EXPLANATORY STATEMENT

National Health Act 1953

National Health (Price and Special Patient Contribution)

Amendment Determination 2011 (No. 3)

PB 25 of 2011

Purpose

This legislative instrument amends the *National Health (Price and Special Patient Contribution) Determination 2010* (PB 109 of 2010) which provides for price determinations in relation to brands of pharmaceutical items for which the Minister and the responsible person have not been able to make a price agreement. The Determination is made under section 85B of the *National Health Act 1953* (the Act). The amendment amends Schedules 1 and 2 of PB 109 of 2010.

Background – the Pharmaceutical Benefits Scheme

Part VII of the Act is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) under which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) provides that pharmaceutical benefits are to be provided by the Commonwealth in accordance with Part VII.

In the case of ready-prepared pharmaceutical benefits, the pharmaceutical benefit is a brand of a pharmaceutical item. That is, it is a brand of a listed drug, in a form and with a manner of administration, declared and determined under various provisions of Part VII.

Part VII also provides for numerous other matters, including pricing matters and matters relating to payments by the Commonwealth and charges to patients for pharmaceutical benefits. This Determination concerns such matters.

Background – the Determination

The Act provides for the Minister and the responsible person to agree a price that is taken to be the appropriate maximum price for sales of a brand of a pharmaceutical item to approved pharmacists (section 85AD). Section 85B of the Act applies if the Minister and the responsible person have been unable to reach an agreement.

Subsection 85B(2) provides that the Minister may determine an amount that is taken to be the appropriate maximum price for sales of a brand of a pharmaceutical item to approved pharmacists. This is termed the 'Determined Price'.

Subsection 85B(3) provides that the Minister may determine an amount that is taken to be the price claimed by the responsible person as the appropriate maximum price for sales of the brand of the pharmaceutical item to approved pharmacists. This is termed the 'Claimed Price'.

The Determined Price is the *approved price to pharmacists* and is used as the basis for working out the Commonwealth price for the brand of the pharmaceutical item (section 98B of the Act). 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 (ie, the price that would be the Commonwealth price if the responsible person's claimed price had become the approved price to pharmacists) and the Commonwealth price for the brand is defined in subsection 85B(4) 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(5) 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(5) 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 Determination contains determinations of:

- Determined Prices (under subsection 85B(2) of the Act);
- Claimed Prices (under subsection 85B(3) of the Act; and
- the circumstances in which the Commonwealth is to pay the special patient contribution (under subsection 85B(5) of the Act).

Changes effected by this Determination

A provision-by-provision description of this instrument is contained in Attachment 1.

This instrument amends PB 109 of 2010 by amending Schedule 1, *Determined and Claimed Prices* and Schedule 2, *Pharmaceutical benefits for which the Commonwealth will pay the special patient contribution*. Sections 1-7 in the Determination continue to operate.

The effect of the Schedule 1 amendments is to alter the claimed price of specified brands of pharmaceutical items listed in Schedule 1 of the principal determination. It also adds to Schedule 1, one new pharmaceutical item candesartan, removes one pharmaceutical item terbinafine and removes one strength of the pharmaceutical item cyclosporin. The amendment also adds candesartan to the list of drugs contained in Schedule 2 of the principal determination. The Commonwealth will pay the special patient contribution for candesartan under the specified circumstances.

The effect of the Schedule 2 amendment is to alter the determined price and the claimed price for one brand of pharmaceutical item, alendronic acid in the form tablet 70 mg (as alendronate sodium), Fosamax Once Weekly brand, in Schedule 1 of the principal determination, as a consequence of price disclosure. This amendment is to commence one day after the determined and claimed prices are reduced by force of the price disclosure provisions in the Act.

The changes made in this instrument to matters determined under section 85B of the Act since the last amendment made on 1 March 2011, are set out in Attachment 2 to this Explanatory Statement and is titled Summary of Changes.

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 price to pharmacists 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 Determination

A provision by provision description of the Determination is contained in Attachment 1.

Schedule 1 of the Amendment Determination commences on 1 April 2011.

Schedule 2 of the Amendment Determination commences on 2 April 2011.

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

ATTACHMENT 1

PROVISION BY PROVISION DESCRIPTION OF THE AMENDMENT DETERMINATION

Section 1 Name of Determination

This section provides that this Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2011 (No. 3)* and may also be cited as PB 25 of 2011.

Section 2 Commencement

This section provides that Schedule 1 of the Amendment Determination commences on 1 April 2011.

Schedule 2 of the Amendment Determination commences on 2 April 2011.

Section 3 Amendment of PB 109 of 2010

This section provides that Schedules 1 and 2 to the Instrument amend the determination under section 85B of the Act the *National Health (Price and Special Patient Contribution) Determination 2010* (PB 109 of 2010).

Schedule 1 Amendments

Schedules 1 and 2 set out the amendments to Determination PB 109 of 2010.

ATTACHMENT 2

SUMMARY OF CHANGES

SCHEDULE 1

Brands to which a Therapeutic Group premium now applies

Candesartan	Tablet containing candesartan cilexetil 8 mg	Atacand
	Tablet containing candesartan cilexetil 16 mg	Atacand
	Tablet containing candesartan cilexetil 32 mg	Atacand

Brands with an increased brand premium

Amoxycillin	Capsule 250 mg (as trihydrate)	Amoxil
	Capsule 500 mg (as trihydrate)	Amoxil
	Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100mL	Amoxil
	Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100mL	Amoxil
Amoxycillin with Clavulanic acid	Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Augmentin Duo Forte
Atenolol	Tablet 50 mg	Tenormin
Betaxolol	Eye drops, solution, 5 mg (as hydrochloride) per mL, 5 mL	Betoptic
Brinzolamide	Eye drops 10 mg per mL, 5 mL	Azopt
Carbamazepine	Tablet 100 mg	Tegretol
	Tablet 200 mg	Tegretol
Carbomer	Eye gel 2 mg per g, 10 g	Viscotears
Ciprofloxacin	Eye drops 3 mg (as hydrochloride) per mL, 5 mL	Ciloxan
Citalopram	Tablet 20 mg (as hydrobromide)	Cipramil
Clomipramine	Tablet containing clomipramine hydrochloride 25 mg	Anafranil 25
Codeine with Paracetamol	Tablet containing codeine phosphate 30 mg with paracetamol 500 mg	Panadeine Forte
Cyclosporin	Capsule 50 mg	Neoral 50
	Capsule 100 mg	Neoral 100
Dexamethasone with Framycetin and Gramicidin	Ear drops containing dexamethasone 500 micrograms (as sodium metasulfobenzoate), framycetin sulphate 5mg and gramicidin 50 micrograms per mL, 8mL	Sofradex
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg	Voltaren 25
	Tablet (enteric coated) containing diclofenac sodium 50 mg	Voltaren 50
Escitalopram	Tablet 10 mg (as oxalate)	Lexapro
	Tablet 20 mg (as oxalate)	Lexapro
Fluoxetine	Tablet, dispersible, 20 mg (as hydrochloride)	Prozac Tab
	Capsule 20 mg (as hydrochloride)	Prozac 20
Frusemide	Tablet 20 mg	Lasix-M
	Tablet 40 mg	Lasix
Glibenclamide	Tablet 5 mg	Daonil
Glimepiride	Tablet 1 mg	Amaryl
	Tablet 2 mg	Amaryl
	Tablet 3 mg	Amaryl

	Tablet 4 mg	Amaryl
Hypromellose	Eye drops 3 mg per mL, 15mL	Genteal
Hypromellose with Carbomer 980	Ocular lubricating gel 3 mg-2 mg per g, 10g	Genteal gel
Hypromellose with Dextran	Eye drops containing 3 mg hypromellose 4500 with 1 mg dextran 70 per mL, 15 mL	Tears Naturale
Ketoprofen	Capsule 200 mg (sustained release)	Orudis SR 200
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
Metoprolol	Tablet containing metoprolol tartrate 50 mg	Lopresor 50
	Tablet containing metoprolol tartrate 100 mg	Lopresor 100
Metronidazole	Tablet 400 mg	Flagyl
	Tablet 200 mg	Flagyl
Paraffin	Eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	Duratears
Paroxetine	Tablet 20 mg (as hydrochloride)	Aropax
Potassium Chloride	Tablet 600 mg (sustained release)	Slow K
Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg	Stemetil
Ranitidine	Tablet 150 mg (as hydrochloride)	Zantac
	Tablet 300 mg (as hydrochloride)	Zantac
Roxithromycin	Tablet 150 mg	Rulide
	Tablet 300 mg	Rulide
Salbutamol	Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation)	Ventolin CFC-free inhaler
Valproic Acid	Tablet (eneteric coated) containing sodium valproate 500 mg	Epilim EC

Brands with a decreased brand premium

Alendronic Acid	Tablet 70 mg (as alendronate sodium)	Fosamax Once Weekly
Amoxycillin with Clavulanic Acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)	Augmentin Duo
	Powder for oral suspension containing 125 mg amoxycillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75mL	Augmentin
	Powder for oral suspension containing 400 mg amoxycillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60mL	Augmentin Duo 400
Isotretinoin	Capsule 20 mg	Roaccutane
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

Brands to which a brand premium no longer applies

Cyclosporin	Capsule 25 mg	Neoral 25
Terbinafine	Tablet 250 mg (as hydrochloride)	Lamisil

Brands with an increased therapeutic group premium

Ranitidine	Tablet, effervescent, 150 mg (as hydrochloride)	Zantac

SCHEDULE 2

Addition of brands for which the Commonwealth will pay the special patient contribution

Candesartan	Tablet containing candesartan cilexetil 8 mg	Atacand
	Tablet containing candesartan cilexetil 16 mg	Atacand
	Tablet containing candesartan cilexetil 32 mg	Atacand

Note: Brand premiums and therapeutic group premiums are both *special patient contributions*.

A special patient contribution is termed a *brand premium* in this Attachment in relation to a brand of a pharmaceutical item if there is at least one other brand of that pharmaceutical item which has an agreed price (and thus does not have a price determined under section 85B and a special patient contribution).

A special patient contribution is termed a *therapeutic group premium* in this Attachment in relation to a brand of a pharmaceutical item (the relevant brand) if there is at least one brand of a pharmaceutical item (the other brand) that has a drug in the same therapeutic group as the drug in the relevant brand, and the other brand has an agreed price (and thus does not have a price determined under section 85B and a special patient contribution).