EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 100 OF 2010

NATIONAL HEALTH ACT 1953

AMENDMENT DETERMINATION UNDER SECTION 84AH

Summary
This instrument amends the principal instrument, PB 58 of 2007, which determines the exempt status of a pharmaceutical item which has a particular form and manner of administration listed on the Pharmaceutical Benefits Scheme (PBS). It adds one drug which meets the criteria under section 84AH and removes another.

Background
Part VII of the *National Health Act 1953* (the Act) is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which 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 declared by the Minister by legislative instrument to be so under subsection 85(2). These are listed drugs as defined in subsection 84(1). Part VII also applies to certain extemporaneously-prepared medicinal preparations as a result of declarations under paragraph 85(2)(b).

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)), for example a 70 milligram tablet;
- the manner of administration of the form of the listed drug so determined (subsection 85(5)) for example, oral; 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 (except for certain extemporaneously-prepared pharmaceutical benefits) what constitutes the pharmaceutical benefit (defined in subsection 84(1)) under Part VII of the Act.

Certain provisions of the Act relating to brands of pharmaceutical items, including in relation to statutory price reductions, price disclosure, and guarantee of supply, are the result of amendments by the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007* (the amending Act), expressed to commence on 1 August 2007. Included in these amendments is the insertion of section 84AH into the Act.

Section 84AH empowers the Minister by legislative instrument to determine that a pharmaceutical item is an “exempt item”. This is permitted if there is only one listed brand

of the pharmaceutical item; there are no listed brands of other pharmaceutical items that are bioequivalent or biosimilar; and the listed drug in the pharmaceutical item is common to at least one brand of another pharmaceutical item. The Minister has also to be satisfied, having regard to any advice from the Pharmaceutical Benefits Advisory Committee (PBAC), that the listed drug in the relevant pharmaceutical item represents suitable therapy for a particular patient population; that the relevant item is suitable for use by a particular subgroup of that patient population because of either or both of the form and manner of administration of the drug in the item; and that no other pharmaceutical item that has that drug is suitable for use by that subgroup due to either or both of the form and manner of administration of the drug in that other item.

Exempt items are excluded from the statutory price reductions and from price disclosure requirements under the Act. The intention is to encourage availability of certain, and quite particular, pharmaceutical items by providing exemptions for particular formulations of drugs (eg oral solution) used by a demographic subgroup (eg children or geriatric patients) for whom other formulations of the drug are not suitable.

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

The instrument is expressed to commence on 1 November 2010. The instrument is expressed to commence in this way so that the items determined to be exempt by the instrument are exempt from statutory price reductions and any price disclosure obligations.

This instrument constitutes a legislative instrument for the purpose of the *Legislative Instruments Act 2003.*

Consultations

This instrument affects pharmaceutical companies with medicines listed on the PBS. In relation to the introduction of the exempt items measure in the *National Health Amendment (Pharmaceutical Benefits Scheme) Act 2007*, which commenced on 1 August 2007, pharmaceutical companies have been consulted during both the policy development and implementation phases.

The responsible person for the brand of the pharmaceutical item affected by this instrument has been consulted.

The Pharmaceutical Benefits Advisory Committee (PBAC) was also consulted in relation to issues relevant to this determination. 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 and about other matters as required under the Act. Under subsection 101(4AB) of the Act PBAC provides advice to the Minister if it is satisfied of certain matters concerning suitability of pharmaceutical items for use by particular sub-groups. Consideration given by PBAC, under section 101(4AB), to the pharmaceutical items affected by the instrument, was considered by the delegate of the Minister who made the instrument.

ATTACHMENT

Paragraph 1: Provides that the instrument will commence on 1 November 2010.

Paragraph 2: Determines that Schedule 1 amends PB 58 of 2007.

Schedule 1: Determines, under section 84AH that the 'Tablet (dispersible) 20 mg-120 mg' form of the listed drug artemether with lumefantrine, which is taken orally, is an exempt item. It also determines under section 84AH that the 'Suppository 3 mg' form of the listed drug containing prochlorperazine maleate 5 mg which is administered rectally is not an exempt item as it is no longer listed on the PBS.