EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 131 OF 2008

NATIONAL HEALTH ACT 1953

AMENDMENT DETERMINATION UNDER PARAGRAPH 98C(1)(b)

Purpose and operation

Part VII of the *National Health Act 1953* (the Act) is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by 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.

Drugs and medicinal preparations to which Part VII applies are (with the exception of some medicinal preparations with additives) declared by the Minister by legislative instrument to be so under subsection 85(2). These are listed drugs as defined in subsection 84(1).

The Minister by legislative instrument can determine the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3)); the manner of administration of the form of the listed drug so determined (subsection 85(5)); and a brand of the pharmaceutical item (defined in subsection 84(1)) that has the listed drug in that form with that manner of administration (subsection 85(6)). These determinations govern what constitutes the pharmaceutical benefit (defined in subsection 84(1)) under Part VII of the Act. Under section 84AF, the Minister may determine a responsible person for a brand of a pharmaceutical item.

Paragraph 98C(1)(b) of the Act provides that the Minister may, from time to time, determine the conditions subject to which payments will be made by the Commonwealth in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

The determination under paragraph 98C(1)(b) of the Act sets out the conditions under which payments will be made in respect of the supply of pharmaceutical benefits by approved pharmacists and approved medical practitioners.

This legislative instrument amends the determination under section 98C(1)(b) made by legislative instrument number PB 119 of 2008 which came into effect on 1 December 2008. The amendments are set out in the items of Schedule 1 to the instrument.

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

This instrument, expressed to commence on 1 January 2009, was made on 3 December 2008.

Consultations

The Pharmaceutical Benefits Advisory Committee (PBAC) is the independent expert body, established by section 100A of the Act, which makes recommendations to the Minister for Health and Ageing about which drugs and medicinal preparations should be available as pharmaceutical benefits. Under subsection 101(4) of the Act, a drug or medicinal preparation may not be declared to be a drug or medicinal preparation to which Part VII of the Act applies unless the PBAC has recommended that it be so declared. When recommending a medicine be listed on the PBS, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

ATTACHMENT

Paragraph 1: provides that this instrument commences on 1 January 2009.

Paragraph 2: provides that Schedule 1 amends PB 119 of 2008.

Schedule 1: provides for the following amendments:

SCHEDULE 4

Addition of Listed Drug

Posaconazole	Oral suspension 40 mg per mL, 105 mL