EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health and Ageing

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2011 (No. 6)

PB 46 of 2011

Purpose

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* (PB 116 of 2010) (the Special Arrangement), to make changes to the special arrangement relating to the highly specialised drugs program for hospitals.

The pharmaceutical benefits supplied under the Special Arrangement are for the treatment of chronic conditions which, because of their clinical use or other special features, may only be supplied to patients receiving treatment at or from a public or private hospital having access to appropriate specialised facilities.

Section 100 special arrangements and Part VII of the Act

Subsection 100(1) enables the Minister to make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

(a) who are living in isolated areas: or

(b) who are receiving treatment in circumstances in which generally available pharmaceutical benefits are inadequate for that treatment; or

(c) if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(3) provides that Part VII of the Act, and regulations and other legislative instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1). A section 100 arrangement may thus modify the operation of Part VII, the regulations and other relevant instruments.

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

Changes to the Special Arrangement made by this Instrument

This instrument:

- inserts a new pharmaceutical benefit that has a new Complex Authority Required ("CAR") drug;
- inserts the maximum quantity, number of repeats and prescribing circumstances for pharmaceutical benefits with the new CAR drug;
- inserts two new pharmaceutical benefits that have currently listed drugs; and
- changes the responsible person for various pharmaceutical benefits.

Consultation

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC).

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC. PBAC is an independent expert body established by section 100A of the Act 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 PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (PBS), 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.

Pharmaceutical companies were consulted throughout the process of changes to the prescribing circumstances for listings on the PBS and for this Instrument. This includes consultation through the PBAC process, and agreement to final listing details.

General

This Instrument commences on 1 July 2011.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2011 (No.6)*

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2011 (No.6)* and that it may also be cited as PB 46 of 2011.

Section 2 Commencement

This section provides that this Instrument commences on 1 July 2011.

Section 3 Amendments to PB 116 of 2010

This section provides that Schedule 1 amends the *National Health (Highly specialised drugs program for hospitals) Special Arrangement 2010* (PB 116 of 2010) (the Principal Instrument).

Schedule 1

Item 1 amends the definition of CAR drug in section 4 of the Principal Instrument to insert the new listed drug 'Omalizumab' in the list of CAR drugs.

Item 2 amends section 24 of the Principal Instrument to insert the maximum quantity of a pharmaceutical benefit with the new CAR drug 'Omalizumab' that may be supplied to a patient on one occasion.

Item 3 amends section 25 of the Principal Instrument to insert the maximum number of repeat supplies that may be authorised in a prescription for the supply of a pharmaceutical benefit with the new CAR drug 'Omalizumab'.

Item 4 amends the entry in Schedule 1 of the Principal Instrument pharmaceutical benefits that have the listed drug 'Interferon Alfa-2b' to change the responsible person from 'Schering-Plough Pty Limited' to 'Merck Sharp & Dohme (Australia) Pty Ltd'.

Item 5 amends the entry in Schedule 1 of the Principal Instrument to add a new pharmaceutical benefit with the listed drug 'Omalizumab'.

Item 6 amends the entry in Schedule 1 of the Principal Instrument for the pharmaceutical benefits that have the listed drug 'Peginterferon Alfa-2b' to change the responsible person from 'Schering-Plough Pty Limited' to 'Merck Sharp & Dohme (Australia) Pty Ltd'.

Item 7 amends the entry in Schedule 1 of the Principal Instrument for the pharmaceutical benefits that have the listed drug 'Ribarivin and Peginterferon Alfa-2b' to change the responsible person from 'Schering-Plough Pty Limited' to 'Merck Sharp & Dohme (Australia) Pty Ltd'.

Item 8 amends the entry in Schedule 1 of the Principal Instrument for the pharmaceutical benefits that have the listed drug 'Valaciclovir' to add two new brands, 'Valaciclovir RBX' and 'Valvala', and to amend the responsible person for the brand 'Zelitrex' from 'GlaxoSmithKline Australia Pty Ltd' to 'Aspen Pharma Pty Ltd'.

Item 9 amends Schedule 2 of the Principal Instrument to insert a new responsible person code ('GM') for the new responsible person 'Aspen Pharma Pty Ltd'.

Item 10 amends Schedule 2 of the Principal Instrument to omit the responsible person code 'RE' for the responsible person GlaxoSmithKine Pty Ltd. This responsible person is now only represented by the code 'GK' in the Principal Instrument. Item 10 also insert a new responsible person code ('RA') for the new responsible person 'Ranbaxy Australia Pty Ltd'.

Item 11 amends Schedule 3 of the Principal Instrument to insert an entry for pharmaceutical benefits that have the listed drug 'Omalizumab'. This entry contains description of the circumstance codes 'C3740', 'C3741' 'C3742'.