EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (Growth Hormone Program) Special Arrangement Amendment (Adult Use) Instrument 2018

PB 96 of 2018

Authority

This instrument is made under section 100 of the *National Health Act 1953* (the Act). Subsection 100(1) of 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 *National Health (Growth Hormone Program) Special Arrangement Amendment (Adult Use) Instrument 2018* (the Instrument) amends the *National Health (Growth Hormone Program) Special Arrangement 2015* (PB 85 of 2015) (the Special Arrangement). The purpose of the amendments is to include provision for the supply under the Pharmaceutical Benefits Scheme (PBS) of the pharmaceutical benefit somatropin (growth hormone) for the treatment of adults who have severe growth hormone deficiency and substantially impaired quality of life. Currently the Special Arrangement operates so that growth hormone can only be prescribed to children.

In July 2017 the Pharmaceutical Benefits Advisory Committee (PBAC) considered, and gave a positive recommendation to, a submission by the Endocrine Society of Australia and the Australian Paediatric Endocrine Group to list somatropin for use in adults with severe growth hormone deficiency and substantially impaired quality of life. 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 and the circumstances in which they should be available. The Instrument is intended to implement PBAC's recommendation to make somatropin available to adults.

PBAC recommended that somatropin be made available to adults through a special arrangement. The Instrument amends the Special Arrangement to provide for an adequate supply of PBS medicine for adults who require treatment with somatropin. Somatropin is not otherwise available on the PBS for adult use.

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

Consultation

In developing the operational aspects of the Instrument, the Department has consulted with the Department of Human Services.

The Endocrine Society of Australia and the Australian Paediatric Endocrine Group were consulted as part of the finalisation of restrictions criteria to support the listing of somatropin on the PBS for adult use.

The Instrument commences on 1 December 2018.

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 (Adult Use) Instrument 2018*

Section 1 - Name of Instrument

This section provides that this Instrument is the *National Health (Growth Hormone Program) Special Arrangement Amendment (Adult Use) Instrument 2018*, and that it may also be cited as PB 96 of 2018.

Section 2 - Commencement

This section provides that this Instrument commences on 1 December 2018.

Section 3 - Authority

This section provides that this Instrument is made under section 100 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.

Schedule 1 - Amendments

Items 1-6: Definitions

Item 1 inserts a definition of 'adult' in subsection 4(1) of the Special Arrangement. An adult is defined as a person who has turned 18.

Items 2 and 3 amend paragraphs (a), (b) and (c) of the definition of an 'authorised prescriber' in subsection 4(1) to clarify that an authorised prescriber, as defined in those paragraphs, is an authorised prescriber for a child.

Item 4 adds new paragraph (d) to the definition of 'authorised prescriber' in subsection 4(1) of the Special Arrangement. New paragraph (d) specifies that for the initial or the continuing treatment phase for an adult, an authorised prescriber is a specialist or consultant physician in endocrinology.

Item 5 inserts a definition of 'child' in subsection 4(1) of the Special Arrangement. A child is defined as a person who has not turned 18.

Items 6 adds a note at the end of the definition of 'pharmaceutical benefit' in subsection 4(1) of the Special Arrangement. The note states that pharmaceutical benefits mentioned in Part 1 of Schedule 1 of the Special Arrangement may only be supplied on a prescription written for a child and that pharmaceutical benefits mentioned in Part 2 of Schedule 1 may only be supplied on a prescription written for an adult. The note directs readers to sections 7A and 9AA.

Item 7: At the end of subsection 5(1)

This item adds a note at the end of subsection 5(1) of the Special Arrangement. The note states that pharmaceutical benefits mentioned in Part 1 of Schedule 1 of the Special Arrangement may only be supplied on a prescription written for a child and that pharmaceutical benefits mentioned in Part 2 of Schedule 1 may only be supplied on a prescription written for an adult. The note directs readers to sections 7A and 9AA.

Item 8: Subsection 7(1)

This item inserts 'of a table' after 'column' in subsection 7(1) of the Special Arrangement. This amendment is necessary because the Instrument inserts a second table into Schedule 1 (see items 41 to 43).

Items 10 to 18, 20 to 24, and 26 to 30: Prescriptions for children

The Special Arrangement previously only covered the prescribing and supply of human growth hormone to children. The purpose of these amendments is to amend existing requirements relating to the prescribing to clearly specify that they relate to prescribing for children, to distinguish them from new requirements relating to prescribing human growth hormone for adults.

These amendments are technical in nature and do not alter existing arrangement for prescribing to children under the Special Arrangement.

Item 10 adds a new heading before section 8 *'Subdivision A – Prescriptions for Children'*. This item also adds a section '*7A Prescription of pharmaceutical benefits in Part 1 of Schedule 1 for children'*.

Item 11 repeals the heading to section 8 'Prescription – Maximum quantity' and replaces it with the heading '*Prescription for child – maximum quantity*'.

Item 12 amends subsection 8(1) of the Special Arrangement to insert 'for a child' after 'one prescription'.

Items 13 through to 15 replace 'a person' in paragraph 8(1)(a), 'the person' (wherever occurring) in paragraph 8(1)(b), and 'a person' in paragraph 8(1)(c) with 'the child'. These amendments clarify that the maximum quantity requirements during an initial treatment period set out in subsection 8(1) only apply to a child.

Item 16 inserts 'for a child' in subsection 8(2) of the Special Arrangement after 'one prescription'.

Items 17 and 18 replaces 'a person' in paragraph 8(2)(a) and a 'person' (first occurring) in paragraph 8(2)(b) with 'the child'.

Items 20 and 21 respectively replace 'person' (second occurring) in paragraph 8(2)(b) with 'child for that treatment period' and 'a person' in paragraph 8(2)(c) with 'the child'.

Item 22 amends subsection 8(3) of the Special Arrangement to insert 'for a child' after 'one prescription'.

Items 23 and 24 replaces 'a person' in paragraph 8(3)(a) of the Special Arrangement and person' (first occurring) in paragraph 8(3)(b) with 'the child'.

Items 26 and 27 replaces 'person' (second occurring) in paragraph 8(3)(b) with 'the child' and 'a person' in paragraph 8(3)(c) with 'child for that treatment period'.

Item 28 repeals the heading to section 9 of the Special Arrangement '*Prescription – maximum number of repeats*' and replaces it with '*Prescription for child – maximum number of repeats'*.

Item 29 inserts 'for a child' in subsection 9(1) of the Special Arrangement after 'one prescription'.

Item 30 replaces 'a person' in paragraphs 9(1)(a), (b) and (c) of the Special Arrangement with 'the child'.

Item 31: After section 9

This item adds two new subdivisions after section 9 of the Special Arrangement. New Subdivision B, made up of new sections 9AA, 9AB and 9AC, deals with the prescription requirements for adults under the Special Arrangement, including the pharmaceutical benefits that can be prescribed to an adult, the maximum quantity that can be prescribed, and the maximum number of repeats that can be included in one prescription. New Subdivision C, made up of new section 9AD, limits the prescribing under treatment phases for a child or an adult to the appropriate authorised prescriber.

Item 32: Section 9A (heading)

This item repeals the heading to section 9A of the Special Arrangement and replaces it with '*9A Prescription for child or adult – authority required procedures'*. This is intended to indicate that the authority required procedures set out in section 9A apply to the writing of a prescription for supply of a pharmaceutical benefit for both a child and adult.

Items 35 and 36: Treatment doses for children

Item 35 repeals the heading to Part 3 of the Special Arrangement and replaces it with '*Treatment doses for children*'. This is intended to make clear that the dose requirements set out in Part 3 only apply to a prescription for a child.

Item 36 inserts new section 9B in the Special Arrangement. New section 9B clarifies that the calculation for determining the treatment dose for growth hormone only applies to a child being prescribed a pharmaceutical benefit listed in Part 1 of Schedule 1 of the Special Arrangement.

Item 40: Repeal of Part 8

This item repeals *'Part 8 – Transitional Provisions'* as the Part is no longer effective.

Items 41 to 43: Amendments to Schedule 1

Item 41 repeals the note to the Schedule 1 heading 'sections 5 and 7' and replaces it with 'sections 5, 7, 7A and 9AA' to reflect the insertion of the new subdivisions (refer Items 10 and 31).

Item 42 inserts the heading '*Part 1 – Pharmaceutical benefits for treatment of children*' before the table at Schedule 1. Part 1 of the Schedule lists the pharmaceutical benefits available for the treatment of children under the Special Arrangement.

Item 43 inserts the heading '*Part 2 – Pharmaceutical benefits for treatment of adults*' at the end of Schedule 1 and an associated table, which lists the somatropin pharmaceutical benefits available for the treatment of adults under the Special Arrangement.

Items 9, 19, 25, 33, 34, 37, 38 and 39: Various technical amendments

The opportunity has been taken to make a number of minor technical amendments to the Special Arrangement to correct errors and improve drafting.

Item 9 repeals subsections 7(3), (4), (5), (6) of the Special Arrangement and the note at the end of subsection 7(6). Those subsections set out rules applying where a pharmaceutical benefit is listed in the Schedule to the Special Arrangement with a code of 'PB(100)' or 'C(100)'. No pharmaceutical benefits are listed with these codes and therefore these subsections are redundant.

Item 19 removes 'continuing' from paragraph 8(2)(b) of the Special Arrangement, as the context of subsection 8(2) makes the word redundant.

Item 25 removes 'recommencement' from paragraph 8(3)(b) of the Special Arrangement, as the context of subsection 8(3) makes the word redundant.

Items 33 and 34 amend minor drafting oversights in section 9A. Item 33 inserts ‘of that instrument’ in subsection 9A(1) after ‘section 12’ and item 34 adds ‘of this section’ at the end of subsection 9A(1).

Item 37 amends omits reference to ‘meter of the body surface of the person area’ in paragraph 10(2)(a) of the Special Arrangement and replaces it with ‘metre of the body surface area of the person’ to correct a minor drafting error.

Item 38 replaces ‘patient’ in subsection 11(2) with ‘person’ for consistency with the rest of section 11.

Item 39 inserts ‘approved pharmacist, approved medical practitioner or’ after ‘The’ in subsection 23(2) of the Special Arrangement to be consistent with subsection 23(1) regarding patient contributions.

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 (Adult Use) Instrument 2018

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 section 100 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 enable the supply of pharmaceutical benefits relating to somatropin (growth hormone) for the treatment of adults with severe growth hormone deficiencies and substantially impaired quality of life.

Assessment, eligibility and dosage requirements set out in this Legislative Instrument for the treatment of adults with PBS subsidised somatropin (growth hormone) have been based on clinical evidence and the expert opinion of the Pharmaceutical Benefits Advisory Committee (PBAC).

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 adults with severe growth hormone deficiency to the enjoyment of the highest attainable standard of physical and mental health.

The changes made by this Legislative Instrument assist with the advancement of this human right by enabling appropriate access to Pharmaceutical Benefits Scheme (PBS) subsidised somatropin (growth hormone) treatment for adults.

Conclusion

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

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