EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2020 (No. 1)

PB 10 of 2020

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 2010* (PB 109 of 2010) (the Principal Determination).

Subsections 85B(2), (3) and (4) of the *National Health Act 1953* (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 109 of 2010 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 109 of 2010.

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* (ie, 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 increasing the brand premium to multiple brands of pharmaceutical items in addition to adding a new brand premium to nine brands of nine pharmaceutical items. It also reinstates one brand premium to one pharmaceutical item in addition to removing one brand of one pharmaceutical item that will no longer be PBS listed on 1 February 2020.

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. Consultation was considered unnecessary (or inappropriate) because this instrument essentially involves a price negotiation between the Minister (or delegate) and the responsible persons. In addition, for the delisting brand, consultation was considered unnecessary (or inappropriate) because this instrument removes one brand of one pharmaceutical item that will no longer have a premium on 1 February 2020 as the product will be removed from the PBS at the request of the responsible person.

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

This Determination commences on 1 February 2020.

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 2020 (No. 1)*

(PB 10 of 2020)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2020 (No. 1)* and may also be cited as PB 10 of 2020.

Section 2 Commencement

This section provides that the Determination commences on 1 February 2020.

Section 3 Amendment of the *National Health (Price and Special Patient Contribution) Determination 2010* (PB 109 of 2010).

This section provides that Schedule 1 amends the *National Health (Price and Special Patient Contribution) Determination 2010* (PB 109 of 2010).

Schedule 1 Amendments commencing 1 February 2020

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 February 2020.

SUMMARY OF CHANGES

SCHEDULE 1

Brands with increased brand premiums		
Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL	Ceclor
	Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL	Ceclor
	Tablet (sustained release) 375 mg (as monohydrate)	Ceclor CD
Levonorgestrel with Ethinylestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	Levlen ED
Telmisartan	Tablet 40 mg	Micardis
	Tablet 80 mg	Micardis
Telmisartan with amlodipine	Tablet 40 mg-5 mg (as besilate)	Twynsta
	Tablet 40 mg-10 mg (as besilate)	Twynsta
	Tablet 80 mg-5 mg (as besilate)	Twynsta
	Tablet 80 mg-10 mg (as besilate)	Twynsta
Telmisartan with hydrochlorothiazide	Tablet 40 mg-12.5 mg	Micardis Plus 40/12.5 mg
	Tablet 80 mg-12.5 mg	Micardis Plus 80/12.5 mg
	Tablet 80 mg-25 mg	Micardis Plus 80/25 mg
Brands with a new brand premium		
Dicloxacillin	Capsule 250 mg (as sodium)	Distaph 250
	Capsule 500 mg (as sodium)	Distaph 500
Dosulepin	Capsule containing dosulepin hydrochloride 25 mg	Dothep 25
	Tablet containing dosulepin hydrochloride 75 mg	Dothep 75
Hydrocortisone	Tablet 4 mg	Hysone 4
	Tablet 20 mg	Hysone 20
Hydromorphone	Injection containing hydromorphone hydrochloride 2 mg in 1 mL	Dilaudid
	Injection containing hydromorphone hydrochloride 10 mg in 1 mL	Dilaudid-HP
Oxycodone	Tablet containing oxycodone hydrochloride 5 mg	Endone
Reinstatement of a brand premium		
Methyldopa	Tablet 250 mg (as sesquihydrate)	Aldomet
Deletion of brand		
Ranitidine	Tablet, effervescent, 150 mg (as hydrochloride)	Zantac

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 2020 (No. 1) (PB 10 of 2020)

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 2010* (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 increasing the brand premium to multiple brands of pharmaceutical items in addition to adding a new brand premium to nine brands of nine pharmaceutical items. It also reinstates one brand premium to one pharmaceutical item in addition to removing one brand of one pharmaceutical item that will no longer be PBS listed on 1 February 2020.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) 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 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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