

Ontario Public Drug Programs Drug Submission Status

Generic Name: somatropin

Brand Name: Genotropin GoQuick
Genotropin MiniQuick

Strength: 5.3mg and 12mg pre-filled pen, GoQuick
0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg and 2mg pre-filled syringe, MiniQuick

Manufacturer: Pfizer Canada Inc.

Indication: The long-term treatment of children who have growth failure due to an inadequate secretion of endogenous growth hormone (growth hormone deficiency (GHD))

Rapid Review: Not requested

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review (Initial Submission) | 12/11/2013 | 12/02/2014 | EO decision rendered | Funding considered through the Special Drug Program (SDP) |

Rapid Review:

Details of the Rapid Review process can be found at:

http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/rapid_review_process.aspx

Review Status:

- Screening – Ministry is screening the manufacturer’s submission to ensure all regulatory and policy requirements have been met in order to proceed with the drug review.

- Submission incomplete – Manufacturer did not meet the necessary requirements to allow review to proceed.
- Submission complete & under review – Manufacturer met all requirements to proceed with the drug review, and evaluation of the drug submission is underway.
- Committee to Evaluate Drugs (CED) review completed, manufacturer requesting reconsideration – A recommendation was made by the CED, however the manufacturer has submitted or will be submitting additional information.
- Committee to Evaluate Drugs (CED) review completed – A recommendation was made by the CED.
- Executive Officer (EO) decision rendered.

Funding Status:

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision, if available, can be found at:

http://www.health.gov.on.ca/en/pro/programs/drugs/ced_rec_table.aspx

Updated: August 21, 2014