

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 4)

PB 35 of 2012

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits. 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) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

Purpose

The purpose of this legislative instrument, made under subsections 100(1) and 100(2) of the 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.

This instrument makes changes to 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 provides for the addition of a listed brand with the listed drug ‘Mycophenolic Acid’ and a new listed drug ‘Tenofovir with Emtricitabine and Rilpivirine’ to this Special Arrangement.

This instrument also adds the new listed drug ‘Tenofovir with Emtricitabine and Rilpivirine’ to the list of medication for the treatment of HIV or AIDS under this Special Arrangement.

This instrument also corrects an error in the identification of section 100 only status for listed brands with the listed drug ‘Mycophenolic Acid’.

A provision by provision description of this Instrument is contained in [Attachment 1](#).

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 listings on the PBS and for this Instrument. This includes consultation through the PBAC process, and agreement to final listing details.

This Instrument commences on 1 June 2012.

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

ATTACHMENT 1**PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2012 (No. 4)****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.4)* and that it may also be cited as PB 35 of 2012.

Section 2 Commencement

This section provides that this Instrument commences on 1 June 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 Special Arrangement).

Schedule 1**SUMMARY OF CHANGES****Listed Drug Added to this Special Arrangement**

Tenofovir with Emtricitabine and Rilpivirine

Brand Added to this Special Arrangement

| | | |
|-------------------|--|-----------------------------|
| Mycophenolic Acid | Capsule containing mycophenolate mofetil 250mg | Pharmacor Mycophenolate 250 |
|-------------------|--|-----------------------------|

Listed Drug added to the definition of ‘medication for the treatment of HIV or AIDS’ in this Special Arrangement

Tenofovir with Emtricitabine and Rilpivirine

Circumstances Added to this Special Arrangement

| | |
|--|--|
| Tenofovir with Emtricitabine and Rilpivirine | For initial and continuing treatment of Human Immunodeficiency Virus (HIV) infection |
|--|--|

Correction to Section 100 only status

For listed brands with the listed drug ‘Mycophenolic Acid’ the letter indicated in the column headed ‘Section 100 only’ is amended to reflect that it is only for specific circumstances that those listed brands are only available under this Special Arrangement.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Highly specialised drugs program for hospitals) Special Arrangement Amendment Instrument 2012 (No.4)

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*.

Overview of the Legislative Instrument

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.

This instrument adds one new listed drug, one new brand for a listed drug, the new listed drug to the list of medication for the treatment of HIV or AIDS and corrects an error in the identification of section 100 only status for listed brands with the listed drug 'Mycophenolic Acid'.

Human rights implications

This legislative instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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