EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2014 (No. 5)

PB 53 of 2014

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.

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: adding new brand premiums to 15 brands of pharmaceutical items and increases or removes brand and therapeutic group premiums to other brands of pharmaceutical items in Schedule 1. Schedule 2 to the Principal Determination is amended by removing one listed drug.

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 August 2014.

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 2014 (No. 5)*

(PB 53 of 2014)

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2014 (No. 5)* and may also be cited as PB 53 of 2014.

Section 2 Commencement

This section provides that the Determination commences on 1 August 2014.

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 August 2014

Schedule 1 sets out the amendments to the Principal Determination which commence on 1 August 2014.

SUMMARY OF CHANGES

SCHEDULE 1

Brands with an increased 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
Amlodipine	Tablet 5 mg (as besylate)	Norvasc
	Tablet 10 mg (as besylate)	Norvasc
Amoxycillin	Capsule 250 mg (as trihydrate)	Amoxil
	Capsule 500 mg (as trihydrate)	Amoxil
	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL	Amoxil
	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL	Amoxil Forte
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
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
Cephalexin	Capsule 250 mg (anhydrous)	Keflex
	Capsule 500 mg (anhydrous)	Keflex
	Granules for oral suspension 125 mg per 5 mL, 100 mL	Keflex
	Granules for oral suspension 250 mg per 5 mL, 100 mL	Keflex
Citalopram	Tablet 20 mg (as hydrobromide)	Cipramil
Clindamycin	Capsule 150 mg (as hydrochloride)	Dalacin C
Doxepin	Capsule 10 mg (as hydrochloride)	Sinequan
	Capsule 25 mg (as hydrochloride)	Sinequan
Escitalopram	Tablet 10 mg (as oxalate)	Lexapro
	Tablet 20 mg (as oxalate)	Lexapro
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg	Luvox
	Tablet containing fluvoxamine maleate 100 mg	Luvox
Frusemide	Tablet 20 mg	Lasix-M
	Tablet 40 mg	Lasix
Glipizide	Tablet 5 mg	Minidiab
Indomethacin	Capsule 25 mg	Indocid
Lamotrigine	Tablet 5 mg	Lamictal
	Tablet 25 mg	Lamictal
	Tablet 50 mg	Lamictal
	Tablet 100 mg	Lamictal
	Tablet 200 mg	Lamictal
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg	Zanidip
	Tablet containing lercanidipine hydrochloride 20 mg	Zanidip
Medroxyprogesterone	Tablet containing medroxyprogesterone acetate 10 mg *(pricing quantity 30)*	Provera
	Tablet containing medroxyprogesterone acetate 10 mg *(pricing quantity 100)*	Provera
Meloxicam	Capsule 7.5 mg	Mobic
	Capsule 15 mg	Mobic
	Tablet 7.5 mg	Mobic
	Tablet 15 mg	Mobic
Metformin	Tablet containing metformin hydrochloride 500 mg	Diabex

	Tablet containing metformin hydrochloride 850 mg	Diabex 850
	Tablet containing metformin hydrochloride 1 g	Diabex 1000
Paroxetine	Tablet 20 mg (as hydrochloride)	Aropax
Piroxicam	Capsule 10 mg	Feldene
	Capsule 20 mg	Feldene
	Dispersible tablet 20 mg	Feldene-D
Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg	Stemetil
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
Spironolactone	Tablet 25 mg	Aldactone
	Tablet 100 mg	Aldactone
Sulfasalazine	Tablet 500 mg (enteric coated)	Salazopyrin-EN
Sumatriptan	Tablet 50 mg (as succinate)	Imigran
Tinidazole	Tablet 500 mg	Fasigyn
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
Valproic Acid	Tablet (enteric coated) containing sodium valproate 200 mg	Epilim EC
	Tablet (enteric coated) containing sodium valproate 500 mg	Epilim EC
Brands with an increased price and brand premium		
Medroxyprogesterone	Injection containing medroxyprogesterone acetate 150 mg in 1 mL	Depo-Provera
	Tablet containing medroxyprogesterone acetate 5 mg	Provera
Brands with a new brand premium		
Candesartan	Tablet containing candesartan cilexetil 4 mg	Atacand
	Tablet containing candesartan cilexetil 8 mg	Atacand
	Tablet containing candesartan cilexetil 16 mg	Atacand
	Tablet containing candesartan cilexetil 32 mg	Atacand
Candesartan with Hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg	Atacand Plus 16/12.5

	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg	Atacand Plus 32/12.5
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg	Atacand Plus 32/25
Doxycycline	Capsule 100 mg (as hydrochloride) (containing enteric coated pellets) *(pricing quantity 7)*	Mayne Pharma Doxycycline
	Capsule 100 mg (as hydrochloride) (containing enteric coated pellets) *(pricing quantity 21)*	Mayne Pharma Doxycycline
	Capsule 50 mg (as hydrochloride) (containing enteric coated pellets)	Mayne Pharma Doxycycline
Lactulose	Solution BP 3.34 g per 5 mL, 500 mL	Actilax
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	Diabex XR
Perindopril	Tablet containing perindopril arginine 2.5 mg	Coversyl 2.5mg
		PREXUM 2.5
Sumatriptan	Tablet (fast disintegrating) 50 mg (as succinate)	Imigran FDT

Brands that no longer have a brand premium

Norethisterone	Tablets 350 micrograms, 28	Noriday 28 Day
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 that no longer have a therapeutic group premium

Telmisartan	Tablet 40 mg	Micardis
	Tablet 80 mg	Micardis

SCHEDULE 2

Deletion

Telmisartan

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 2014 (No. 5) (PB 53 of 2014)

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: adding new brand premiums to 15 brands of pharmaceutical items and increases or removes brand and therapeutic group premiums to other brands of pharmaceutical items in Schedule 1 Schedule 2 to the Principal Determination is amended by removing one listed drug.

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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