

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

I, Julianne Quaine, as delegate of the Minister for Health, make the following instrument.

Dated 27 November 2018

Julianne Quaine

Assistant Secretary
Pharmacy Branch
Technology Assessment and Access Division
Department of Health

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1 Name

 (1) This instrument is the *National Health (Growth Hormone Program) Special Arrangement Amendment (Adult Use) Instrument 2018*.

 (2) This instrument may also be cited as PB 96 of 2018.

2 Commencement

 (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information |
| --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | 1 December 2018. | 1 December 2018 |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

 (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

 This instrument is made under section 100 of the *National Health Act 1953.*

4 Schedules

 Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Growth Hormone Program) Special Arrangement 2015 (PB 85 of 2015)

1 Subsection 4(1)

Insert:

***adult*** means a person who has turned 18.

2 Subsection 4(1) (paragraphs (a) and (b) of the definition of *authorised prescriber*)

After “phase”, insert “for a child”.

3 Subsection 4(1) (paragraph (c) of the definition of *authorised prescriber*)

After “phase” (wherever occurring), insert “for a child”.

4 Subsection 4(1) (at the end of the definition of *authorised prescriber*)

Add:

 (d) for the initial treatment phase for an adult or the continuing treatment phase for an adult, means a specialist or consultant physician in endocrinology.

5 Subsection 4(1)

Insert:

***child*** means a person who has not turned 18.

6 Subsection 4(1) (at the end of the definition of *pharmaceutical benefit*)

Add:

Note: Only pharmaceutical benefits mentioned in Part 1 of Schedule 1 may be supplied on a prescription written for a child, and only pharmaceutical benefits mentioned in Part 2 of Schedule 1 may be supplied on a prescription written for an adult: see sections 7A and 9AA.

7 At the end of subsection 5(1)

Add:

Note: Only pharmaceutical benefits mentioned in Part 1 of Schedule 1 may be supplied on a prescription written for a child, and only pharmaceutical benefits mentioned in Part 2 of Schedule 1 may be supplied on a prescription written for an adult: see sections 7A and 9AA.

8 Subsection 7(1)

After “column”, insert “of a table”.

9 Subsections 7(3), (4), (5) and (6)

Repeal the subsections.

10 Before section 8

Insert:

Subdivision A—Prescriptions for children

7A Prescription of pharmaceutical benefits in Part 1 of Schedule 1 for children

 A pharmaceutical benefit must not be supplied on a prescription written for a person who is a child when the prescription is written unless the pharmaceutical benefit is mentioned in Part 1 of Schedule 1.

11 Section 8 (heading)

Repeal the heading, substitute:

8 Prescription for child—maximum quantity

12 Subsection 8(1)

After “one prescription”, insert “for a child”.

13 Paragraph 8(1)(a)

Omit “a person”, substitute “the child”.

14 Paragraph 8(1)(b)

Omit “the person” (wherever occurring), substitute “the child”.

15 Paragraph 8(1)(c)

Omit “a person”, substitute “the child”.

16 Subsection 8(2)

After “one prescription”, insert “for a child”.

17 Paragraph 8(2)(a)

Omit “a person”, substitute “the child”.

18 Paragraph 8(2)(b)

Omit “person” (first occurring), substitute “child”.

19 Paragraph 8(2)(b)

Omit “continuing”.

20 Paragraph 8(2)(b)

Omit “person” (second occurring), substitute “child for that treatment period”.

21 Paragraph 8(2)(c)

Omit “a person”, substitute “the child”.

22 Subsection 8(3)

After “one prescription”, insert “for a child”.

23 Paragraph 8(3)(a)

Omit “a person”, substitute “the child”.

24 Paragraph 8(3)(b)

Omit “person” (first occurring), substitute “child”.

25 Paragraph 8(3)(b)

Omit “recommencement”.

26 Paragraph 8(3)(b)

Omit “person” (second occurring), substitute “child for that treatment period”.

27 Paragraph 8(3)(c)

Omit “a person”, substitute “the child”.

28 Section 9 (heading)

Repeal the heading, substitute:

9 Prescription for child—maximum number of repeats

29 Subsection 9(1)

After “one prescription”, insert “for a child”.

30 Paragraphs 9(1)(a), (b) and (c)

Omit “a person”, substitute “the child”.

31 After section 9

Insert:

Subdivision B—Prescriptions for adults

9AA Prescription of pharmaceutical benefits in Part 2 of Schedule 1 for adults

 A pharmaceutical benefit must not be supplied on a prescription written for a person who is an adult when the prescription is written unless the pharmaceutical benefit is mentioned in Part 2 of Schedule 1.

9AB Prescription for adult—maximum quantity

 The maximum quantity or number of units of the pharmaceutical benefit that may, in one prescription for an adult, be directed to be supplied during an initial treatment period or a continuing treatment period is an amount that is sufficient for the first month of treatment of the adult in that period.

9AC Prescription for adult—maximum number of repeats

 The maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription for an adult, be directed to be repeated is 5, with each direction for a repeated supply directing a supply, on one occasion, of pharmaceutical benefit sufficient for one month.

Subdivision C—Prescriptions for children and adults

9AD Prescription by authorised prescriber only

 A pharmaceutical benefit must not be supplied on prescription for a phase of treatment of a person unless the prescription is written by an authorised prescriber for that phase.

32 Section 9A (heading)

Repeal the heading, substitute:

9A Prescription for child or adult—authority required procedures

33 Subsection 9A(1)

After “section 12”, insert “of that instrument”.

34 At the end of subsection 9A(1)

Add “of this section”.

35 Part 3 (heading)

Repeal the heading, substitute:

Part 3—Treatment doses for children

36 Before section 10

Insert:

9B This Part applies to children

 This Part applies in relation to:

 (a) a person who is a child; and

 (b) a pharmaceutical benefit mentioned in Part 1 of Schedule 1.

37 Paragraph 10(2)(a)

Omit “meter of the body surface of the person area”, substitute “metre of the body surface area of the person”.

38 Subsection 11(2)

Omit “patient”, substitute “person”.

39 Subsection 23(2)

After “The”, insert “approved pharmacist, approved medical practitioner or”.

40 Part 8

Repeal the Part.

41 Schedule 1 (note to Schedule heading)

Repeal the note, substitute:

Note: See sections 5, 7, 7A and 9AA.

42 Schedule 1 (before the table)

Insert:

Part 1—Pharmaceutical benefits for treatment of children

43 At the end of Schedule 1

Add:

Part 2—Pharmaceutical benefits for treatment of adults

| Listed Drug | Form | Manner of Administration | Brand | Section 100 only |
| --- | --- | --- | --- | --- |
| Somatropin | Injection 12 mg (36 i.u.) in 1 mL cartridge (with preservative) | Injection | Genotropin | D(100) |
|  | Powder for injection 5 mg (15 i.u.) with diluent in pre‑filled pen (with preservative) | Injection | Genotropin GoQuick | D(100) |
|  | Powder for injection 12 mg (36 i.u.) with diluent in pre‑filled pen (with preservative) | Injection | Genotropin GoQuick | D(100) |