

EXPLANATORY STATEMENT
NATIONAL HEALTH ACT 1953
NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION)
AMENDMENT DETERMINATION (No. 6) 2025
PB 81 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 removing the brand premium from two brands of one pharmaceutical item due to the supply issues of the only premium-free alternative brand on the PBS. In addition, this instrument amends the Principal Determination by removing the brand premium from three brands of two pharmaceutical items due to the delists of the brands from the PBS as requested by the responsible persons, and by removing the brand premium from two brands of two pharmaceutical items due to the delisting of the only premium-free alternative brand for the item on the PBS.

The amendments provided by this instrument takes effect on 1 July 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.

For the brands Aldactone and Spiractin 100, the claimed price and brand premium will be removed due to the supply issue of the only premium-free alternative brand of spironolactone 100 mg tablets on the PBS. The responsible persons of these brands have 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 Genteal gel, Imigran, and Imigran Migraine, the claimed price and brand premium will be removed from the brand consistent with the request made by the responsible persons to delist these brands from the PBS.

For the brands Atrovent and Atrovent Adult, the claimed price and brand premium will be removed due to the delisting of the only premium-free alternative brand of nebuliser solution containing ipratropium 250 micrograms and nebuliser solution containing ipratropium 500 micrograms 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.

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

This Determination commences on 1 July 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 .6)* (PB 81 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. 6)* and may also be cited as PB 81 of 2025.

Section 2 Commencement

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

SUMMARY OF CHANGES

SCHEDULE 1

Brands with removed brand premiums

- Ipratropium
 - Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, Atrovent
 - Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, Atrovent Adult
- Spironolactone
 - Tablet 100 mg, Aldactone
 - Tablet 100 mg, Spiractin 100

Deletion of brands

- Hypromellose with carbomer 980
 - Ocular lubricating gel 3 mg-2 mg per g, 10 g, Genteal gel
- Sumatriptan
 - Tablet 50 mg (as succinate), 2, Imigran
 - Tablet 50 mg (as succinate), Imigran Migraine

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. 6) (PB 81 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 removing the brand premium from two brands of one pharmaceutical item due to the supply issues of the only premium-free alternative brand on the PBS. In addition, this instrument amends the Principal Determination by removing the brand premium from three brands of two pharmaceutical items due to the delists of the brands from the PBS as requested by the responsible persons, and from two brands of two pharmaceutical items due to the delist of the only premium-free alternative brand for the item on the PBS.

These changes take effect on 1 July 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 removal of the brand premium and claimed price from the brands Atrovent, Atrovent Adult, Aldactone, Spiractin 100 was requested due to supply issues with the premium-free alternative brand. It is longstanding Government policy that pharmaceutical companies are only able to charge brand price premiums where there is at least one premium-free alternative 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.

No brands will remain PBS listed for hypermellose with carbomer 980 ocular lubricating gels following the deletion of Genteal gel. This is because the only premium-free alternative brand, HPMC PAA, will also be delisting from the PBS at the same time as Genteal gel. The PBAC considered the delist of both brands at its July 2024 meeting and advised that there

were therapeutic alternatives that remain on PBS for the same listed indications as Genteal gel and HPMC PAA.

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. 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.

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