

## **EXPLANATORY STATEMENT**

### ***NATIONAL HEALTH ACT 1953***

#### ***National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2017 (No. 2)***

**PB 91 of 2017**

#### **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 the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2017 (No. 2)* (the Instrument) 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 circumstances in which growth hormone can be prescribed as a pharmaceutical benefit under the Pharmaceutical Benefits Scheme (PBS) Growth Hormone Program.

The Special Arrangement ensures 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.

The Instrument:

- a) allows the calculation of ideal body weight (IBW) (required for assessment of eligibility and dosage for treatment with PBS-subsidised growth hormone) for patients with Prader-Willi Syndrome (PWS) whose height is greater than 176.8 centimetres (males) or 163.3 centimetres (females); and
- b) removes the requirement for prescribers to provide an original PBS Authority prescription when applying for authority to prescribe PBS-subsidised growth hormone through the Department of Human Services' (DHS) Online PBS Authorities system. Instead, prescribers will obtain authority by providing written details of the prescription to the Chief Executive Medicare, electronically and in a form approved by the Chief Executive Medicare.

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

#### **Consultation**

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 Pharmaceutical Benefits Advisory Committee (PBAC).

The PBAC is 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 and the

circumstances in which they should be available. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC.

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 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.

The amendments to the Special Arrangement concerning the calculation of IBW were made having regard to advice provided by the PBAC at its July 2017 meeting, as well as prior clinical advice sought internally to the Department of Health (the Department).

In developing the operational aspects of the amendments, the Department has also consulted with the DHS.

The Instrument incorporates reference to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* as in force from time to time.

The Instrument commences on 1 November 2017.

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

## ATTACHMENT

***DETAILS OF THE NATIONAL HEALTH (GROWTH HORMONE PROGRAM)  
SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2017 (No. 2)*****Section 1 Name of Instrument**

This section provides that this Instrument is the *National Health (Growth Hormone Program) Special Arrangement Amendment Instrument 2017 (No. 2)*, and that it may also be cited as PB 91 of 2017.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 November 2017.

**Section 3 Authority**

This section provides that this Instrument is made under subsection 100(2) of the *National Health Act 1953*.

**Section 4 Schedule**

This section provides that each instrument that is specified in a Schedule to this Instrument is amended or repealed as set out in the applicable items in the Schedule concerned. It also provides that any other item in a Schedule to this Instrument has effect according to its terms. The *National Health (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement) is amended by the Schedule.

**Schedule 1 Amendments**

**Item 1** inserts a definition of ‘ideal body weight’ (IBW) in subsection 4(1) of the Special Arrangement that replaces the existing definition of ‘ideal weight for height’. The definition of IBW includes the existing method of calculation previously referred to within the definition of ‘ideal weight for height’, to be used for patients with Prader-Willi Syndrome (PWS) whose height is less than or equal to 176.8 centimetres (males) or 163.3 centimetres (females). The definition also includes an alternative method of calculation that will apply to patients with PWS whose height is greater than 176.8 centimetres (males) or 163.3 centimetres (females). This allows prescribers to determine IBW for patients whose height exceeds the maximum applicable limit on the Centers for Disease Control and Prevention (CDC) 2000 growth charts. This CDC document, which is referred to within the definition of IBW, is incorporated as dated May 2002; it is available online and free of charge at [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](https://www.cdc.gov/growthcharts/clinical_charts.htm).

**Item 2** removes the definition of ‘ideal weight for height’ from subsection 4(1) of the Special Arrangement.

**Item 3** inserts a definition of ‘main listing instrument’ in subsection 4(1) of the Special Arrangement. The definition refers to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, or an instrument made to replace that instrument. The main listing instrument is incorporated as in force from time to time. This definition is relevant for new section 9A (see item 5).

**Item 4** replaces the definition of ‘Regulations’ in subsection 4(1) with reference to the *National Health (Pharmaceutical Benefits) Regulations 2017*. This is a consequential change resulting from the repeal of the *National Health (Pharmaceutical Benefits) Regulations 1960* and remaking as the *National Health (Pharmaceutical Benefits) Regulations 2017*.

**Item 5** adds a new section 9A *Prescription – Authority required procedures*. This section is intended to adjust the ‘Authority required’ procedures set out in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* as they apply to somatropin (growth hormone). Growth hormone is listed within this instrument as a ‘Written Authority Required’ medicine. Written Authority required prescriptions require the prior authorisation of the Chief Executive Medicare, including by means of submission of the prescription itself to the Chief Executive Medicare.

New section 9A will remove the requirement for a prescriber to submit the authority prescription form to the Chief Executive Medicare when lodging an electronic application for authority to prescribe growth hormone. Instead, the prescriber will be required to submit details of the prescription to the Chief Executive Medicare in writing, by means of an electronic communication and in a form approved by the Chief Executive Medicare.

A prescription submitted in accordance with section 9A will be taken to have been authorised where the Chief Executive Medicare provides authorisation by an electronic communication to the prescriber.

**Item 6** replaces the reference to ‘ideal weight for height (kg)’ in subsection 10(2) of the Special Arrangement with a reference to ‘ideal body weight (kg)’. Section 10 sets out definitions for the purposes of Part 3 of the Special Arrangement, which deals with the calculation of the treatment dose for growth hormone.

**Item 7** replaces the reference to ‘ideal weight for height’ in subsection 10(3) of the Special Arrangement with a reference to ‘ideal body weight in kilograms’.

**Item 8** replaces the reference to ‘ideal weight for height’ in subsection 11(4) of the Special Arrangement with a reference to ‘ideal body weight in kilograms’. Section 11 of the Special Arrangement sets out the maximum dosages that may be prescribed under the Special Arrangement for various categories of patient. Subsection 11(4) deals with calculating the maximum dosage for a patient with PWS whose BMI is greater than the 85<sup>th</sup> percentile for age and sex.

## 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 2017 (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*, 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 circumstances in which growth hormone can be prescribed as a pharmaceutical benefit under the Pharmaceutical Benefits Scheme (PBS) Growth Hormone Program.

The Special Arrangement ensures 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:

- a) allows the calculation of ideal body weight (IBW) (required for assessment of eligibility and dosage for treatment with PBS-subsidised growth hormone) for patients with Prader-Willi Syndrome (PWS) whose height is greater than 176.8 centimetres (males) or 163.3 centimetres (females); and
- b) removes the requirement for prescribers to provide an original PBS Authority prescription when applying for authority to prescribe PBS-subsidised growth hormone through the Department of Human Services' Online PBS Authorities system. Instead, prescribers will obtain authority by providing written details of the prescription to the Chief Executive Medicare, electronically and in a form approved by the Chief Executive Medicare. The Chief Executive Medicare will also be able to provide authorisation of the prescription by electronic communication to the prescriber.

#### **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 changes made by this Instrument assist with the advancement of this human right by enabling appropriate access to PBS-subsidised growth hormone for PWS patients whose height is greater than 176.8 centimetres (males) or 163.3 centimetres (females); and by improving general ease of access to PBS-subsidised growth hormone by simplifying administrative procedures for prescribing.

#### **Conclusion**

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

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