



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

made under subsections 100(1) and (2) of the

National Health Act 1953

Compilation No. 13

Compilation date: 1 February 2020

Includes amendments up to: PB 6 of 2020

Registered: 6 February 2020

Prepared by the Office of Parliamentary Counsel, Canberra

About this compilation

This compilation

This is a compilation of the *National Health (Growth Hormone Program) Special Arrangement 2015 (PB 85 of 2015)* that shows the text of the law as amended and in force on 1 February 2020 (the *compilation date*).

The notes at the end of this compilation (the *endnotes*) include information about amending laws and the amendment history of provisions of the compiled law.

Uncommenced amendments

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

Application, saving and transitional provisions for provisions and amendments

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

Editorial changes

For more information about any editorial changes made in this compilation, see the endnotes.

Modifications

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

Self-repealing provisions

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

Contents

Part 1—Preliminary	1
1 Name of Special Arrangement	1
4 Definitions	1
Part 2—Pharmaceutical benefits covered by this Special Arrangement	4
Division 1—General	4
5 Pharmaceutical benefits covered by this Special Arrangement	4
6 Application of Part VII of the Act.....	4
7 Section 100 only supply	4
Division 2—Prescriptions for pharmaceutical benefits	5
Subdivision A—Prescriptions for children	5
7A Prescription of pharmaceutical benefits in Part 1 of Schedule 1 for children.....	5
8 Prescription for child—maximum quantity.....	5
9 Prescription for child—maximum number of repeats	5
Subdivision B—Prescriptions for adults	6
9AA Prescription of pharmaceutical benefits in Part 2 of Schedule 1 for adults	6
9AB Prescription for adult—maximum quantity.....	6
9AC Prescription for adult—maximum number of repeats	6
Subdivision C—Prescriptions for children and adults	6
9AD Prescription by authorised prescriber only	6
9A Prescription for child or adult—authority required procedures.....	6
Part 3—Treatment doses for children	8
Division 1—General	8
9B This Part applies to children.....	8
10 Definitions	8
11 Assessment of dosage of pharmaceutical benefit.....	9
Division 2—Reclassification	11
12 Dose for change of treatment category (reclassification).....	11
Division 3—Recommended treatment	12
13 Dose for recommenced treatment	12
Part 4—Payment amounts	13
Division 1—Payments to suppliers that are approved hospital authorities for public hospitals	13
14 Payments to approved hospital authorities for public hospitals	13
Division 2—Payments to suppliers that are approved hospital authorities for private hospitals, approved pharmacies or approved medical practitioners	14
15 Payments to certain suppliers of pharmaceutical benefits	14

Part 5—Dispensed price	15
Division 1—Dispensed price for supply of a pharmaceutical benefit by a hospital authority for a public hospital	15
16 The dispensed price—supply by public hospital.....	15
17 Where quantity is less than a pack quantity	15
Division 2—Dispensed price for supply of a pharmaceutical benefit by certain suppliers	16
18 The dispensed price—supply by an approved hospital authority for a private hospital, an approved pharmacist or an approved medical practitioner.....	16
19 Mark-up	16
20 Where quantity is less than a pack quantity	17
21 Dispensing fee.....	17
Division 3—Dispensed price—Other matters	19
22 Rounding up of dispensed price.....	19
Part 6—Patient contributions	20
23 Patient contributions	20
Part 7—Approved Hospital Authorities	21
24 Modified application of section 94 approved hospital authorities.....	21
Schedule 1—Pharmaceutical benefits covered by this Special Arrangement and related information	22
Part 1—Pharmaceutical benefits for treatment of children	22
Part 2—Pharmaceutical benefits for treatment of adults	26
Endnotes	27
Endnote 1—About the endnotes	27
Endnote 2—Abbreviation key	28
Endnote 3—Legislation history	29
Endnote 4—Amendment history	30

Part 1—Preliminary

1 Name of Special Arrangement

- (1) This Special Arrangement is the *National Health (Growth Hormone Program) Special Arrangement 2015*.
- (2) This Special Arrangement may also be cited as PB 85 of 2015.

4 Definitions

- (1) In this Special Arrangement:

Act means the *National Health Act 1953*.

adult means a person, who is any of the following:

- (a) is 18 years of age or older and has adult onset growth hormone deficiency;
or
- (b) has a mature skeleton; or
- (c) has a diagnosis of Prader-Willi syndrome and is aged 18 years or older.

authorised prescriber

- (a) for the initial treatment phase for a child means:
 - a specialist or consultant physician in paediatric endocrinology;
or
 - a specialist or consultant physician in general paediatrics in consultation with a nominated specialist or consultant physician in paediatric endocrinology.
- (b) for the continuing treatment phase for a child means:
 - a medical practitioner.
- (c) for the recommencement treatment phase for a child, continuing treatment as a reclassified patient phase for a child and recommencement of treatment as a reclassified patient phase for a child means:
 - a medical practitioner in consultation with a nominated specialist or consultant physician in paediatric endocrinology; or
 - a medical practitioner in consultation with a nominated specialist or consultant physician in general paediatrics.
- (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.

CDC 2000 means the growth charts in the document entitled *2000 CDC Growth Charts for the United States: Methods and Development*, published by the Centers for Disease Control and Prevention, US Department of Health and Human Services, dated May 2002, and available on that Department’s website at <http://www.cdc.gov/GROWTHcharts>.

Section 4

child means a person who, is any of the following:

- (a) is not an adult; or
- (b) has a diagnosis of Prader-Willi syndrome and is less than 18 years of age.

dispensed price:

- (a) for the supply of a pharmaceutical benefit by a hospital authority for a public hospital—has the meaning given by section 16; and
- (b) for the supply of a pharmaceutical benefit by an approved hospital authority for a private hospital or by an approved pharmacist or by an approved medical practitioner—has the meaning given by section 18.

growth hormone treatment, for a person, means treatment of the person using a pharmaceutical benefit in accordance with this Special Arrangement.

ideal body weight means:

- (a) for a person who is male with a height less than or equal to 176.8 centimetres, or female with a height less than or equal to 163.3 centimetres - that person's 50th percentile weight for height, calculated using CDC 2000;
- (b) for a person who is male with a height greater than 176.8 centimetres, or female with a height greater than 163.3 centimetres - that person's body mass index at the 50th percentile for age multiplied by height (in metres) squared, calculated using CDC 2000.

main listing instrument means the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012*, or an instrument made to replace that instrument.

mature skeleton means:

- (a) for a female, where the person has a bone age of 13.5 years or more; and
- (b) for a male, where the person has a bone age of 15.5 years or more.

maximum dose, for a category for treatment and a pharmaceutical benefit, means the highest dose of the pharmaceutical benefit that can be approved under the table in section 11 for the category.

medical practitioner has the meaning it has in the *Health Insurance Act 1973*.

non-mature skeleton means:

- (a) for a female, where the person has a bone age of less than 13.5 years; and
- (b) for a male, where the person has a bone age of less than 15.5 years.

other Special Arrangement means another Special Arrangement under section 100 of the Act.

percentile is a measure used in statistics indicating the value below which a given percentage of observations in a group of observations fall. For the purposes of this Special Arrangement, percentile is used to compare a person's measurements with the referenced growth standards (eg a body mass index at the 85th percentile means that 85 percent of the population encompassed by the

referenced standards have a body mass index below the person's body mass index).

pharmaceutical benefit means a pharmaceutical benefit mentioned in Schedule 1.

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.

Regulations means the *National Health (Pharmaceutical Benefits) Regulations 2017*.

Part 2—Pharmaceutical benefits covered by this Special Arrangement

Division 1—General

5 Pharmaceutical benefits covered by this Special Arrangement

- (1) This Special Arrangement applies to each pharmaceutical benefit mentioned in Schedule 1.

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.

- (2) Each pharmaceutical benefit to which this Special Arrangement applies is a brand of a listed drug mentioned in Schedule 1:
 - (a) in the form mentioned in Schedule 1 for the listed drug; and
 - (b) with the manner of administration mentioned in Schedule 1 for the form of the listed drug.

Note: Each listed drug mentioned in Schedule 1 has been declared by the Minister under subsection 85(2) of the Act. The form, manner of administration and brand mentioned in Schedule 1 have been determined by the Minister under subsections 85(3), (5) and (6) of the Act respectively.

6 Application of Part VII of the Act

- (1) Each pharmaceutical benefit supplied in accordance with this Special Arrangement is supplied under Part VII of the Act.
- (2) A provision of Part VII of the Act, or of regulations or other instruments made for Part VII of the Act, applies subject to this Special Arrangement.

Note: See subsection 100(3) of the Act.

7 Section 100 only supply

- (1) If the code 'D(100)' is mentioned in the column of a table in Schedule 1 headed 'Section 100 only' for a listed drug, the listed drug may be supplied only in accordance with this Special Arrangement and any other Special Arrangement relating to the listed drug.
- (2) A pharmaceutical benefit that has a drug mentioned in subsection (1) is not available for general supply on the Pharmaceutical Benefits Scheme.

Note: The Minister has declared, under subsection 85(2A) of the Act, that the listed drug can only be supplied under a section 100 Special Arrangement.

Division 2—Prescriptions for pharmaceutical benefits

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.

8 Prescription for child—maximum quantity

- (1) The maximum quantity or number of units of the pharmaceutical benefit that may, in one prescription for a child, be directed to be supplied during an initial treatment period is an amount that is sufficient for:
 - (a) the first 16 weeks of treatment of the child; or
 - (b) if a prescription mentioned in paragraph (a) has already been written for the child for the treatment period—the remaining 16 weeks of treatment of the child for that treatment period; or
 - (c) a total of 32 weeks of treatment of the child.
- (2) The maximum quantity or number of units of the pharmaceutical benefit that may, in one prescription for a child, be directed to be supplied during a continuing treatment period is an amount that is sufficient for:
 - (a) the first 13 weeks of treatment of the child; or
 - (b) if a prescription mentioned in paragraph (a) has already been written for the child for the treatment period—the remaining 13 weeks of treatment of the child for that treatment period; or
 - (c) a total of 26 weeks of treatment of the child.
- (3) The maximum quantity or number of units of the pharmaceutical benefit that may, in one prescription for a child, be directed to be supplied during a recommencement treatment period is an amount that is sufficient for:
 - (a) the first 16 weeks of treatment of the child; or
 - (b) if a prescription mentioned in paragraph (a) has already been written for the child for the treatment period—the remaining 16 weeks of treatment of the child for that treatment period; or
 - (c) a total of 32 weeks of treatment of the child.

9 Prescription for child—maximum number of repeats

- (1) The maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription for a child, be directed to be repeated is:
 - (a) for a prescription for initial treatment of the child:
 - (i) one repeat for a prescription that directs a supply, on one occasion, of pharmaceutical benefit sufficient for a 16 week period; or

Section 9AA

- (ii) no repeats for a prescription that directs a supply, on one occasion, of a pharmaceutical benefit sufficient for a 32 week period.
- (b) (i) for a prescription for recommencement treatment of the child:
 - one repeat for a prescription that directs a supply, on one occasion, of pharmaceutical benefit sufficient for a 16 week period; or
 - (ii) no repeats for a prescription that directs a supply, on one occasion, of a pharmaceutical benefit sufficient for a 32 week period.
- (c) for a prescription for continuing treatment of the child:
 - (i) one repeat for a prescription that directs a supply, on one occasion, of a pharmaceutical benefit sufficient for a 13 week period; or
 - (ii) no repeats for a prescription that directs a supply, on one occasion, of a pharmaceutical benefit sufficient for a 26 week period.

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.

9A Prescription for child or adult—authority required procedures

- (1) For the purposes of the main listing instrument, a prescription for a pharmaceutical benefit is also taken to have been submitted in accordance with

section 12 of that instrument where the authorised prescriber submits details of that prescription in accordance with subsection (2) of this section.

- (2) The details must be:
- (a) given to the Chief Executive Medicare in writing; and
 - (b) by means of an electronic communication; and
 - (c) in a form approved by the Chief Executive Medicare; and
 - (d) in accordance with any other requirements that would need to be met in order for the requirements to give the information in writing to be taken to have been met under the *Electronic Transactions Act 1999*.
- (3) For the purposes of the main listing instrument, a prescription submitted in accordance with subsection (2) is also taken to have been authorised under subsection 13(3) of the main listing instrument where the Chief Executive Medicare sends his or her authorisation, by electronic communication, including computer automated electronic communication, to the authorised prescriber.

Part 3—Treatment doses for children

Division 1—General

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.

10 Definitions

- (1) In this Part:

dose, for a person and a pharmaceutical benefit, means a dose of pharmaceutical benefit mentioned in the table in section 11 that is measured as a dose that applies to the body surface area of the person for a week, with the body surface area of the person calculated using the formula:

$$\text{body surface area} = \sqrt{\frac{\text{height in cm} \times \text{weight in kg}}{3600}}$$

- (2) The measurement ‘m²’ refers to:

- (a) where a person is:
 - (i) mentioned in item 1 or 2 in the table in section 11; or
 - (ii) mentioned in item 3 in the table in section 11 and has a body mass index less than the 85th percentile for age and sex;

a square metre of the body surface area of the person calculated by weight; or

- (b) where a person is:
 - (i) mentioned in item 3 in the table in section 11; and
 - (ii) has a body mass index greater than the 85th percentile for age and sex,
- a square metre of the body surface area of the person, calculated using ideal body weight (kg).

- (3) The measurement ‘kg’ refers to:

- (a) where a person is mentioned in item 4 in the table in section 11 and has a body mass index equal to or less than the 85th percentile for age and sex, the person’s body weight in kilograms; or
- (b) where a person is mentioned in item 4 in the table in section 11 and has a body mass index greater than the 85th percentile for age and sex, the person’s ideal body weight in kilograms.

11 Assessment of dosage of pharmaceutical benefit

- (1) The authorised prescriber must prescribe a dose of pharmaceutical benefit that is appropriate for treatment of a person under this Special Arrangement in accordance with the table in this section and this Division.

Item	Person's condition	Dose of a pharmaceutical benefit
1	in the category of: (a) short stature and slow growth; or (b) short stature associated with biochemical growth hormone deficiency; or (c) growth retardation secondary to an intracranial lesion or cranial irradiation; or (d) risk of hypoglycaemia secondary to biochemical growth hormone deficiency in neonates/infants; or (e) biochemical growth hormone deficiency and precocious puberty; or (f) hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth	Up to 7.5mg/m ² /week
2	in the category of: (a) short stature associated with Turner Syndrome; or (b) short stature due to short stature homeobox (SHOX) gene disorders; or (c) short stature associated with chronic renal insufficiency	Up to 9.5mg/m ² /week
3	in the category of short stature and poor body composition due to Prader-Willi Syndrome, where the person has a non-mature skeleton	Up to 7.5mg/m ² /week
4	in the category of short stature and poor body composition due to Prader-Willi Syndrome, where the person has a mature skeleton	0.04mg/kg/week

- (2) The dose mentioned in the table in this section for a category of treatment mentioned in any of the items of that table, is the maximum dose that can be used for any person.
- (3) However, if the form of the pharmaceutical benefit and the manufacturer's pack is unable to accommodate the dose mentioned in the item of the table that applies to a person, the dose of pharmaceutical benefit may be within 3% of the maximum dose for the item of the table that applies to the person.

Part 3 Treatment doses for children

Division 1 General

Section 11

- (4) For items 3 and 4 of the table in this section, if the person's body mass index is greater than the 85th percentile for age and sex, the dose prescribed for the person must be calculated using the person's ideal body weight in kilograms.

Division 2—Reclassification

12 Dose for change of treatment category (reclassification)

- (1) An authorised prescriber must prescribe a dose of pharmaceutical benefit, for a person who is reclassified to a different category for treatment, in accordance with the dose in the table in section 11 that applies to the category to which the person has been reclassified.
- (2) The dose cannot exceed the maximum dose permitted for the category for treatment to which the person has been reclassified.

Section 13

Division 3—Recommended treatment

13 Dose for recommended treatment

- (1) This section applies if a person is recommending growth hormone treatment, in a category mentioned in the table in section 11.
- (2) The dose cannot exceed the maximum dose permitted for the category for treatment for which the person has recommended.

Part 4—Payment amounts

Division 1—Payments to suppliers that are approved hospital authorities for public hospitals

14 Payments to approved hospital authorities for public hospitals

- (1) An approved hospital authority for a public hospital is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for its supply of the pharmaceutical benefit is greater than the amount that the approved hospital authority was entitled to charge under section 16.
- (2) The dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a public hospital must be determined in accordance with Division 1 of Part 5.
- (3) No mark-ups may be added to the cost of a pharmaceutical benefit for which payment is claimed by an approved hospital authority for a public hospital.

Part 4 Payment amounts

Division 2 Payments to suppliers that are approved hospital authorities for private hospitals, approved pharmacies or approved medical practitioners

Section 15

Division 2—Payments to suppliers that are approved hospital authorities for private hospitals, approved pharmacies or approved medical practitioners

15 Payments to certain suppliers of pharmaceutical benefits

- (1) An approved hospital authority for a private hospital is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for its supply of the pharmaceutical benefit is greater than the amount that the approved hospital authority was entitled to charge under section 18.
- (2) An approved pharmacist or an approved medical practitioner is entitled to be paid by the Commonwealth the amount, if any, by which the dispensed price for the supply of a pharmaceutical benefit is greater than the amount that the approved pharmacist or approved medical practitioner was entitled to charge under section 18.
- (3) The dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a private hospital, an approved pharmacist or an approved medical practitioner must be determined in accordance with Division 2 of Part 5.

Part 5—Dispensed price

Division 1—Dispensed price for supply of a pharmaceutical benefit by a hospital authority for a public hospital

16 The dispensed price—supply by public hospital

- (1) The dispensed price for the supply of a pharmaceutical benefit by a hospital authority for a public hospital is as follows:
 - (a) if the quantity of the pharmaceutical benefit that is ordered and supplied is equal to a multiple of a pack quantity of the benefit—the sum of the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity;
 - (b) if the quantity of the pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit—the amount calculated in accordance with section 17;
 - (c) if the quantity of the pharmaceutical benefit that is ordered and supplied is more than a multiple of a pack quantity of the benefit—the sum of:
 - (i) the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity; and
 - (ii) the amount calculated in accordance with section 17 for the remainder of the quantity supplied that is less than a pack quantity.

17 Where quantity is less than a pack quantity

- (1) If the quantity of a pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit (a **broken quantity**), the amount mentioned in paragraph 16(1)(b) and subparagraph 16(1)(c)(ii) is to be calculated by:
 - (a) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and
 - (b) applying that percentage to the approved ex-manufacturer price or proportional ex-manufacturer price for the pack quantity.

Division 2—Dispensed price for supply of a pharmaceutical benefit by certain suppliers

18 The dispensed price—supply by an approved hospital authority for a private hospital, an approved pharmacist or an approved medical practitioner

- (1) The dispensed price for the supply of a pharmaceutical benefit by an approved hospital authority for a private hospital, an approved pharmacist or an approved medical practitioner, is as follows:
 - (a) if the quantity of the pharmaceutical benefit that is ordered and supplied is equal to a multiple of a pack quantity, the sum of:
 - (i) the approved ex-manufacturer price or the proportional ex-manufacturer price for each pack quantity, plus the mark-up mentioned in section 19 taken to the nearest cent, with one half cent being rounded up to 1 cent; and
 - (ii) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the pharmaceutical benefit; or
 - (b) if a quantity of the pharmaceutical benefit that is ordered and supplied is less than a pack quantity, the sum of:
 - (i) the amount calculated in accordance with section 20; and
 - (ii) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the pharmaceutical benefit; or
 - (c) if a quantity of the pharmaceutical benefit that is ordered and supplied is more than a multiple of a pack quantity, the sum of:
 - (i) for each pack quantity, the approved ex-manufacturer price or the proportional ex-manufacturer price for the pack quantity, plus the mark-up mentioned in section 19 taken to the nearest cent, with one half cent being rounded up to 1 cent; and
 - (ii) the amount calculated in accordance with section 20 for the remainder of the quantity supplied that is less than a pack quantity; and
 - (iii) a dispensing fee equal to the dispensing fee for the supply of a ready prepared pharmaceutical benefit, mentioned in the determination made under paragraph 98B(1)(a) of the Act, as in force at the time of the supply of the pharmaceutical benefit.

19 Mark-up

For subparagraphs 18(1)(a)(i) and 18(1)(c)(i) and for paragraph 20(a), the mark-up for a pack quantity of a ready-prepared pharmaceutical benefit is:

- (a) if the pack quantity for which a mark-up is to be calculated under this section is equal to a maximum quantity of the pharmaceutical benefit, the

mark-up is the amount mentioned in the table below for the approved ex-manufacturer price (AEMP) or for the proportional ex-manufacturer price (PEMP) for that quantity.

Item	AEMP or PEMP for Maximum Quantity	Mark-up for Maximum Quantity
1	< \$40	10% of AEMP or PEMP
2	≥ \$40, ≤ \$100	\$4.00
3	> \$100, ≤ \$1,000	4% of AEMP or PEMP
4	> \$1,000	\$40.00

- (b) if the pack quantity for which a mark-up is to be calculated under this section is not equal to a maximum quantity of the pharmaceutical benefit, the mark-up is worked out as follows:
- (i) if the mark-up that would apply to the maximum quantity is shown in the table in paragraph (a) as a monetary amount—the mark-up for the pack quantity is that monetary amount, reduced proportionately for the relative quantities; and
 - (ii) if the mark-up that would apply to the maximum quantity is shown in the table in paragraph (a) as a percentage of AEMP or PEMP—the mark-up for the pack quantity is that percentage of the AEMP or PEMP for the pack quantity.

20 Where quantity is less than a pack quantity

If the quantity of a pharmaceutical benefit that is ordered and supplied is less than a pack quantity of the benefit (a **broken quantity**), the amount mentioned in subparagraph 18(1)(b)(i) and 18(1)(c)(ii) is to be calculated by:

- (a) adding the mark-up mentioned in section 19 to the approved ex-manufacturer price or the proportional ex-manufacturer price for the pack quantity, taking the result to the nearest cent, with one half cent being rounded up to 1 cent; and
- (b) dividing the quantity or number of units in the broken quantity by the pack quantity, expressed as a percentage to 2 decimal places; and
- (c) applying the percentage worked out under subparagraph (b) to the amount worked out under subparagraph (a).

21 Dispensing fee

If an eligible medical practitioner, instead of directing a repeated supply of a pharmaceutical benefit, directs the supply on one occasion of a quantity or number of units of the drug, not exceeding the total quantity or number of units that could be prescribed if the eligible medical practitioner directed a repeated supply, the

Part 5 Dispensed price

Division 2 Dispensed price for supply of a pharmaceutical benefit by certain suppliers

Section 21

dispensed price for the supply of the pharmaceutical benefit will include only one dispensing fee.

Division 3—Dispensed price—Other matters

22 Rounding up of dispensed price

The dispensed price for the supply of a pharmaceutical benefit will in each case be taken to the nearest cent, with one half cent being rounded up to 1 cent.

Part 6—Patient contributions

23 Patient contributions

- (1) This section applies if an approved pharmacist, an approved medical practitioner, or an approved hospital authority for a public hospital or a private hospital supplies a pharmaceutical benefit to a patient and makes a claim for payment.
- (2) The approved pharmacist, approved medical practitioner or approved hospital authority may charge the patient an amount equivalent to the amount that may be charged under section 87 of the Act for the supply of a pharmaceutical benefit to the patient.

Part 7—Approved Hospital Authorities

24 Modified application of section 94 approved hospital authorities

- (1) Section 94 of the Act applies in a modified manner to pharmaceutical benefits supplied under this Special Arrangement.
- (2) An approved hospital authority may supply pharmaceutical benefits that are subject to this Special Arrangement to patients receiving treatment in or at the hospital of which it is the governing body or proprietor, or outside of the hospital of which it is the governing body or proprietor.

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Part 1 Pharmaceutical benefits for treatment of children

Schedule 1—Pharmaceutical benefits covered by this Special Arrangement and related information

Note: See sections 5, 7, 7A and 9AA.

Part 1—Pharmaceutical benefits for treatment of children

Listed Drug	Form	Manner of Administration	Brand	Section 100 only
Somatropin	Injection 0.4 mg (1.2 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 0.6 mg (1.8 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 0.8 mg (2.4 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 1 mg (3 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 1.2 mg (3.6 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 1.4 mg (4.2 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 1.6 mg (4.8 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)

Pharmaceutical benefits covered by this Special Arrangement and related information **Schedule 1**
Pharmaceutical benefits for treatment of children **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Section 100 only
	Injection 1.8 mg (5.4 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 2 mg (6 i.u.) with diluent in single use syringe (without preservative)	Injection	Genotropin MiniQuick	D(100)
	Injection 4 mg (12 i.u.) vial with diluent (with preservative)	Injection	Zomacton	D(100)
	Injection 18 i.u. (6 mg) cartridge with 3.15 mL diluent (with preservative)	Injection	Humatrope	D(100)
	Injection 36 i.u. (12 mg) cartridge with 3.15 mL diluent (with preservative)	Injection	Humatrope	D(100)
	Injection 72 i.u. (24 mg) cartridge with 3.15 mL diluent (with preservative)	Injection	Humatrope	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)
	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Norditropin SimpleXx	D(100)
			Omnitrope Surepal 5	D(100)
			Scitropin A	D(100)

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Part 1 Pharmaceutical benefits for treatment of children

Listed Drug	Form	Manner of Administration	Brand	Section 100 only
	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in a pre-filled pen	Injection	Norditropin FlexPro	D(100)
	Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	Injection	Saizen	D(100)
	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Norditropin SimpleXx	D(100)
			Omnitrope Surepal 10	D(100)
			SciTropin A	D(100)
	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) in a pre-filled pen	Injection	Norditropin FlexPro	D(100)
	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)	Injection	NutropinAq	D(100)
	Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Saizen	D(100)
	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative)	Injection	Norditropin SimpleXx	D(100)
			Omnitrope Surepal 15	D(100)
	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) in a pre-filled pen	Injection	Norditropin FlexPro	D(100)

Pharmaceutical benefits covered by this Special Arrangement and related information **Schedule 1**
Pharmaceutical benefits for treatment of children **Part 1**

Listed Drug	Form	Manner of Administration	Brand	Section 100 only
	Solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative)	Injection	Saizen	D(100)

Schedule 1 Pharmaceutical benefits covered by this Special Arrangement and related information

Part 2 Pharmaceutical benefits for treatment of adults

Part 2—Pharmaceutical benefits for treatment of adults

Listed Drug	Form	Manner of Administration	Brand	Section 100 only
Somatropin	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)
	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) in pre-filled pen	Injection	Norditropin FlexPro	D(100)
	Solution for injection 10 mg (30 i.u.) in 2 mL cartridge (with preservative)	Injection	NutropinAq	D(100)

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

Abbreviation key—Endnote 2

The abbreviation key sets out abbreviations that may be used in the endnotes.

Legislation history and amendment history—Endnotes 3 and 4

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

Editorial changes

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

Misdescribed amendments

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnotes

Endnote 2—Abbreviation key

Endnote 2—Abbreviation key

ad = added or inserted	o = order(s)
am = amended	Ord = Ordinance
amdt = amendment	orig = original
c = clause(s)	par = paragraph(s)/subparagraph(s) /sub-subparagraph(s)
C[x] = Compilation No. x	pres = present
Ch = Chapter(s)	prev = previous
def = definition(s)	(prev...) = previously
Dict = Dictionary	Pt = Part(s)
disallowed = disallowed by Parliament	r = regulation(s)/rule(s)
Div = Division(s)	reloc = relocated
ed = editorial change	renum = renumbered
exp = expires/expired or ceases/ceased to have effect	rep = repealed
F = Federal Register of Legislation	rs = repealed and substituted
gaz = gazette	s = section(s)/subsection(s)
LA = <i>Legislation Act 2003</i>	Sch = Schedule(s)
LIA = <i>Legislative Instruments Act 2003</i>	Sdiv = Subdivision(s)
(md) = misdescribed amendment can be given effect	SLI = Select Legislative Instrument
(md not incorp) = misdescribed amendment cannot be given effect	SR = Statutory Rules
mod = modified/modification	Sub-Ch = Sub-Chapter(s)
No. = Number(s)	SubPt = Subpart(s)
	<u>underlining</u> = whole or part not commenced or to be commenced

Endnote 3—Legislation history

Endnote 3—Legislation history

Name	Registration	Commencement	Application, saving and transitional provisions
PB 85 of 2015	1 Sept 2015 (F2015L01368)	1 Sept 2015 (s 2)	
PB 96 of 2015	1 Dec 2015 (F2015L01904)	1 Dec 2015 (s 2)	—
PB 87 of 2016	30 Sept 2016 (F2016L01553)	1 Oct 2016 (s 2)	—
PB 116 of 2016	22 Dec 2016 (F2016L02029)	1 Jan 2017 (s 2)	—
PB 78 of 2017	26 Sept 2017 (F2017L01263)	1 Oct 2017 (s 2)	—
PB 91 of 2017	31 Oct 2017 (F2017L01405)	1 Nov 2017 (s 2)	—
PB 28 of 2018	28 Mar 2018 (F2018L00429)	1 Apr 2018 (s 2)	—
PB 35 of 2018	30 Apr 2018 (F2018L00548)	1 May 2018 (s 2)	—
PB 96 of 2018	29 Nov 2018 (F2018L01634)	1 Dec 2018 (s 2(1) item 1)	—
PB 113 of 2018	20 Dec 2018 (F2018L01815)	1 Jan 2019 (s 2)	—
PB 22 of 2019	28 Mar 2019 (F2019L00452)	1 Apr 2019 (s 2)	—
PB 80 of 2019	30 Sept 2019 (F2019L01299)	1 Oct 2019 (s 2)	—
PB 109 of 2019	20 Dec 2019 (F2019L01679)	1 Jan 2020 (s 2(1) item 1)	—
PB 6 of 2020	31 Jan 2020 (F2020L00071)	1 Feb 2020 (s 2)	—

Endnotes

Endnote 4—Amendment history

Endnote 4—Amendment history

Provision affected	How affected
Part 1	
s 2	rep LIA s 48D
s 3	rep LIA s 48C
s 4	am PB 91 of 2017; PB 96 of 2018; PB 109 of 2019
Part 2	
Division 1	
s 5	am PB 96 of 2018
s 7	am PB 96 of 2018
Division 2	
Subdivision A	
Subdivision A heading.....	ad PB 96 of 2018
s 7A	ad PB 96 of 2018
s 8	am PB 96 of 2018
s 9	am PB 96 of 2018
Subdivision B	
Subdivision B	ad PB 96 of 2018
s 9AA	ad PB 96 of 2018
s 9AB.....	ad PB 96 of 2018
s 9AC.....	ad PB 96 of 2018
Subdivision C	
Subdivision C heading.....	ad PB 96 of 2018
s 9AD	ad PB 96 of 2018
s 9A	ad PB 91 of 2017 am PB 96 of 2018
Part 3	
Part 3 heading.....	rs PB 96 of 2018
Division 1	
s 9B	ad PB 96 of 2018
s 10	am PB 91 of 2017; PB 96 of 2018
s 11	am PB 91 of 2017; PB 96 of 2018
Part 6	
s 23	am PB 96 of 2018
Part 8	rep PB 96 of 2018
s 25	rep PB 96 of 2018
s 26	rep PB 96 of 2018
s 27	rep PB 96 of 2018
s 28	rep PB 96 of 2018

Endnote 4—Amendment history

Provision affected	How affected
s 29	rep PB 96 of 2018
Schedule 1	
Schedule 1	am PB 96 of 2015; PB 87 of 2016; PB 116 of 2016; PB 78 of 2017; PB 28 of 2018; PB 35 of 2018; PB 96 of 2018; PB 113 of 2018; PB 22 of 2019 ed C10 am PB 80 of 2019; PB 6 of 2020