EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 70 OF 2008

NATIONAL HEALTH ACT 1953

AMENDMENT TO THE INSTRUMENT THAT MAKES DETERMINATIONS UNDER SECTIONS 85, 85A and 88

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 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).

Subsection 85(3) authorises the Minister by legislative instrument to determine by reference to strength, type of unit, size of unit, or otherwise, the form or forms of a listed drug.

Subsection 85(5) authorises the Minister by legislative instrument to determine the manner of administration of a form of a listed drug where the form has been determined under subsection 85(3).

Subsection 85(6) authorises the Minister by legislative instrument to determine a brand of a pharmaceutical item. A "brand" is defined in subsection 84(1) to mean the trade name which the person who is or will be the "responsible person" supplies the pharmaceutical item, or if there is no trade name, the name of the responsible person. The responsible person for a brand of a pharmaceutical item is determined by the Minister by legislative instrument under section 84AF.

This legislative instrument amends the principal instrument that makes determinations under sections 85, 85A and 88 (PB 89 of 2007 which came into effect on 1 December 2007). This amending instrument revokes the brand determination made under subsection 85(6) for the brand 'Duatrol SR' of the pharmaceutical item that has the 'tablet 665mg (modified release)' form of the listed drug Paracetamol.

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

This instrument is expressed to commence at 11.59 pm on 31 July 2008 and was made on 19 June 2008. It commences at 11.59 pm on 31 July 2008 so that the brand may remain available on the PBS until that time, but still permit an exempt item determination (made under section 84AH in relation to the pharmaceutical item of which Duatrol SR is presently a brand) to be made before the expiration of 31 July 2008. The exempt item determination will provide for the remaining brand of the pharmaceutical item to be excluded from statutory price reductions and price disclosure obligations, including those occurring on 1 August 2008.

Consultations

The responsible person that supplies the 'Duatrol SR' brand of the pharmaceutical item that has the 'tablet 665mg (modified release)' form of the listed drug Paracetamol was consulted before the delegate of the Minister decided to make the amendments set out in this instrument. It is intended that another instrument will, immediately after this instrument commences, determine that the pharmaceutical item that has the 'tablet 665mg (modified release)' form of the listed drug Paracetamol is an exempt item under section 84AH. While Duatrol SR remains a brand of the relevant pharmaceutical item, that item cannot be determined to be exempt under s84AH.

The Pharmaceutical Benefits Advisory Committee (PBAC) was also consulted in relation to issues relevant to this determination. 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 relevant to suitability of pharmaceutical items for use by particular sub-groups.

Advice from PBAC under section 101(4AB) of the Act was considered by the person making decisions under s84AH concerning exempt item determinations as part of the process which also included consultations with the responsible person mentioned above.

ATTACHMENT

Paragraph 1: provides that this instrument commences at 11.59pm on 31 July 2008.

Paragraph 2: provides that Schedule 1 amends PB 89 of 2007.

Item 1, Item 2 and Item 3 of Schedule 1:

Revoke the brand determination for 'Duatrol SR', which is currently a brand of the pharmaceutical item that contains the listed drug Paracetamol in the form 'tablet 665 mg (modified release)', by removing it from Schedule 1, Part 1; Schedule 2, Part 1; and Schedule 2, Part 2.