

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (Growth Hormone Program) Special Arrangement

Amendment Instrument 2015 (No.1)

PB 96 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 (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement), to make changes relating to the Growth Hormone Program.

The purpose of the Special Arrangement is to allow for growth hormone to be supplied to specific patients through eligible medical practitioners.

This instrument:

- adds two new pharmaceutical benefits to the schedule of pharmaceutical benefits covered by the Special Arrangement (schedule 1); and
- amends the brand name of a pharmaceutical benefit listed in the schedule of pharmaceutical benefits covered by the Special Arrangement (schedule 1).

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

Consultation

The addition of these amendments was made having regard to advice provided by the Pharmaceutical Benefits Advisory Committee (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 has broad representation with members appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists; at least one member is 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 are consulted throughout the process for additions and changes to listings on the PBS and for this Special Arrangement. This includes consultation through the PBAC process, which provides for consumers making submissions to the Committee in respect of proposals to be discussed, and agreement to final listing details.

General

This instrument commences on 1 December 2015.

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

PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (GROWTH HORMONE PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2015 (No. 1)

Section 1 Name of Instrument

This section provides that this instrument is the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2015 (No. 1)* and that it may also be cited as PB 96 of 2015.

Section 2 Commencement

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

Section 3 Amendment of PB 85 of 2015

This section provides that Schedule 1 amends the *National Health (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement).

Schedule 1

Item 1 amends Schedule 1 of the Special Arrangement by adding a pharmaceutical benefit which is the listed drug ‘Somatropin’, in the form ‘Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)’, with the manner of administration of ‘Injection’, and brand ‘Omnitrope Surepal 5’.

Item 2 amends Schedule 1 of the Special Arrangement by adding a pharmaceutical benefit which is the listed drug ‘Somatropin’, in the form ‘Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)’, with the manner of administration of ‘Injection’, and brand ‘Omnitrope Surepal 10’.

Item 3 amends the entry in Schedule 1 of the Special Arrangement for the listed drug ‘Somatropin’, in the form ‘Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)’, with the manner of administration of ‘Injection’, and brand Omnitrope SurePal’, by substituting the brand ‘Omnitrope SurePal’ with the brand ‘Omnitrope Surepal 15’.

Statement of Compatibility with Human Rights

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

National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2015 (No. 1)

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 (2) of the *National Health Act 1953*, is to amend the *National Health (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement) to make changes relating to the Growth Hormone Program.

The purpose of the Special Arrangement is to allow for growth hormone to be supplied to specific patients through eligible medical practitioners.

This instrument:

- adds two new pharmaceutical benefits to the schedule of pharmaceutical benefits covered by the Special Arrangement (schedule 1); and
- amends the brand name of a pharmaceutical benefit listed in the schedule of pharmaceutical benefits covered by the Special Arrangement (schedule 1).

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 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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