EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM FOR HOSPITALS) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2013 (No.5)

PB 56 of 2013

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.

The amendments made by this Instrument reflect changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, which commence on the same day.

This instrument inserts two new brands of the drug Filgrastim and two new forms of the drug Raltegravir.

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 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 September 2013.

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 2013 (No.5)*

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 2013 (No.5)* and that it may also be cited as PB 56 of 2013.

Section 2 Commencement

This section provides that this Instrument commences on 1 September 2013.

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 Amendments

Item 1 Schedule 1, after entry for Filgrastim in the form Injection 300 micrograms in 0.5 mL single use pre-filled syringe (TevaGrastim)

This item inserts a new brand, Zarzio, of the drug Filgrastim in the form Injection 300 micrograms in 0.5 mL single use pre-filled syringe.

Item 2 Schedule 1, after entry for Filgrastim in the form Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Nivestim)

This item inserts a new brand, Zarzio, of the drug Filgrastim in the form Injection 480 micrograms in 0.5 mL single use pre-filled syringe.

Item 3 Schedule 1, entry for Raltegravir

This item inserts two new forms, Tablet 100 mg (as potassium) and Tablet 25 mg (as potassium), of the drug Raltegravir, manner of administration Oral with the brand Isentress.

Item 4 Schedule 3, entry for Raltegravir

This item inserts the text for the new restrictions which apply to the two new forms of Raltegravir.

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 2013 (No.5)

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 inserts two new brands of the drug Filgrastim and two new forms of the drug Raltegravir. The changes are due to take effect from 1 September 2013.

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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