**EXPLANATORY STATEMENT**

***National Health Act 1953***

***National Health (Price and Special Patient Contribution)***

***Amendment Determination 2011 (No. 8)***

**PB 84 of 2011**

## Purpose

The purpose of this legislative instrument, made under section 85B of the *National Health Act 1953* (the Act) is to amend the *National Health (Price and Special Patient Contribution) Determination 2010* (PB 109 of 2010) to make changes to both the brands of pharmaceutical item that have a determined price and a claimed price and to the amount of the claimed price for certain brands of pharmaceutical items.

PB 109 of 2010 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.

## Authority

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* (subsection 98B(3) of the Act) and is used as the basis for working out the Commonwealth price for the brand of the pharmaceutical item (subsection 98B(2) 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 applicable patient co-payment (subsection 87(2A) of the Act).

Subsection 85B(5) of the Act provides that the Minister may determine the circumstances in which the Commonwealth, rather than the patient, is to pay the special patient contribution for a brand of a pharmaceutical item.

**Changes to PB 109 of 2010 made by this instrument**

This instrument amends PB 109 of 2010 by:

- removing one brand of a pharmaceutical item;
- changing the amount (either an increase or a decrease) to the claimed and the determined amounts to existing pharmaceutical items;
- altering the form description for two pharmaceutical items; and
- removing three pharmaceutical items, hydrocortisone in the form cream containing hydrocortisone acetate 10 mg per g, 50 g, Cortef brand; and norethisterone with ethinyloestradiol, in the forms tablets 500 micrograms-35 micrograms, 21, Brevinor brand and tablets 1 mg-35 micrograms, 21, Brevinor-1 brand. These pharmaceutical benefits ceased to be pharmaceutical benefits and were delisted from the PBS on 1 April 2011 by the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2011 (No. 4)* (PB 24 of 2011). Due to a clerical oversight these pharmaceutical items were not removed from this instrument at that time.

## 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.

## General

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

The instrument commences on 1 December 2011.

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

**ATTACHMENT 1**

**PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (PRICE AND SPECIAL PATIENT CONTRIBUTION) AMENDMENT DETERMINATION 2011 (No.8)***

**Section 1 Name of Instrument**

This section provides that this Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2011 (No. 8)* and may also be cited as PB 84 of 2011.

**Section 2 Commencement**

This section provides that the Amendment Determination commences on 1 December 2011.

**Section 3 Amendment of PB 109 of 2010**

This section provides that Schedule 1 of the Instrument amends 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**

Schedule 1 sets out the amendments to Determination PB 109 of 2010 (Attachment 2).

**ATTACHMENT 2**

# SUMMARY OF CHANGES

*SCHEDULE 1*

**Deletion of Brand**

| | | |
|---|---|---|
| Norethisterone with Ethinyloestradiol | Pack containing 12 tablets 500 micrograms-35 micrograms, 9 tablets 1 mg-35 micrograms and 7 inert tablets | Synphasic |

**Brands with an increased brand premium**

| | | |
|---|---|---|
| Alendronic Acid | Tablet 70 mg (as alendronate sodium) | Fosamax Once Weekly |
| Enalapril | Tablet containing enalapril maleate 5 mg | Renitec M |
| | Tablet containing enalapril maleate 10 mg | Renitec |
| | Tablet containing enalapril maleate 20 mg | Renitec 20 |
| Erythromycin | Capsule 250 mg (containing enteric coated pellets) | Eryc |
| Escitalopram | Tablet 10 mg (as oxalate) | Lexapro |
| | Tablet 20 mg (as oxalate) | Lexapro |
| Lisinopril | Tablet 5 mg | Prinivil 5 |
| | Tablet 10 mg | Prinivil 10 |
| | Tablet 20 mg | Prinivil 20 |
| Meloxicam | Tablet 7.5 mg | Mobic |
| | Tablet 15 mg | Mobic |
| Mianserin | Tablet containing mianserin hydrochloride 10 mg | Tolvon |
| | Tablet containing mianserin hydrochloride 20 mg | Tolvon |
| Simvastatin | Tablet 5 mg | Zocor |
| | Tablet 10 mg | Lipex 10 |
| | Tablet 10 mg | Zocor |
| | Tablet 20 mg | Lipex 20 |
| | Tablet 20 mg | Zocor |
| | Tablet 40 mg | Lipex 40 |
| | Tablet 40 mg | Zocor |
| | Tablet 80 mg | Lipex 80 |
| | Tablet 80 mg | Zocor |
| Salbutamol | Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation) | Ventolin CFC-free |
| Valproic Acid | Tablet (enteric coated) containing sodium valproate 200 mg | Epilim EC |
| | Tablet (enteric coated) containing sodium valproate 500 mg | Epilim EC |

**Brands with a price change and decreased brand premium**

| | | |
|---|---|---|
| Erythromycin | Powder for oral liquid 200 mg ( as ethyl succinate) per 5 mL, 100 mL | E.E.S. 200 |
| | Powder for oral liquid 400 mg (as ethyl succinate) per 5 mL, 100 mL | E.E.S. Granules |
| Indomethacin | Capsule 25 mg | Indocid |

**Brands with a price change and an increased brand premium**

| | | |
|---|---|---|
| Pravastatin | Tablet containing pravastatin sodium 10 mg | Pravachol |
| | Tablet containing pravastatin sodium 20 mg | Pravachol |
| | Tablet containing pravastatin sodium 40 mg | Pravachol |
| | Tablet containing pravastatin sodium 80 mg | Pravachol |

**Brands with a price change and no change to brand premium**

| | | |
|---|---|---|
| Imipramine | Tablet containing imipramine hydrochloride 25 mg | Tofranil 25 |
| Sucralfate | Tablet equivalent to 1 g anhydrous sucralfate | Carafate |

**Alteration of Form Description**

| | |
|---|---|
| Alendronic acid with colecalciferol | *From*: Tablet equivalent to 70 mg (as alendronate sodium) with 140 micrograms colecalciferol |
| | *To:* Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol |
| Bleomycin | *From:* Powder for injection containing bleomycin sulfate 15,000 I.U. (with any determined brand of sodium chloride injection as the required solvent) |
| | *To:* Powder for injection containing bleomycin sulfate 15,000 I.U. |