5.25 SOMATROPIN
Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative),
SciTropin A™, SciGen (Australia) Pty Ltd

1. Purpose of Application
	1. The minor submission sought the re-listing of a previously listed somatropin product, which was removed from the PBS on 1 September 2017, and now re-marketed by a new sponsor under a new brand name.
2. Requested listing
	1. The submission sought the same listing (restriction and price per mg) as the previously-listed somatropin product, Omnitrope® which is identical to SciTropin A™.

*For more detail on PBAC’s view, see section 5 PBAC outcome.*

1. Background
	1. Omnitrope® branded somatropin 5 mg/1.5ml injection is a recombinant human growth hormone previously marketed by Sandoz that was de-listed from the PBS on 1 September 2017.
	2. Sandoz subsequently licensed the marketing rights for Omnitrope® somatropin 5 mg/1.5ml to SciGen (Australia) Pty Ltd and it is currently available under the trade name SciTropin A™.
	3. The pharmacological and clinical characteristics, dosage and administration, composition (active ingredients and excipients), manufacturing processes, and indications for SciTropin A™ somatropin 5 mg/1.5ml and Omnitrope® somatropin 5 mg/1.5ml are identical.

*For more detail on PBAC’s view, see section 5 PBAC outcome.*

# Consideration of the evidence

## Sponsor hearing

* 1. There was no hearing for this item as it was a minor submission.

## Consumer comments

* 1. The PBAC noted that no consumer comments were received for this item.

## Estimated PBS usage & financial implications

* 1. The minor submission estimated there to be no financial implications to the PBS/changes in PBS usage as the drug involves the re-listing of a previously-listed somatropin product, and as such those patients previously treated by Omnitrope® 5mg/1.5ml will be replaced by Scitropin A™ 5mg/1.5ml. Furthermore, the market for somatropin is well established with several brands currently PBS listed, and somatropin is in the F2 formulary.

# PBAC Outcome

* 1. The PBAC recommended the re-listing of 5 mg (15 i.u.) in 1.5 mL form of somatropin under the SciTropin A brand in the Section 100 Growth Hormone Programme under the same conditions under the same conditions for which the Omnitrope® brand was listed.
	2. The PBAC noted that this brand of somatropin sought the same listing as the previously listed product, Omnitrope®, which was removed from the PBS on 1 September 2017, and is now re-marketed by SciGen (Australia) Pty Ltd under a new brand name, SciTropin A.
	3. The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

# Recommended listing

* 1. Add new items:

Restrictions not reproduced in full due to size and complexity. Restrictions to be the same as Omnitrope Surepal 5 PBS listings, item codes 10507B, 10512G, 10518N.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name, Restriction,Manner of administration and form | Max.Qty | №.ofRpts |  | Proprietary Name and Manufacturer |
| somatropin5 mg/1.5 mL injection, 1.5 mL cartridge | 1 | 1 |  | SciTropin A | SciGen (Australia) Pty Ltd |
|  |
| **Category /** **Program** | Section 100 – Growth Hormone Program |
| **Prescriber type:** | [ ] Dental [x] Medical Practitioners [ ] Nurse practitioners [ ] Optometrists[ ] Midwives |
| **Episodicity:** |  |
| **Severity:** |  |
| **Condition:** | Short stature and slow growth |
| **PBS Indication:** | Short stature and slow growth |

# Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

# Sponsor’s Comment

The sponsor had no comment.