EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 68 OF 2009

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 August 2009, was made on 6 July 2009.

Consultations

The Department consulted with the Pharmaceutical Benefits Advisory Committee (PBAC) during the regular process of its meetings to consider applications in order to recommend to the Minister which medicines should be subsidised through the Pharmaceutical Benefits Scheme. The Committee is independent of Government and includes members from the following interests or professions: consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and medical specialists. The Committee has received submissions and representations from interested pharmaceutical companies and has recommended the changes to the Minister who has determined the changes to the conditions under paragraph 98C(1)(b) which appear in this Determination.

ATTACHMENT

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

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

Schedule 1: provides for the following amendments:

SCHEDULE 1

Addition of Listed Drug

Voriconazole with Water – Purified BP

SCHEDULE 4

Addition of Listed Drugs

Bimatoprost with timolol

Oxybutynin

Rivaroxaban

Voriconazole

Addition of Form

Hypromellose	Oral gel 20 mg per g, 100 g

Deletion of Form

Glucose Indicator—Blood	Electrode strips, 100 (TrueSense)