EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2024 (No. 3)

PB 35 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 persons'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 removing the brand premium for two pharmaceutical items as requested by the sponsor and changes to AEMP due to price increase. Furthermore, by adding a brand premium for one form of olmesartan with amlodipine and three forms of methylprednisolone. The instrument also increases the brand premiums for two forms of olmesartan with amlodipine and one form of olmesartan with hydrochlorothiazide.

The instrument also varies the brand premiums for listed brands of pharmaceutical items with the following drugs as a result of direct and flow-on price disclosure reductions: anastrozole, donepezil, duloxetine, fluconazole, gliclazide, lamotrigine, letrozole, levonorgestrel with ethinylestradiol, metformin, moclobemide, modafinil, olmesartan, olmesartan with hydrochlorothiazide, tamoxifen and valproic acid.

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

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.

All responsible persons with listed brands which are subject to price disclosure reductions under section 99ADH of the Act were informed of the changes through information published on the pbs.gov.au website in December 2023.

For the brand Copaxone, the claimed price and brand premium will be removed as requested by the sponsor for commercial reasons. 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 brand Depo-Medrol, the claimed price and brand premium will be removed due to the new increased AEMP effective 1 April 2024 ($13.62) being higher than the current claimed price ($13.01) for Depo-Nisolone. Depo-Medrol and Depo-Nisolone are the same pharmaceutical item and are sponsored by Pfizer Australia Pty Ltd. The sponsor agreed to the removal of the BPP for Depo-Medrol effective 1 April 2024.

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

This Determination commences on 1 April 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. 3)*

(PB 35 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. 3)* and may also be cited as PB 35 of 2024.

Section 2 Commencement

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

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

SUMMARY OF CHANGES
SCHEDULE 1

Brands that no longer have a brand premium

Glatiramer	Injection containing glatiramer acetate 40 mg in 1 mL single dose pre filled pen	Copaxone
Methylprednisolone	Injection containing methylprednisolone acetate 40 mg in 1 mL	Depo-Medrol

Brands with brand price premiums imposed

Methylprednisolone	Cream containing methylprednisolone aceponate 1 mg per g, 15 g	Advantan
Methylprednisolone	Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g	Advantan (Fatty)
Methylprednisolone	Ointment containing methylprednisolone aceponate 1 mg per g, 15 g	Advantan
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate)	Sevikar 20/5

Brands with increased brand price premiums

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 hydrochlorothiazide	Tablet containing olmesartan medoxomil 20 mg with hydrochlorothiazide 12.5 mg	Olmetec Plus

Brands with reduced brand premiums

Anastrozole	Tablet 1 mg	Arimidex
Donepezil	Tablet containing donepezil hydrochloride 5 mg	Aricept
Donepezil	Tablet containing donepezil hydrochloride 10 mg	Aricept
Duloxetine	Capsule 60 mg (as hydrochloride)	Cymbalta
Fluconazole	Capsule 50 mg	Diflucan
Fluconazole	Capsule 100 mg	Diflucan
Fluconazole	Capsule 200 mg	Diflucan
Gliclazide	Tablet 60 mg (modified release)	Diamicron 60mg MR
Lamotrigine	Tablet 25 mg	Lamictal
	Tablet 50 mg	Lamictal
	Tablet 100 mg	Lamictal
	Tablet 200 mg	Lamictal
Letrozole	Tablet 2.5 mg	Femara 2.5 mg

Levonorgestrel with ethinylestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	Levlen ED
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Diabex XR 500
	Tablet containing metformin hydrochloride 1 g	Diabex 1000
	Tablet (extended release) containing metformin hydrochloride 1 g	Diabex XR 1000
Moclobemide	Tablet 150 mg	Aurorix
	Tablet 300 mg	Aurorix 300 mg
Modafinil	Tablet 100 mg	Modavigil
Olmesartan	Tablet containing olmesartan medoxomil 40 mg	Olmetec
Olmesartan with hydrochlorothiazide	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 12.5 mg	Olmetec Plus
	Tablet containing olmesartan medoxomil 40 mg with hydrochlorothiazide 25 mg	Olmetec Plus
Tamoxifen	Tablet 20 mg (as citrate)	Nolvadex-D
Valproic Acid	Tablet (enteric coated) containing sodium valproate 200 mg	Epilim EC
	Tablet (enteric coated) containing sodium valproate 500 mg	Epilim EC

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. 3) (PB 35 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 (the Amendment Determination) amends the Principal Determination by removing the brand premium for two pharmaceutical items as a result of sponsor's request and a price increase granted resulting in the AEMP being higher than the current claimed price. These changes take effect on 1 April 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.

The removal of the brand premiums and claimed prices from the brands Copaxone and Depo-Medrol was as per the request of the sponsors.

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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