EXPLANATORY STATEMENT

National Health Act 1953

National Health (Price and Special Patient Contribution) Determination 2010

PB 109 of 2010

Purpose

This legislative instrument 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. It also provides for the circumstances in which the Commonwealth will pay the special patient contribution resulting from these price determinations.

The Determination is made under section 85B of the *National Health Act 1953* (the Act) and it revokes the previous determination (PB 72 of 2010) made under that section.

Background – the Pharmaceutical Benefits Scheme

Part VII of the Act is the legislative basis for 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 benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

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 – this 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' in this Determination.

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' in this Determination.

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).

Amendments to the Act and other Instruments commencing at the same time as this Determination

A number of amendments to the Act contained in the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2010* commence on the same day as this Determination. These amendments do not directly affect this Determination but they do affect the process for listing medicines on the PBS. This listing process is being further streamlined by a new composite listing instrument which provides for all non-pricing matters concerning the listing of medicines on the PBS. This new listing instrument (the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010*), which also commences on 1 December 2010, contains a number of declarations and determinations which are made under the amended provisions of the Act. This Determination is being made in reliance on the declarations and determinations in the new listing instrument.

Changes to the PBS effected by this Determination

This Determination revokes the previous legislative instrument made under section 85B of the Act (PB 72 of 2010).

Many of the matters declared and determined in this Determination are the same as in the previous instrument. Some changes have been made, however, and these are summarised in Attachment 2.

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 work out the special patient contribution that will apply to the brand.

This Determination

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

The Determination commences on 1 December 2010.

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

ATTACHMENT 1

PROVISION BY PROVISION DESCRIPTION OF DETERMINATION

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Determination 2010* and may also be cited as PB 109 of 2010.

Section 2 Commencement

This section provides that the Determination commences on 1 December 2010.

Section 3 Revocation

This section revokes the previous Determination under section 85B of the Act (PB 72 of 2010). The changes effected by this Determination are summarised in Attachment 2 to this Explanatory Statement.

Section 4 Definitions

A number of expressions used in the Determination are defined in this section.

Section 5 Determined price

This section determines, for subsection 85B(2) of the Act, a price for a brand of a pharmaceutical item where the Minister and the responsible person have not been able to agree a price. The price determined is defined in paragraph 98B(3)(b) of the Act to be the *approved price to pharmacists* of the brand and becomes the basis for calculating the amount that the Commonwealth will pay to pharmacists in respect of the supply of the brand as a pharmaceutical benefit.

Section 6 Claimed price

This section determines, for subsection 85B(3) of the Act, the price claimed by the responsible person as their price for sales of their brand to approved pharmacists. It is the price they requested as their approved price to pharmacists, but which the Minister did not agree to. The purpose of determining this price is to enable the special patient contribution to be worked out. This is the additional amount the patient will be required to pay to obtain the brand in question. Brands for which there is an agreed price (ie, the Minister and the responsible person have agreed a price under section 85AD of the Act) have no special patient contribution.

The special patient contribution is defined in subsection 85B(4) as the difference between the responsible person's Commonwealth price for the brand (ie, what the Commonwealth price would have been had the Claimed Price been agreed to and become the approved price to pharmacists) and the Commonwealth price for the brand. The special patient contribution is thus not simply the difference between the claimed and determined prices; it is the difference between these two prices marked up (by the addition of the pharmacy mark-up, dispensing and other fees) to the Commonwealth price level.

Section 7 Commonwealth payment of special patient contribution

This section determines, for subsection 85B(5) of the Act, the circumstances in which the Commonwealth is to pay the special patient contribution for a brand. The Commonwealth will pay the special patient contribution for a brand mentioned in Schedule 2 to the Determination, if the brand has been prescribed in a circumstance set out in that Schedule for that brand, and if the prescription has been authorised by the Medicare Australia CEO. These matters are provided for in subsection 7(1) of the Determination.

Authorisation for prescribing a number of these brands is already required as part of the allowable circumstances for prescribing the brand, which have been determined for the brand under paragraph 85(7)(b) of the Act. In such cases, an authorisation for prescribing is taken to be an authorisation for the Commonwealth payment of the special patient contribution (subsection 7(2) of the Determination). In any other case authorisation of the prescription must be obtained for the purposes of Commonwealth payment of the special patient contribution under the same authority required procedures (subsection 7(3) of the Determination).

Schedule 1 Determined and Claimed Prices

Schedule 1 relates to sections 5 and 6 of the Determination. It sets out the Determined Price and the Claimed Price for each brand of a pharmaceutical item mentioned in the Schedule.

Schedule 2 Pharmaceutical benefits for which the Commonwealth will pay the special patient contribution

Schedule 1 relates to section 7 of the Determination. It sets out the brands for which the Commonwealth will pay the special patient contribution and the circumstances for each brand in which such payments will be made. The brand must have been prescribed in one of the circumstances set out for the brand. Section 7 of the Determination also requires that the prescription be authorised by the Medicare Australia CEO.

ATTACHMENT 2
SUMMARY OF CHANGES

Brands with an increased brand premium

Alendronic Acid	Tablet 70 mg (as alendronate sodium)	Fosamax Once Weekly
Betamethasone	Cream 200 micrograms (as valerate) per g, 100 g	Betnovate 1/5
	Cream 500 micrograms (as valerate) per g, 15 g	Betnovate 1/2
	Ointment 500 micrograms (as valerate) per g, 15 g	Betnovate 1/2
Digoxin	Tablet 62.5 micrograms	Lanoxin PG
	Tablet 250 micrograms	Lanoxin
Hydrocortisone	Cream containing hydrocortisone acetate 10 mg per g, 30 g	Sigmacort
	Cream containing hydrocortisone acetate 10 mg per g, 50 g	Sigmacort
	Ointment containing hydrocortisone acetate 10 mg per g, 30 g	Sigmacort
	Ointment containing hydrocortisone acetate 10 mg per g, 50 g	Sigmacort
Labetalol	Tablet containing labetalol hydrochloride 100 mg	Trandate
	Tablet containing labetalol hydrochloride 200 mg	Trandate
Levonorgestrel with Ethinyloestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	Nordette 28
	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	Triphasil 28
Mirtazapine	Tablet 30 mg	Avanza
	Tablet 45 mg	Avanza
Norethisterone	Tablets 350 micrograms, 28	Noriday 28 Day
Norethisterone with Ethinyloestradiol	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	Brevinor
	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	Brevinor-1
	Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets	Synphasic
Oxazepam	Tablet 15 mg	Serepax
	Tablet 30 mg	Serepax

Sulfasalazine	Tablet 500 mg (enteric coated)	Salazopyrin-EN
Thyroxine	Tablet containing 50 micrograms anhydrous thyroxine sodium	Oroxine
	Tablet containing 75 micrograms anhydrous thyroxine sodium	Oroxine
	Tablet containing 100 micrograms anhydrous thyroxine sodium	Oroxine
	Tablet containing 200 micrograms anhydrous thyroxine sodium	Oroxine
Trandolapril	Capsule 4 mg	Gopten
Triamcinolone	Cream containing triamcinolone acetonide 200 micrograms per g, 100 g	Aristocort 0.02%
	Ointment containing triamcinolone acetonide 200 micrograms per g, 100 g	Aristocort 0.02%
Triamcinolone with Neomycin, Gramicidin and Nystatin	Ear drops containing triamcinolone acetonide 1 mg with neomycin 2.5 mg(as sulfate), gramicidin 250 micrograms and nystatin 100,000 units per g, 7.5 mL	Kenacomb Otic
	Ear ointment containing triamcinolone acetonide 1 mg with neomycin 2.5 mg (as sulfate), gramicidin 250 micrograms and nystatin 100,000 uints per g, 5 g	Kenacomb Otic

Brands with a decreased brand premium

Pravastatin	Tablet containing pravastatin sodium 10 mg	Pravachol
Trandolapril	Capsule 2 mg	Gopten

Brands with a price change but no change in brand premium

Pravastatin	Tablet containing pravastatin sodium 20 mg	Pravachol
	Tablet containing pravastatin sodium 40 mg	Pravachol
Trandolapril	Capsule 500 micrograms	Gopten
	Capsule 1 mg	Gopten

Brands with therapeutic group premium replaced by brand premium

Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg	Zanidip
	Tablet containing lercanidipine hydrochloride 20 mg	Zanidip

New brands with brand premiums

Betamethasone	Cream 500 micrograms (as dipropionate) per g, 15 g	Diprosone
	Cream 200 micrograms (as valerate) per g, 100 g	Celestone-M
	Ointment 500 micrograms (as dipropionate) per g, 15 g	Diprosone
	Ointment 200 micrograms (as valerate) per g, 100 g	Celestone-M
Mometasone	Cream containing mometasone furoate 1 mg per g, 15 g	Elocon
	Ointment containing mometasone furoate 1 mg per g, 15 g	Elocon
	Lotion containing mometasone furoate 1 mg per g, 30 mL	Elocon
Phenoxymethylpenicillin	Oral suspension 150 mg (as benzathine) per 5 mL, 100 mL	Abbocillin-V

Deletion of brand

Colchicine	Tablets 500 micrograms, 100	Colgout

Change to pack size with no brand premium changes

Carbamazepine	Tablet 200 mg	Tegretol 200

Change to pack size with brand premium changes

Carbamazepine	Tablet 100 mg	Tegretol 100

Brands with a price change and an increase in brand premium

Glyceryl Trinitrate	Tablets 600 micrograms, 100	Anginine stabilised
Medroxyprogesterone	Injection containing medroxyprogesterone acetate 150 mg in 1 mL	Depo-Provera
Tinidazole	Tablet 500 mg	Fasigyn

Deletion of brands from the list of brands for which the Commonwealth will pay the special patient contribution (ie, deletion from Schedule 2)

Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg	Zanidip
	Tablet containing lercanidipine hydrochloride 20 mg	Zanidip

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).