EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2013 (No. 3)

PB 22 of 2013

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 *National Health (Price and Special Patient Contribution) Determination 2010* (the Principal Determination) contains determinations of these matters.

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: removing two brands that are no longer listed and reflecting for plain English reasons the removal of brands with therapeutic group premiums and price changes and decreases with one exceptional increase to multiple brand premiums which took legal effect on 1 April 2013 due to price disclosure reductions.

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 cannot 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.

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

This Determination commences on 1 May 2013.

This Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2013 (No. 3)*

(PB 22 of 2013)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination (No. 3) 2013* and may also be cited as PB 22 of 2013.

Section 2 Commencement

This section provides that the Determination commences on 1 May 2013.

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 May 2013

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 May 2013.

SUMMARY OF CHANGES

SCHEDULE 1

Brands with a price change and a decreased brand premium

Aciclovir	Tablet 200 mg *(pricing quantity 25)*	Zovirax 200 mg
	Tablet 200 mg *(pricing quantity 90)*	Zovirax 200 mg
	Tablet 800 mg	Zovirax 800 mg
Allopurinol	Tablet 100 mg	Zyloprim
	Tablet 300 mg	Zyloprim
Alprazolam	Tablet 250 micrograms	Xanax
	Tablet 500 micrograms	Xanax
	Tablet 1 mg	Xanax
	Tablet 2 mg	Xanax Tri-Score
Amlodipine	Tablet 5 mg (as besylate)	Norvasc
	Tablet 10 mg (as besylate)	Norvasc
Amoxycillin with Clavulanic Acid	Powder for oral suspension containing 125 mg amoxycillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL	Augmentin
	Powder for oral suspension containing 400 mg amoxycillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL	Augmentin Duo 400
	Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Augmentin Duo
	Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Augmentin Duo forte
Atenolol	Tablet 50 mg	Tenormin
Baclofen	Tablet 10 mg	Lioresal 10
Cyproterone	Tablet containing cyproterone acetate 50 mg *(pricing quantity 20)*	Androcur
	Tablet containing cyproterone acetate 50 mg *(pricing quantity 50)*	Androcur
	Tablet containing cyproterone acetate 100 mg	Androcur-100
Desferrioxamine	Powder for injection containing desferrioxamine mesylate 500 mg	Desferal 500 mg
	Powder for injection containing desferrioxamine mesylate 2 g	Desferal 2 g
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg	Voltaren 25
	Tablet (enteric coated) containing diclofenac sodium 50 mg	Voltaren 50
Doxycycline	Capsule 100 mg (as hydrochloride) (containing enteric coated pellets) *(pricing quantity 7)*	Doryx

	Capsule 100 mg (as hydrochloride) (containing enteric coated pellets) *(Pricing quantity 21)*	Doryx
	Capsule 50 mg (as hydrochloride) (containing enteric coated pellets)	Doryx
	Tablet 50 mg (as hydrochloride)	Vibra-Tabs
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg	Luvox
	Tablet containing fluvoxamine maleate 100 mg	Luvox
Gabapentin	Capsule 100 mg	Neurontin
	Capsule 300 mg	Neurontin
	Capsule 400 mg	Neurontin
	Tablet 600 mg	Neurontin
	Tablet 800 mg	Neurontin
Glimepiride	Tablet 1 mg	Amaryl
	Tablet 2 mg	Amaryl
	Tablet 3 mg	Amaryl
	Tablet 4 mg	Amaryl
Ipratropium	Nebuliser solution containing ipratropium bromide 250 micrograms (anhydrous) in 1 mL single dose units, 30	Atrovent
	Nebuliser solution containing ipratropium bromide 500 micrograms (anhydrous) in 1 mL single dose units, 30	Atrovent Adult
Isosorbide Mononitrate	Tablet 60 mg (sustained release)	Imdur Durule Monodur 60 mg
	Tablet 120 mg (sustained release)	Imdur 120 mg
Lactulose	Solution BP 3.34 g per 5 mL, 500 mL	Duphalac
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg	Zanidip
	Tablet containing lercanidipine hydrochloride 20 mg	Zanidip
Metoprolol	Tablet containing metoprolol tartrate 50 mg	Betaloc Lopresor 50
	Tablet containing metoprolol tartrate 100 mg	Betaloc Lopresor 100
Mirtazapine	Tablet 15 mg (orally disintegrating)	Avanza SolTab
	Tablet 30 mg	Avanza
	Tablet 30 mg (orally disintegrating)	Avanza SolTab
	Tablet 45 mg	Avanza
	Tablet 45 mg (orally disintegrating)	Avanza SolTab
Moclobemide	Tablet 150 mg	Aurorix
	Tablet 300 mg	Aurorix 300 mg
Norfloxacin	Tablet 400 mg	Noroxin
Pindolol	Tablet 15 mg	Visken 15
Ranitidine	Tablet 150 mg (as hydrochloride)	Zantac
	Tablet 300 mg (as hydrochloride)	Zantac

Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30	Ventolin Nebules
	Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30	Ventolin Nebules
Sotalol	Tablet containing sotalol hydrochloride 80 mg	Sotacor
	Tablet containing sotalol hydrochloride 160 mg	Sotacor
Sucralfate	Tablet equivalent to 1 g anhydrous sucralfate	Carafate
Sumatriptan	Tablet 50 mg (as succinate)	Imigran
Tamoxifen	Tablet 20 mg (as citrate)	Nolvadex-D
Tramadol	Capsule containing tramadol hydrochloride 50 mg	Tramal
	Tablet (sustained release) containing tramadol hydrochloride 100 mg	Tramal SR 100
	Tablet (sustained release) containing tramadol hydrochloride 150 mg	Tramal SR 150
	Tablet (sustained release) containing tramadol hydrochloride 200 mg	Tramal SR 200
Trandolapril	Capsule 500 micrograms	Gopten
	Capsule 1 mg	Gopten
	Capsule 2 mg	Gopten
	Capsule 4 mg	Gopten

Brand with a price change and an increased brand premium

Baclofen	Tablet 25 mg	Lioresal 25

Brands that no longer have a therapeutic group premium

Ranitidine	Syrup 150 mg (as hydrochloride) per 10 mL, 300 mL	Zantac Syrup
	Tablet , effervescent, 150 mg (as hydrochloride)	Zantac

Deletion of Brands

Alendronic Acid	Tablet 70 mg (as alendronate sodium)	Fosamax Once Weekly
Metformin	Tablet containing metformin hydrochloride 500 mg	Glucophage

SCHEDULE 2

Deletion of a pharmaceutical benefit for which the Commonwealth will pay the special patient contribution

Ranitidine

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 2013 (No. 3)

PB 22 of 2013

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 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 (the Amending Determination) amends the Principal Determination by: removing two brands that are no longer listed and reflecting for plain English reasons the removal of brands with therapeutic group premiums and price changes and decreases with one exceptional increase to multiple brand premiums which took legal effect on 1 April 2013 due to price disclosure reductions.

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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