EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2021 (No. 7)

PB 127 of 2021

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 2021* (PB 35 of 2021) (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 35 of 2021 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 35 of 2021.

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 Amending Determination) amends the Principal Determination by reflecting the increase to existing brand premiums for multiple pharmaceutical items in addition to removing the brand premium for one pharmaceutical item as requested by the sponsor company and another brand premium for one pharmaceutical item as requested by the Department due to supply issues with the available generic brand. It also removes two brands of two pharmaceutical items that are delising from the PBS as requested by the responsible person. These changes are taking effect on 1 December 2021.

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 persons affected by this determination for increases to existing brand premiums for dutasteride with tamsulosin, ezetimibe, ezetimibe with rosuvastatin and metoprolol each made a submission about the claimed price the Minister should determine in relation to their brand. 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. For Feldene in the strength of 10 mg, the changes made by this determination are consistent with the request made by the responsible person for the removal of the brand premium for this brand and strength of piroxicam. For Avodart, the Department approached the responsible person and requested the removal of the claimed price and brand premium due to supply issues with the other listed generic brand. For Doryx in the 100 mg strength in the pack size of 21, and Ventolin CFC-free, the changes made by this determination are consistent with the requests made by the responsible persons for the delist of these two brands from the PBS for effect from 1 December 2021. As a result, further consultation with the responsible persons affected by this determination were unnecessary. All changes are taking effect on 1 December 2021.

No additional consultation with experts was undertaken regarding this Determination because consultation with the 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 Amending Determination is contained in the Attachment.

This Determination commences on 1 December 2021.

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 2021 (No. 7)*

(PB 127 of 2021)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2021 (No. 7)* and may also be cited as PB 127 of 2021.

Section 2 Commencement

This section provides that the Determination commences on 1 December 2021.

Section 3 Amendment of the *National Health (Price and Special Patient Contribution) Determination 2021* (PB 35 of 2021).

This section provides that Schedule 1 amends the *National Health (Price and Special Patient Contribution) Determination 2021* (PB 35 of 2021).

Schedule 1 Amendments commencing 1 December 2021

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 December 2021.

SUMMARY OF CHANGES

SCHEDULE 1

Brands with increased brand premiums		
Dutasteride with tamsulosin	Capsule containing dutasteride 500 micrograms with tamsulosin hydrochloride 400 micrograms	Duodart 500ug/400ug
Ezetimibe	Tablet 10 mg	Ezetrol
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 5 mg (as calcium)	Rosuzet Composite Pack
	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium)	Rosuzet Composite Pack
	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium)	Rosuzet Composite Pack
	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium)	Rosuzet Composite Pack
Metoprolol	Tablet containing metoprolol tartrate 100 mg	Betaloc
Brands that no longer have a brand premium		
Dutasteride	Capsule 500 micrograms	Avodart
Piroxicam	Capsule 10 mg	Feldene
Deletion of brands		
Doxycycline	Capsule 100 mg (as hyclate) (containing enteric coated pellets) *[pack quantity 21]*	Doryx
Salbutamol	Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)	Ventolin CFC-free

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 2021 (No. 7) (PB 127 of 2021)

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 2021* (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 determiations. This instrument (the Amending Determination) amends the Principal Determination by reflecting the increase to existing brand premiums for multiple pharmaceutical items in addition to removing the brand premium for one pharmaceutical item as requested by the sponsor company and another brand premium for one pharmaceutical item as requested by the Department due to supply issues with the available generic brand. It also removes two brands of two pharmaceutical items that are delising from the PBS as requested by the responsible person. These changes are taking effect on 1 December 2021.

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. 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 for quality and safety and determined to be bioequivalent, which means they are clinically equivalent and work in the same way. Increasing 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 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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