EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 67 OF 2008

NATIONAL HEALTH ACT 1953

AMENDMENT SPECIAL ARRANGEMENTS UNDER SUBSECTION 100(1)

CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Purpose and operation

The purpose of the Australian Pharmaceutical Benefits Scheme (PBS) is to provide timely, reliable and affordable access for the Australian community to necessary and cost-effective medicines.

The PBS is regulated by Part VII of the *National Health Act 1953* (the Act), which provides for the supply of listed drugs and medicinal preparations as pharmaceutical benefits.

Subsection 85(1) of the Act provides that benefits shall be provided by the Commonwealth in accordance with Part VII of the Act in respect of pharmaceutical benefits.

Subsection 100(1) of the Act provides that the Minister may make special arrangements for providing that an adequate supply of special pharmaceutical products will be available to persons:

(a) who are living in isolated areas; or

(b) who are receiving medical treatment in such circumstances that pharmaceutical benefits:

  (i) cannot be conveniently or efficiently supplied in accordance with Part VII of the Act; or

  (ii) are inadequate for that medical treatment.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) provides that Part VII of the Act has effect subject to a special arrangement made under subsection 100(1).

The declaration made under subsection 85(2) of the Act sets out the drugs and medicinal preparations to which Part VII of the Act applies and the restrictions, if any, that apply to the prescribing of such drugs and medicinal preparations as pharmaceutical benefits. Schedule 6 of the declaration under subsection 85(2) lists those drugs and medicinal preparations that may be made available under arrangements provided for by section 100 of the Act.

The Chemotherapy Pharmaceuticals Access Program is a set of Arrangements made under subparagraph 100(b)(i) of the Act for the purpose of the supply of chemotherapy pharmaceuticals at public hospitals to non-admitted patients, day admitted patients and patients on discharge.

These Arrangements constitute a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

This legislative instrument in giving effect to recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC) amends Chemotherapy Pharmaceuticals Access Program Arrangements under subparagraph 100(b)(i) made by legislative instrument number PB 93 of 2007 which came into effect on 1 December 2007. 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 July 2008, was made on 3 June 2008.

Consultations

The PBAC is an independent expert body established by section 100A which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. When recommending the listing of a medicine 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.

The public hospital pharmaceutical reforms provide Australian Government subsidised access to a range of cancer chemotherapy drugs, listed on the PBS, for day admitted and non-admitted public hospital patients within a clinical setting under the Chemotherapy Pharmaceutical Access Program. The pharmaceutical reforms are implemented by means of an agreement between the Australian Government and participating States through the Australian Health Care Agreements. To date, Victoria, Western Australia, Queensland and the Northern Territory are participating in the reforms.

ATTACHMENT

Paragraph 1: provides that this instrument commences on 1 July 2008.

Paragraph 2: provides that Schedule 1 amends PB 93 of 2007.

Schedule 1: provides for the following amendments:

SCHEDULE 2

Alteration of Brand

In all instances the brand "Hospira Australia Pty Ltd" is changed to the brand "Hospira Pty Limited"

Folinic acid [Tablet containing calcium folinate equivalent to 15 mg folinic acid, injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL and injection containing calcium folinate equivalent to 300 mg folinic acid in 30 mL]

From: Leucovorin Calcium (Hospira Australia Pty Ltd)

To: Leucovorin Calcium (Hospira Pty Limited)

SCHEDULE 4

Alteration of Brand

Bleomycin [Powder for injection containing bleomycin sulfate 15,000 I.U. (with any determined brand of sodium chloride injection as the required solvent)]

From: "Hospira Australia Pty Ltd"

To: "Hospira Pty Limited"

Folinic acid [Injection containing calcium folinate equivalent to 50 mg folinic acid in 5 mL]

From: Leucovorin Calcium (Hospira Australia Pty Ltd)

To: Leucovorin Calcium (Hospira Pty Limited)