EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION (No. 5) 2025

PB 63 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 increasing the brand premium for six 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 removing the brand premium for one brand of one pharmaceutical item due to the delisting of the brand from the PBS as requested by the responsible person.

The amendments provided by this instrument take effect on 1 June 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 increasing the brand premium for fluticasone propionate with salmeterol and olmesartan with amlodipine and hydrochlorothiazide each made a submission about the claimed price that the Minister should determine in relation to their brand. For the following brands, the claimed price and brand premium will be increased for the listing of this brand consistent with the request made by the responsible person:

- Fluticasone propionate with salmeterol
    - pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation), Seretide MDI 125/25
    - powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses, Seretide Accuhaler 250/50
- Olmesartan with amlodipine and hydrochlorothiazide
    - tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 20/5/12.5
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 40/5/12.5

- tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg, Sevikar HCT 40/5/25
- tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg, Sevikar HCT 40/10/25

For the brand Refresh Night Time, the claimed price and brand premium will be removed due to the delisting of the brand as requested by the responsible person. 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 June 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. 5) 2025*

(PB 63 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. 5) 2025* and may also be cited as PB 63 of 2025.

Section 2 Commencement

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

SUMMARY OF CHANGES
SCHEDULE 1

Brands with increased brand price premiums

- Fluticasone propionate with salmeterol
    - pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation), Seretide MDI 125/25
    - powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses, Seretide Accuhaler 250/50
- Olmesartan with amlodipine and hydrochlorothiazide
    - tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 20/5/12.5
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 12.5 mg, Sevikar HCT 40/5/12.5
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) and hydrochlorothiazide 25 mg, Sevikar HCT 40/5/25
    - tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg, Sevikar HCT 40/10/25

Brands with removed brand premiums

- Paraffin
    - pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g, Refresh Night Time

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. 5) 2025 (PB 63 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 six brands of six pharmaceutical items as requested by the responsible persons. This instrument also amends the Principal Determination by removing the brand premium from one brand of one pharmaceutical item due to the delisting of the brand as requested by the responsible person.

These changes take effect on 1 June 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 for Refresh Night Time was due to the delisting of the brand as requested by the responsible person. A premium-free brand alternative to Refresh Night Time remains available on the PBS.

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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