

EXPLANATORY STATEMENT
NATIONAL HEALTH ACT 1953
NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION)
AMENDMENT DETERMINATION 2024 (No. 9)
PB 120 of 2024

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 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 removing the brand premiums from three brands of four pharmaceutical items that are delisting from the PBS as requested by the responsible person. In addition, this instrument amends the Principal Determination by increasing the claimed price and brand premium for two brands of olmesartan with amlodipine to correct the administrative error that occurred on the previous month during the scheduled price disclosure reductions.

The Determination also updates the pricing for two brands of diltiazem to align with the reduced prices provided under subsections 99ADH(3) and (4) of the Act as a result of price disclosure. In accordance with price disclosure requirements, the determined prices and claimed prices were reduced under the Act on 1 October 2024 and reduced brand premiums have been paid by patients since that date.

The amendments provided by this instrument take effect on 1 November 2024.

Consultation

The Determination affects certain responsible persons 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 pharmaceutical items affected by the Determination for reductions to the existing brand premiums for olmesartan with amlodipine. The responsible person had been informed and agreed to the brand premium reduction due an administrative error. The error is rectified. For the following brands, the claimed price will be reduced to give effect to reduced brand premiums:

- Olmesartan with amlodipine
 - tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate), Sevikar 20/5
 - tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate), Sevikar 40/10

For the brand Cardizem CD, the pharmaceutical item was misdescribed in the *National Health (Price and Special Patient Contribution) Amendment Determination 2024 (No. 8)* as ‘diltiazem hydrochlorothiazide’ instead of ‘diltiazem hydrochloride’ and this has been addressed by this Determination.

For the brands Accupril, Karvea, and Movicol, the claimed prices and brand premiums will be removed from the brands consistent with the request made by the responsible person to delist the brands from the PBS.

No additional consultation with experts was undertaken regarding the Determination because consultation with the affected responsible person, which informed the making of the Determination, drew on the knowledge of person with relevant expertise.

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

This Determination commences on 1 November 2024.

The 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 2024 (No. 9)* (PB 120 of 2024)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2024 (No. 9)* and may also be cited as PB 120 of 2024.

Section 2 Commencement

This section provides that the Determination commences on 1 November 2024.

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 November 2024

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 November 2024.

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
 - tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate), Sevikar 40/10

Deletion of brands

- Irbesartan
 - tablet 75 mg, Karvea
- Macrogol 3350
 - sachets containing powder for oral solution 13.125 g with electrolytes, 30, Movicol
- Quinapril
 - tablet 10 mg (as hydrochloride), Accupril
 - tablet 20 mg (as hydrochloride), Accupril

Brands with reduced price premiums*

- Diltiazem
 - capsule (controlled delivery) containing diltiazem hydrochloride 180 mg, Cardizem CD
 - capsule (controlled delivery) containing diltiazem hydrochloride 240 mg, Cardizem CD
 - capsule (controlled delivery) containing diltiazem hydrochloride 360 mg, Cardizem CD

*Note: the brand premium reductions for the brand Cardizem CD have been in effect since 1 October 2024, the amendments in the Instrument are intended to reflect the price changes that have already occurred as a result of price disclosure requirements that have applied under subsections 99ADH(3) and (4) on 1 October 2024.

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 2024 (No. 9) (PB 120 of 2024)

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 removing the brand premiums for four pharmaceutical items on the PBS due to requests by responsible person. In addition, this instrument amends the Principal Determination by increasing the claimed price and brand premium for two brands of two pharmaceutical items to correct the administrative error due to the scheduled price disclosure reductions. These changes take effect on 1 November 2024.

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. Deletion of the above listed brands, by way of the Determination, are unlikely to result in negative financial impact on patient access, therefore ensuring their rights to social security are maintained.

Eight premium-free brands remain PBS listed for irbesartan following the deletion of Karvea. Five premium-free brands remain PBS listed for macrogol 3350 following the deletion of Movicol. Two premium-free brands remain PBS listed for quinapril following the deletion of Accupril.

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.

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.

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 Instrument is compatible with human rights because it advances the protection of human rights.

Nikolai Tsyganov
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care