EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2015 (No. 12)

PB 111 of 2015

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 Act, is to amend the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010) (the Special Arrangement), to make changes to the Special Arrangement relating to the highly specialised drugs program.

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

The amendments in PB 111 of 2015 include adding and removing and changes to the circumstances for prescribing various pharmaceutical benefits, and amendments to responsible person codes.

These changes are summarised, by drug name, in the Attachment.

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), the 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.

Details of the instrument are set out in the Attachment.

This Instrument commences on 1 December 2015.

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

ATTACHMENT

Details of the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment Instrument 2015*

Section 1 Name of Instrument
This section provides the name of this instrument as the *National Health (Highly specialised drugs program) Special Arrangement Amendment Instrument 2015 (No. 12).* It can also be citied as PB 111 of 2015.

Section 2 Commencement
This section provides that this instrument commences on 1 December 2015.

Section 3 Amendment
This section provides that Schedule 1 amends the *National Health (Highly specialised drugs program) Special Arrangement 2010* (PB 116 of 2010).

Items 1 - 14
Provide for deletions to drugs, forms, brands, and changes to the circumstances for prescribing various pharmaceutical benefits.

These changes are summarised below.

Summary of Changes

Alteration of Circumstances

Dornase alfa	Remodelled restrictions
Everolimus	Remodelled restrictions
Mannitol	Remodelled restrictions
Mycophenolic acid	Remodelled restrictions
Octreotide	Remodelled restrictions
Sirolimus	Remodelled restrictions
Tipranavir	Remodelled restrictions
Zoledronic Acid	Remodelled restrictions

Addition of Brands

Infliximab	Inflectra
Zoledronic Acid	APO-Zoledronic Acid
	DBL Zoledronic Acid

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) Special Arrangement Amendment Instrument 2015 (No. 12)

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) Special Arrangement 2010* (PB 116 of 2010) (the Special Arrangement), to make changes to the Special Arrangement relating to the highly specialised drugs program.

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 specialised treatment.

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 Regulation amendments and this instrument are a positive step towards attaining the highest standard of health for all Australians. 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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