EXPLANATORY STATEMENT

National Health Act 1953

National Health (Price and Special Patient Contribution)

Amendment Determination 2011 (No. 2)

PB 15 of 2011

Purpose

This legislative instrument amends the determination *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 is necessary to remove two brands of pharmaceutical items which previously attracted a brand premium and which are discontinued by the manufacturer. The amendment also provides for an additional circumstance for when the Commonwealth will pay the special patient contribution (subsection 85B(5)) for the listed drug naratriptan in the form tablet 2.5 mg (as hydrochloride). This amendment is necessary due to a clerical error resulting in the omission of a circumstance from the legislative instrument (PB109 of 2010) that came into effect on 1 December 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.

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 this Determination is contained in the Attachment.

This Determination commences on 1 March 2011.

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE DETERMINATION

Section 1 Name of Determination

This section provides that the Determination is the *National Health (Price and Special Patient Contribution) Amendment Determination 2011 (No. 2)* and may also be cited as PB 15 of 2011.

Section 2 Commencement

This section provides that this Determination commences on 1 March 2011.

Section 3 Amendment of PB 109 of 2010

This section provides that Schedule 1 to the Instrument amends the determination under section 85B of the Act (PB 109 of 2010).

Schedule 1 Amendments

Schedule 1 provides for the following amendments:

SCHEDULE 1

Deletion of Brands

Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. (with any determined brand of sodium chloride as the required solvent) (Blenoxane)
Pindolol	Tablet 5 mg (Visken 5)

SCHEDULE 2

Schedule 2 is amended to include a circumstance relating to the listed drug naratriptan, in the form tablet 2.5 mg (as hydrochloride) which was inadvertently omitted from PB 109 of 2010 which commenced on 1 December 2010. It was the intention that all the circumstances in which the Commonwealth would pay the special patient contribution would continue to apply to this pharmaceutical benefit.