EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2022 (No. 8)

PB 118 of 2022

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 person 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.

This instrument (the Amendment Determination) amends the Principal Determination by reflecting the increases to existing brand premiums in addition to imposing new brand premiums for multiple pharmaceutical items as requested by responsible persons. It also reflects removal of brand premiums for one brand of one pharmaceutical item due to product discontinuation. The amendments provided by this instrument take effect on 1 December 2022.

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 person which is used to calculate the special patient contribution that will apply to the brand.

The Responsible Person affected by this Determination for increases to existing brand premiums for all pharmaceutical items of rosuvastatin made a submission about the Claimed Price the Minister should determine in relation to their brand. The Responsible Person was advised of the delegate's intention to determine in accordance with their request. No further response from the affected responsible person was received in response to this notification.

The responsible persons affected by this Determination for azathioprine, bisoprolol, cefuroxime, diltiazem, esomeprazole, flecainide, lamotrigine, levonorgestrel with ethinylestradiol, metoprolol, olmesartan with amlodipine, olmesartan with amlodipine and hydrochlorothiazide and quetiapine each made a submission about the claimed price the Minister should determine in relation to their brands. The responsible persons were advised of the delegate's intention to determine in accordance with their requests. No further response from the affected responsible persons were received in response to this notification.

No additional consultation with experts was undertaken regarding this Determination because consultation with affected responsible persons, 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 December 2022.

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 2022 (No.8)*

(PB 118 of 2022)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2022 (No. 8)* and may also be cited as PB 118 of 2022.

Section 2 Commencement

This section provides that the Determination commences on 1 December 2022.

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 December 2022

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 December 2022.

SUMMARY OF CHANGES

SCHEDULE 1

Brands with increased brand premiums

bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg	Bicor
bisoprolol	Tablet containing bisoprolol fumarate 5 mg	Bicor
bisoprolol	Tablet containing bisoprolol fumarate 10 mg	Bicor
diltiazem	Tablet containing diltiazem hydrochloride 60 mg	Cardizem
esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	Nexium
esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	Nexium
flecainide	Tablet containing flecainide acetate 50 mg	Tambocor
flecainide	Tablet containing flecainide acetate 100 mg	Tambocor
lamotrigine	Tablet 25 mg	Lamictal
lamotrigine	Tablet 50 mg	Lamictal
lamotrigine	Tablet 100 mg	Lamictal
lamotrigine	Tablet 200 mg	Lamictal
levonorgestrel with ethinylestradiol	Pack containing 21 tablets 150 micrograms 30 micrograms and 7 inert tablets	Levlen ED
metoprolol	Tablet containing metoprolol tartrate 50 mg	Betaloc
metoprolol	Tablet containing metoprolol tartrate 100 mg	Betaloc
olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate)	Sevikar 40/5
olmesartan with amlodipine	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate)	Sevikar 40/10
olmesartan with amlodipine and hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) and hydrochlorothiazide 25 mg	Sevikar HCT 40/10/25
quetiapine	Tablet 25 mg (as fumarate)	Seroquel
quetiapine	Tablet 100 mg (as fumarate)	Seroquel
quetiapine	Tablet 200 mg (as fumarate)	Seroquel
quetiapine	Tablet 300 mg (as fumarate)	Seroquel

Brands with new brand premiums

azathioprine	Tablet 25 mg	Imuran
azathioprine	Tablet 50 mg	Imuran
cefuroxime	Tablet 250 mg (as axetil)	Zinnat

Delisting of brand

labetalol	Tablet containing labetalol hydrochloride 100 mg	Trandate

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 2022 (No. 8) (PB 118 of 2022)

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 person 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 increasing brand premiums for twenty-seven brands of twenty-seven pharmaceutical items, imposing brand premiums for three brands of three pharmaceutical items and removing brand premiums for one brand of a pharmaceutical item. These changes take effect on 1 December 2022.

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 deletion of the above listed brand, by way of this determination, is unlikely to result in negative financial impact on patient access, therefore ensuring their rights to social security are maintained. One premium-free brand remains PBS listed for labetalol hydrochloride 100 mg tablet, following the deletion of the brand Trandate® which has been discontinued in Australia.

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. All brands subsidised by the PBS are evaluated by the Therapeutic Goods Administration (TGA) for quality and safety and determined to be bioequivalent, which means they are clinically equivalent and work in the same way. Increasing or imposing brand price premiums are therefore unlikely to 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 (PBAC) 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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