EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (Price and Special Patient Contribution) Amendment Determination 2022 (No. 7)

PB 105 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* 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* is used as the basis. Approved pharmacists are entitled to 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 removing the brand premium for one pharmaceutical item as requested by the Department due to the only generic brand delisting. 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. It also removes three brands of three pharmaceutical items that are delisting from the PBS as requested by the responsible persons.

The amendments provided by this instrument take effect on 1 November 2022.

Consultation

This Determination affects certain responsible persons with medicines listed on the PBS.

For the brands Asmol 2.5 uni-dose®, Asmol 5 uni-dose® and Rulide® in 300 mg strength, claimed prices and brand premiums will be removed for each brand consistent with the requests made by the responsible persons to delist these brands from the PBS for effect from 1 November 2022.

For the brand Feldene-D®, the claimed price and brand premium will be removed due to the delisting of only premium free brand listed on the PBS schedule from 1 November 2022. The responsible person of this brand agreed to the removal of this brand premium.

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 November 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.7)*

(PB 105 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. 7)* and may also be cited as PB 105 of 2022.

Section 2 Commencement

This section provides that the Determination commences on 1 November 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 November 2022

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

Brand that no longer has a brand premium

Piroxicam	Dispersible tablet 20 mg	Feldene-D

Deletion of brands

Roxithromycin	Tablet 300 mg	Rulide
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30	Asmol 2.5 uni-dose
	Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30	Asmol 5 uni-dose

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. 7) (PB 105 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 removing the brand premium for one pharmaceutical item as requested by the Department due to the only generic brand delisting. It also removes three brands of three pharmaceutical items that are delisting from the PBS as requested by the responsible persons. These change takes effect on 1 November 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. Deletion of the above listed brands, 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. Six premium-free brands remain PBS listed for roxithromycin tablet 300 mg; following the deletion of the brand Rulide®. One premium-free brand remains PBS listed for salbutamol nebuliser solution 2.5 mg in 2.5 mL single dose units, 30 pack; following the deletion of the brand Asmol 2.5 uni-dose®. Three premium-free brands remain PBS listed for salbutamol nebuliser solution 5 mg in 2.5 mL single dose units, 30 pack; following the deletion of the brand Asmol 5 uni-dose®. 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 the respective delisting brands.

The removal of brand premium and claimed price from the brand Feldene-D® was requested consistent with 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. This is allows continued access for eligible Australians to the remaining PBS listed brand of this medicine at subsidised prices, without the need to pay a 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. 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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