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. 12)

PB 99 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.

This instrument makes changes to the pharmaceutical benefits available under the section 100 special arrangement for 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

The changes made by this instrument reflect changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* made under sections 84AF, 85, 85A, 88 and 101 of the Act, which commence on the same day.

This instrument:

- adds three new pharmaceutical benefits;
- removes all pharmaceutical benefits with the listed drug ‘Peginterferon Alfa-2b’;

- fixes a typographical error in the description of one listed drug; and
- amends the form of one pharmaceutical benefit.

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 January 2012.

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

A provision by provision description of this Instrument is contained in the Attachment.

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2011 (No.12)*

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.12)* and that it may also be cited as PB 99 of 2011.

Section 2 Commencement

This section provides that this Instrument commences on 1 January 2012.

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 by changing the description of the listed drug 'Romiplostin' to 'Romiplostim'.

Item 2 amends paragraph 24(2)(k) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 3 amends paragraph 24(2)(l) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 4 amends paragraph 24(2)(m) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 5 amends paragraph 24(2)(n) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 6 amends paragraph 25(2)(p) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 7 amends paragraph 25(2)(q) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 8 amends paragraph 25(2)(r) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 9 amends paragraph 25(2)(s) of the Principal Instrument by changing the listed drug 'Romiplostin' to 'Romiplostim'.

Item 10 amends the entry in Schedule 1 of the Principal Instrument for the listed drug 'Epoprostenol' to add one pharmaceutical benefit, which is the listed drug 'Epoprostenol' in the form 'Powder for IV infusion, 500 micrograms (as sodium) infusion administration set' with manner of administration 'Injection' and brand 'Flolan Kit'.

Item 11 amends the entry in Schedule 1 of the Principal Instrument for the listed drug 'Epoprostenol' to add one pharmaceutical benefit, which is the listed drug 'Epoprostenol' in the forms 'Powder for IV infusion, 1.5 mg (as sodium) infusion administration set' with manner of administration 'Injection' and brand 'Flolan Kit'.

Item 12 amends the entry in Schedule 1 of the Principal Instrument for the listed drug 'Etravirine' to add one pharmaceutical benefit, which is the listed drug 'Etravirine' in the form 'Tablet 200 mg' with manner of administration 'Oral' and brand 'Intelence'.

Item 13 deletes the entry in Schedule 1 of the Principal Instrument for all pharmaceutical benefits with the listed drug 'Peginterferon Alfa-2b'.

Item 14 amends the entry in Schedule 1 of the Principal Instrument for the listed drug 'Romiplostin' by changing the description of the listed drug from 'Romiplostin' to 'Romiplostim'.

Item 15 amends the entry in Schedule 1 of the Principal Instrument for the pharmaceutical benefit that has the listed drug 'Tacrolimus' in the form '500 micrograms' by changing the form from '500 micrograms' to '0.5 mg'.

Item 16 deletes the entry in Schedule 3 of the Principal Instrument for the listed drug 'Peginterferon Alfa-2b'.

Item 17 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Romiplostin' by changing the listed drug from 'Romiplostin' to 'Romiplostim'

Item 18 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Romiplostin' by changing the listed drug 'Romiplostin' to 'Romiplostim' in the circumstances associated with circumstances code 'C3852'.

Item 19 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Romiplostin' by changing the listed drug 'Romiplostin' to 'Romiplostim' in the circumstances associated with circumstances code 'C3853'.

Item 20 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Romiplostin' by changing the listed drug 'Romiplostin' to 'Romiplostim' in the circumstances associated with circumstances code 'C3854'.