EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2024 (No. 6)

PB 82 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 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 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.

The instrument (the Amendment Determination) amends the Principal Determination by adding a brand premium for four pharmaceutical items as requested by the responsible persons, increasing the brand premium for four pharmaceutical items as requested by the responsible person. 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 August 2024.

Consultation

This 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.

For the brands Aldomet and Sevikar HCT 20/5/12.5, the previous claimed prices will be applied to re-instate the brand premiums as requested by the sponsors Aspen Pharmacare Australia Pty Ltd and Alphapharm Pty Ltd respectively. The sponsors agreed to the re-instatement of the claimed prices and brand premiums for the brands Aldomet and Sevikar HCT 20/5/12.5 effective 1 August 2024. 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.

The responsible person affected by this Determination for imposing the brand premiums for pregabalin made a submission about the claimed price the Minister should determine in relation to their brand. For the following brands, the claimed price and brand premium will be imposed for the listing of these brands consistent with the request made by the responsible person:

- Pregabalin
    - capsule 75 mg, Lyrica

    - capsule 150 mg, Lyrica

The responsible persons affected by this Determination for increases to existing brand premiums for fluconazole, salbutamol, and sertraline, 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:

- Fluconazole
    - capsule 50 mg, Diflucan
- Salbutamol
    - pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation), Ventolin CFC-Free with dose counter
- Sertraline
    - tablet 50 mg (as hydrochloride), Zoloft
    - tablet 100 mg (as hydrochloride), Zoloft

No additional consultation with experts was undertaken regarding this Determination because consultation with 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 August 2024.

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 2024 (No .6)*

(PB 82 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. 6)* and may also be cited as PB 82 of 2024.

Section 2 Commencement

This section provides that the Determination commences on 1 August 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 August 2024

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

SUMMARY OF CHANGES
SCHEDULE 1

Brands with new brand price premiums

- Pregabalin
    - capsule 75 mg, Lyrica
    - capsule 150 mg, Lyrica

Brands with increased brand price premiums

- Fluconazole
    - capsule 50 mg, Diflucan

- Salbutamol
    - pressurised inhalation 100 micrograms (as sulfate) per dose with dose counter, 200 doses (CFC-free formulation), Ventolin CFC-Free with dose counter

- Sertraline
    - tablet 50 mg (as hydrochloride), Zoloft
    - tablet 100 mg (as hydrochloride), Zoloft

Brands with a re-instated brand premiums

- Methyldopa
    - tablet 250 mg (as sesquihydrate), Aldomet
- 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

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. 6) (PB 82 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 inserting claim prices to provide new brand premiums for two pharmaceutical items and varying claimed prices to increase the brand premium for four pharmaceutical items on the PBS due to requests by responsible persons. In addition, this instrument amends the Principal Determination by re-instating the claimed price and brand premium for two brands of two pharmaceutical items as requested by the Responsible Persons. These changes take effect on 1 August 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.

Re-instatement of claimed prices or increases to brand premiums for specific brands is unlikely to result in negative financial impact or 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.

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.

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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