

## EXPLANATORY STATEMENT

### *NATIONAL HEALTH ACT 1953*

#### ***NATIONAL HEALTH (GROWTH HORMONE PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2018 (No. 2)***

***PB 35 of 2018***

#### **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**

This is the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2018 (No. 2)* (the Amendment Instrument). The purpose of the Amendment Instrument is to amend the *National Health (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement), to make changes to the Special Arrangement 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 (somatropin). Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

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

The amendments in PB 35 of 2018 include the addition of a brand of somatropin.

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. This includes consultation through the PBAC process. Further consultation for this Instrument was considered unnecessary due to the nature of the consultation that had already taken place in the decision to list the medication.

Details of the instrument are set out in the Attachment.

This Instrument commences on 1 May 2018.

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

**Details of the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2018 (No. 2)***

**PART 1 PRELIMINARY**

**Section 1 Name of Instrument**

This section provides the name of this instrument as the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2018 (No. 2)*. It can also be cited as PB 35 of 2018.

**Section 2 Commencement**

This section provides that this instrument commences on 1 May 2018.

**Section 3 Amendment**

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

**Schedule - Amendments**

**Item 1** amends Schedule 1 of the Special Arrangement by the addition of a brand of somatropin in the form “Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)”.

## 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 2018 (No. 2)***

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 subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement), to make changes to the Special Arrangement 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.

#### **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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