the brand premium for codeine with paracetamol, irbesartan, and irbesartan with hydrochlorothiazide each made a submission about the claimed price the Minister should determine in relation to their brands. For the following brands, the claimed price and brand premium will be increased, consistent with the request made by the responsible persons:

* Codeine with paracetamol
	+ tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg, Panadeine Forte
* Irbesartan
	+ tablet 150 mg, Avapro
	+ tablet 150 mg, Karvea
	+ tablet 300 mg, Avapro
	+ tablet 300 mg, Karvea
* Irbesartan with hydrochlorothiazide
	+ tablet 150 mg-12.5 mg, Avapro HCT 150/12.5
	+ tablet 150 mg-12.5 mg, Karvezide 150/12.5
	+ tablet 300 mg-12.5 mg, Avapro HCT 300/12.5
	+ tablet 300 mg-12.5 mg, Karvezide 300/12.5
	+ tablet 300 mg-25 mg, Avapro HCT 300/25
	+ tablet 300 mg-25 mg, Karvezide 300/25

For the brand Caduet 5/40, the claimed price and brand premium will be removed due to the supply shortage of the only premium-free alternative brand of amlodipine with atorvastatin 10 mg-40 mg tablets on the PBS. The responsible person of this brand has 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 the brands Atozet (ezetimibe with atorvastatin, tablet 10 mg-40 mg) and Dothep 75 (tablet containing dosulepin hydrochloride 75 mg), the brand premiums were removed on 1 December 2024 and 1 April 2025 respectively 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 persons have been notified that the brand premium will be reinstated on 1 August 2025.

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

This Determination commences on 1 August 2025.

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

ATTACHMENT

**PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2025 (No .7)***

***(PB 92 of 2025)***

**Section 1 Name of Determination**

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2025 (No. 7)* and may also be cited as PB 92 of 2025.

**Section 2 Commencement**

This section provides that the Determination commences on 1 August 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 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 August 2025. These changes are detailed in the summary of changes below.

**SUMMARY OF CHANGES**

***SCHEDULE 1***

**Brands with introduced brand premiums**

* Gabapentin
	+ capsule 100 mg, Neurontin
	+ capsule 300 mg, Neurontin
	+ capsule 400 mg, Neurontin
	+ tablet 600 mg, Neurontin
* Pantoprazole
	+ tablet (enteric coated) 20 mg (as sodium sesquihydrate), Somac
	+ tablet (enteric coated) 40 mg (as sodium sesquihydrate), Somac

**Brands with increased brand premiums**

* Codeine with paracetamol
	+ tablet containing codeine phosphate hemihydrate 30 mg with paracetamol 500 mg, Panadeine Forte
* Irbesartan
	+ tablet 150 mg, Avapro
	+ tablet 150 mg, Karvea
	+ tablet 300 mg, Avapro
	+ tablet 300 mg, Karvea
* Irbesartan with hydrochlorothiazide
	+ tablet 150 mg-12.5 mg, Avapro HCT 150/12.5
	+ tablet 150 mg-12.5 mg, Karvezide 150/12.5
	+ tablet 300 mg-12.5 mg, Avapro HCT 300/12.5
	+ tablet 300 mg-12.5 mg, Karvezide 300/12.5
	+ tablet 300 mg-25 mg, Avapro HCT 300/25
	+ tablet 300 mg-25 mg, Karvezide 300/25

**Brands with reinstated brand premiums**

* Dosulepin
	+ tablet containing dosulepin hydrochloride 75 mg, Dothep 75
* Ezetimibe with atorvastatin
	+ tablet 10 mg-40 mg, Atozet

**Brand with removed brand premiums**

* Amlodipine with atorvastatin
	+ tablet 5 mg (as besilate) with 40 mg atorvastatin (as calcium), Caduet 5/40

**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 2025 (No. 7) (PB 92 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 (Determination) amends the Principal Determination by introducing a brand premium for two brands of six pharmaceutical items and increasing the brand premium for nine brands of six pharmaceutical items on the PBS due to the request by the responsible persons. In addition, this instrument amends the Principal Determination by reinstating the brand premium for two brands of two pharmaceutical items due to the resolved shortage of the premium-free alternative brands on the PBS. Moreover, this instrument amends the Principal Determination by removing the brand premium from one brand of one pharmaceutical item due to the supply shortage of the only premium-free alternative brand on the PBS.

These changes take effect on 1 August 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 recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The introduced, increased and reinstated 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 Caduet 5/40 requested by the department, and the reinstatement of a brand premium and claimed price for Atozet and Dothep 75 were 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.

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.

**Conclusion**

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

**Rebecca Richardson**

 **Assistant Secretary**

**PBS Listing, Pricing and Policy Branch**

**Technology Assessment and Access Division**

**Department of Health, Disability and Ageing**