

29 October 2009

## Proposal for sole supply arrangement for somatropin

PHARMAC and Pfizer New Zealand Limited have entered into a provisional agreement for the ongoing funding of Genotropin, one of two brands of somatropin (also known as human growth hormone) currently funded by PHARMAC. In summary, the proposal would result in:

- Genotropin becoming the only subsidised brand of somatropin from 1 July 2010 to 31 December 2013.
- Subsidised access to somatropin being widened to include adult and adolescent patients with growth hormone deficiency. The date of widening access is yet to be determined, but would occur after 1 January 2010 and prior to 1 July 2010, following establishment of a Panel to determine eligibility.

Further details of the proposal can be found on the following pages.

### Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Thursday, 12 November 2009** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

## Details of the proposal

### ***Genotropin sole subsidised supply***

Genotropin would be the only subsidised brand of somatropin in Section B of the Pharmaceutical Schedule from 1 July 2010. From the start of the sole supply period, the Nordotropon SimpleXx brand of somatropin (supplied by Novo Nordisk) would be delisted from the Pharmaceutical Schedule and Genotropin would be the only subsidised brand of somatropin until 31 December 2013.

A six month transition period would commence on 1 January 2010. During this transition period Pfizer would work with clinicians to assist in switching patients from Norditropon SimpleXx to Genotropin.

### ***Price reductions***

The price and subsidy of Genotropin would reduce from 1 January 2010 and, upon access to somatropin being widened to include adult and adolescent patients who are growth hormone deficient (see below), there would be a further reduction to the price and subsidy. The proposed changes to prices and subsidies are as follows (ex manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy from 1 January 2010	Price and subsidy upon widened access
Somatropin	Inj 16 IU	Genotropin	5	\$1,248.00	\$800.00
Somatropin	Inj 36 IU	Genotropin	5	\$2,808.00	\$1,800.00

### ***Widened Access***

PHARMAC proposes to widen funded access growth hormone to adults and adolescents who are growth hormone deficient and to establish an Adult Growth Hormone Panel to review applications and determine eligibility for funded access. The proposed entry and exit criteria for adult and adolescent patients with growth hormone deficiency are as follows:

#### *Entry Criteria (all of the following):*

- The presence of a medical condition known to cause growth hormone deficiency (e.g. surgical removal of the pituitary for treatment of a pituitary tumour).
- Appropriate treatment of other hormonal deficiencies and psychological illnesses.
- Severe growth hormone deficiency defined as a peak serum GH level  $\leq 3\mu\text{g/l}$  (9mU/l) during an adequately performed insulin tolerance test or cross-validated equivalent test. In patients with multiple pituitary deficiencies one test would be sufficient. In patients with no other anterior pituitary deficiency two growth hormone stimulated tests should be performed.
- Serum IGF-1 more than 1 SD below the mean for age and sex.
- Poor quality of life as defined by a score of  $\geq 16$  using the disease-specific quality of life questionnaire for adult growth hormone deficiency (QoL-AGHDA).

*Exit Criteria (any of the following):*

- Major adverse effects of treatment.
- Patient preference not to continue treatment.
- Failure to reach or maintain serum IGF-I levels within 1SD of the mean normal value for age and sex despite use of ceiling doses of growth hormone (0.7mg/day in males, 1mg/day in females).
- Failure to improve >7 points on the QoL-AGHDA score from baseline.
- Once stable on growth hormone treatment, a deterioration in the QoL-AGHDA score by >5 points unrelated to obvious external factors on 2 measurements >6 months apart.
- Unsatisfactory follow-up or compliance.

The Growth Hormone Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) is currently reviewing the Quality of Life questionnaire to ensure it is suitable for use for adolescents, and this feedback (and any feedback received from this consultation) will be taken into account prior to the entry and exit criteria being finalised.

The date of implementation for widening of access would be dependant on the establishment of the Adult Growth Hormone Panel, but is anticipated to occur between 1 January 2010 and 30 June 2010. The Adult Growth Hormone Panel would run in a similar method to the current paediatric Growth Hormone Panel, where applications for funding would be reviewed and determined by the panel.

## **Background**

There are currently two brands of somatotropin listed in the Pharmaceutical Schedule, Genotropin (Pfizer) and Norditropin SimpleXx (Novo Nordisk).

In June 2009 we initiated a competitive process for the supply of somatotropin. Following completion of that process we have entered into a provisional agreement with Pfizer New Zealand Limited for the sole subsidised supply of Genotropin.