

EXPLANATORY STATEMENT
NATIONAL HEALTH ACT 1953
NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION)
AMENDMENT DETERMINATION (No. 1) 2025
PB 10 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 the 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 the 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 person’s 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 (this is known as a brand price premium or brand premium) 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 Determination) amends the Principal Determination by adding a brand premium for two brands of four pharmaceutical items and increasing the brand premium for four brands of seven pharmaceutical items on the PBS due to requests by responsible persons. In addition, this instrument amends the Principal Determination by reinstating the brand premium for one brand of one pharmaceutical item due to the availability of an alternative, premium-free 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 for equitable access to medicines.

The amendments provided by this instrument take effect on 1 February 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 persons affected by this Determination for imposing the brand premiums for desvenlafaxine and ezetimibe with simvastatin each made a submission about the claimed prices the Minister should determine in relation to their brands. For the following brands, the claimed price and brand premiums will be imposed for the listing of these brands consistent with the request made by the responsible person:

- Desvenlafaxine
 - tablet (extended release) 50 mg (as succinate), Pristiq
 - tablet (extended release) 100 mg (as succinate), Pristiq
- Ezetimibe with simvastatin
 - tablet 10 mg-40 mg, Vytorin
 - tablet 10 mg-80 mg, Vytorin

The responsible persons affected by this Determination for increases to existing brand premiums for azathioprine, fluconazole, mometasone, and pregabalin, each made a submission about the claimed price the Minister should determine in relation to their brand. For the following brands, the claimed price will be increased and to give effect to increased brand premiums for the listing of these brands consistent with the request made by the responsible person:

- Azathioprine
 - tablet 25 mg, Imuran
 - tablet 50 mg, Imuran
- Fluconazole
 - capsule 100 mg, Diflucan
 - capsule 200 mg, Diflucan
- Mometasone
 - lotion containing mometasone furoate 1 mg per g, Elocon
- Pregabalin
 - capsule 75 mg, Lyrica
 - capsule 150 mg, Lyrica

For the brand Renitec Plus 20/6, the previous brand premium has been reinstated as requested by the sponsor Alphapharm Pty Ltd. The brand premium for Renitec Plus 20/6 was removed on 1 June 2022 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 reinstatement would come into effect on 1 February 2025. 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.

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

This Determination commences on 1 February 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 (No. 1) 2025* **(PB 10 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. 1) 2025* and may also be cited as PB 10 of 2025.

Section 2 Commencement

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

Section 3 Amendment of the *National Health (Price and Special Patient Contribution) Determination 2022 (PB 98 of 2022)*.

This section provides that Schedule 1 amends the *National Health (Price and Special Patient Contribution) Determination 2022 (PB 98 of 2022)*.

Schedule 1 Amendments commencing 1 February 2025

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 February 2025.

SUMMARY OF CHANGES

SCHEDULE 1

Brands with new brand price premiums

- Desvenlafaxine
 - tablet (extended release) 50 mg (as succinate), Pristiq
 - tablet (extended release) 100 mg (as succinate), Pristiq
- Ezetimibe with simvastatin
 - tablet 10 mg-40 mg, Vytorin
 - tablet 10 mg-80 mg, Vytorin

Brands with increased brand premiums

- Azathioprine
 - tablet 25 mg, Imuran
 - tablet 50 mg, Imuran
- Fluconazole
 - capsule 100 mg, Diflucan
 - capsule 200 mg, Diflucan
- Mometasone
 - lotion containing mometasone furoate 1 mg per g, Elocon
- Pregabalin
 - capsule 75 mg, Lyrica
 - capsule 150 mg, Lyrica

Brands with reinstated brand premiums

- Enalapril with hydrochlorothiazide
 - tablet containing enalapril maleate 20 mg with hydrochlorothiazide 6 mg, Renitec Plus 20/6

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. 1) 2025 (PB 10 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 amends the Principal Determination by inserting claimed prices to provide new brand premiums for four pharmaceutical items and varying the claimed prices to increase the brand premiums for seven pharmaceutical items on the PBS due to requests by responsible persons. In addition, this instrument amends the Principal Determination by reinstating the previous claimed price and brand premium for one pharmaceutical item as requested by the sponsor. The amendments provided by this instrument take effect on 1 February 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 ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The re-instatement of the claimed price and brand premium for the one brand (enalapril with hydrochlorothiazide, Renitec Plus 20/6) is unlikely to result in negative financial impact on patient access, as a premium free alternative to this brand is available and can be accessed on the PBS.

Premium-free brands are available on the PBS as alternatives to the pharmaceutical items with introduced or increase brand premiums effective on 1 February 2025. 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.

Conclusion

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

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