EXPLANATORY STATEMENT

**NATIONAL HEALTH ACT 1953**

*National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2016 (No. 1)*

PB 87 of 2016

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 (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 ensure that an adequate supply of pharmaceutical benefits is available for patients who require treatment with growth hormone.  Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

This Instrument reflects changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day.

This Instrument adds a new pharmaceutical benefit which is the listed drug ‘Somatropin’ in a specified form, manner of administration and brand.

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

Consultation

This amendment to the Special Arrangement was made having regard to advice provided by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body established by section 100A of the Act, which makes recommendations to the Minister for Health about which drugs and medicinal preparations should be available as pharmaceutical benefits. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC. When making recommendations, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia and its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of these interests or professions.  Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

Pharmaceutical companies were consulted throughout the process for additions and changes to listings on the Pharmaceutical Benefits Scheme (PBS) and for this Special Arrangement. This includes consultation through the PBAC process, and agreement to final listing details.

This Instrument commences on 1 October 2016.

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

**ATTACHMENT**

***PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (GROWTH HORMONE PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2016 (No. 1)***

**Section 1 Name of Instrument**

This section provides that this Instrument is the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2016 (No. 1)* and that it may also be cited as PB 87 of 2016.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 October 2016.

**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 ‘Injection 0.4 mg (1.2 i.u.) with diluent in single use syringe (without preservative)’, with the manner of administration ‘Injection’ and brand ‘Genotropin MiniQuick’.

**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 2016 (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 ensure that an adequate supply of pharmaceutical benefits is available for patients who require treatment with growth hormone.  Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

This Instrument reflects changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day.

This Instrument adds a new pharmaceutical benefit which is the listed drug ‘Somatropin’ in a specified form, manner of administration and brand.

**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 the 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.

**Karen Hall**

**Acting Assistant Secretary**

**Pharmaceutical Access Branch**

**Pharmaceutical Benefits Division**

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