

EXPLANATORY STATEMENT

Issued by Authority of the Minister for Health

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 1)

PB 5 of 2012

Authority

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).

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.

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:

- corrects a typographical error in paragraph 24(2)(m);
- amends a reference in subparagraph 45(2)(b)(ii) to reflect the correct cross-reference;

- amends the circumstances associated with pharmaceutical benefits with the listed drugs ‘Abacavir with Lamivudine and Zidovudine’, ‘Adefovir’, ‘Entecavir’, ‘Interferon Alfa-2a’, ‘Interferon Alfa-2b’, ‘Lamivudine’, ‘Peginterferon Alfa 2a’, ‘Telbivudine’, ‘Tenofovir’ and ‘Tenofovir with emtricitabine and efavirenz’;
- adds a new pharmaceutical benefit with the listed drug ‘Darunavir’;
- adds two new pharmaceutical benefits with the listed drug ‘Filgrastim’;
- amends the responsible person associated with a pharmaceutical benefit with the listed drug ‘Foscarnet’; and
- adds two new responsible persons ‘Aspen Pharmacare Australia Pty Ltd’ and ‘Clinect Pty Ltd’.

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

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.

Statement of Compatibility

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

General

This Instrument commences on 1 March 2012.

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

**PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH
(HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL
ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 1)**

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 2012 (No. 1)* and that it may also be cited as PB 5 of 2012.

Section 2 Commencement

This section provides that this Instrument commences on 1 March 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 paragraph 24(2)(m) of the Principal Instrument by changing the reference to ‘PBSsubsidised’ to ‘PBS-subsidised’

Item 2 amends subparagraph 45(2)(b)(ii) of the Principal Instrument by changing the reference to ‘paragraph (a)’ to ‘subparagraph (i)’

Item 3 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Abacavir with Lamivudine and Zidovudine’ in the form ‘Tablet containing abacavir 300 mg (as sulphate) with lamivudine 150 mg and zidovudine 300 mg’ by omitting the circumstances codes ‘C3590’, ‘C3591’, ‘C3592’ and ‘C3593’ and inserting the circumstances codes ‘C3979’, ‘C3980’, ‘C3981’ and ‘C3982’.

Item 4 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Adefovir’ in the form ‘Tablet containing adefovir dipivoxil 10 mg’ by omitting the circumstances codes ‘C3863’ and ‘C3864’ and inserting the circumstances codes ‘C3971’, ‘C3972’, ‘C3973’ and ‘C3974’.

Item 5 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Darunavir’ to add a pharmaceutical benefit, which is the listed drug ‘Darunavir’ in the form ‘Tablet 600 mg (as ethanolate)’ with manner of administration ‘Oral’ and brand ‘Prezista’.

Item 6 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Entecavir’ in the form ‘Tablet containing entecavir monohydrate 0.5 mg’ by omitting the circumstances codes ‘C3871’ and ‘C3872’ and inserting the circumstances codes ‘C3959’, ‘C3960’, ‘C3961’ and ‘C3962’.

Item 7 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Entecavir’ in the form ‘Tablet containing entecavir monohydrate 1 mg’ by omitting the circumstances codes ‘C3873’ and ‘C3874’ and inserting the circumstances codes ‘C3963’, ‘C3964’, ‘C3965’ and ‘C3966’.

Item 8 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Filgrastim’ to add a pharmaceutical benefit, which is the listed drug ‘Filgrastim’ in the form ‘Injection 300 micrograms in 0.5 mL single use pre-filled syringe (TevaGrastim)’ with manner of administration ‘Injection’ and brand ‘TevaGrastim’.

Item 9 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Filgrastim’ to add a pharmaceutical benefit, which is the listed drug ‘Filgrastim’ in the form ‘Injection 480 micrograms in 0.5 mL single use pre-filled syringe (TevaGrastim)’ with manner of administration ‘Injection’ and brand ‘TevaGrastim’.

Item 10 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Foscarnet’ in the form ‘I.V. infusion containing foscarnet sodium 24 mg per mL, 250 mL’ by omitting the Responsible Person Code ‘AP’ and inserting the Responsible Person Code ‘IX’.

Item 11 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Interferon Alfa-2a’ by omitting the circumstances codes ‘C3869’ and ‘C3870’ and inserting the circumstances codes ‘C3959’, ‘C3960’, ‘C3961’ and ‘C3962’.

Item 12 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Interferon Alfa-2b’ by omitting the circumstances codes ‘C3869’ and ‘C3870’ and inserting the circumstances codes ‘C3959’, ‘C3960’, ‘C3961’ and ‘C3962’.

Item 13 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Lamivudine’ in the form ‘Tablet 100 mg’ by omitting the circumstances codes ‘C3871’ and ‘C3872’ and inserting circumstances codes ‘C3959’, ‘C3960’, ‘C3961’ and ‘C3962’.

Item 14 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Lamivudine’ in the form ‘Oral solution 5 mg per mL, 240 mL’ by omitting the circumstances codes ‘C3871’ and ‘C3872’ and inserting circumstances codes ‘C3959’, ‘C3960’, ‘C3961’ and ‘C3962’.

Item 15 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Peginterferon Alfa-2a’ by omitting the circumstances codes ‘C3867’ and ‘C3868’ and inserting circumstances codes ‘C3975’, ‘C3976’, ‘C3977’ and ‘C3978’.

Item 16 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Telbivudine’ by omitting the circumstances codes ‘C3865’ and ‘C3866’ and inserting the circumstances codes ‘C3967’, ‘C3968’, ‘C3969’ and ‘C3970’.

Item 17 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Tenofovir’ by omitting the circumstances codes ‘C3863’, ‘C3864’, ‘C3865’ and ‘C3866’ and inserting the circumstances codes ‘C3967’, ‘C3968’, ‘C3969’, ‘C3970’, ‘C3971’, ‘C3972’, ‘C3973’ and ‘C3974’.

Item 18 amends the entry in Schedule 1 of the Principal Instrument for the listed drug ‘Tenofovir with emtricitabine and efavirenz’ by omitting the circumstances codes ‘C3586’, ‘C3587’, ‘C3588’ and ‘C3589’ and inserting the circumstances codes ‘C3983’, ‘C3984’, ‘C3985’ and ‘C3986’.

Item 19 amends Schedule 2 of the Principal Instrument by omitting the Responsible Person Code ‘AP’ and associated Responsible Person ‘AstraZeneca Pty Ltd’.

Item 20 amends Schedule 2 of the Principal Instrument by inserting the Responsible Person Code ‘AS’ and associated Responsible Person ‘Aspen Pharmacare Australia Pty Ltd’.

Item 21 amends Schedule 2 of the Principal Instrument by inserting the Responsible Person Code 'IX' and associated Responsible Person 'Clinect Pty Ltd'.

Item 22 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Abacavir with Lamivudine and Zidovudine' by omitting the circumstances codes 'C3590', 'C3591', 'C3592' and 'C3593' and their associated circumstances and inserting the circumstances codes 'C3979', 'C3980', 'C3981' and 'C3982' and their associated circumstances.

Item 23 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Adefovir' by omitting the circumstances codes 'C3863' and 'C3864' and their associated circumstances and inserting the circumstances codes 'C3971', 'C3972', 'C3973' and 'C3974' and their associated circumstances.

Item 24 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Entecavir' by omitting the circumstances codes 'C3871' and 'C3872' and their associated circumstances and inserting the circumstances codes 'C3959', 'C3960', 'C3961' and 'C3962' and their associated circumstances.

Item 25 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Interferon Alfa-2a' by omitting the circumstances codes 'C3869' and 'C3870' and their associated circumstances and inserting the circumstances codes 'C3959', 'C3960', 'C3961' and 'C3962' and their associated circumstances.

Item 26 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Interferon Alfa-2b' by omitting the circumstances codes 'C3869' and 'C3870' and their associated circumstances and inserting the circumstances codes 'C3959', 'C3960', 'C3961' and 'C3962' and their associated circumstances.

Item 27 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Lamivudine' by omitting the circumstances codes 'C3871' and 'C3872' and their associated circumstances and inserting circumstances codes 'C3959', 'C3960', 'C3961' and 'C3962' and their associated circumstances.

Item 28 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Peginterferon Alfa-2a' by omitting the circumstances codes 'C3867' and 'C3868' and their associated circumstances and inserting circumstances codes 'C3975', 'C3976', 'C3977' and 'C3978' and their associated circumstances.

Item 29 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Telbivudine' by omitting the circumstances codes 'C3865' and 'C3866' and their associated circumstances and inserting the circumstances codes 'C3967', 'C3968', 'C3969' and 'C3970' and their associated circumstances.

Item 30 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Tenofovir' by omitting the circumstances codes 'C3863', 'C3864', 'C3865' and 'C3866' and their associated circumstances and inserting the circumstances codes 'C3967', 'C3968', 'C3969', 'C3970', 'C3971', 'C3972', 'C3973' and 'C3974' and their associated circumstances.

Item 31 amends the entry in Schedule 3 of the Principal Instrument for the listed drug 'Tenofovir with emtricitabine and efavirenz' by omitting the circumstances codes 'C3586', 'C3587', 'C3588' and 'C3589' and their associated circumstances and inserting the circumstances codes 'C3983', 'C3984', 'C3985' and 'C3986' and their associated circumstances.