

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: For replacement of endogenous growth hormone in adults with growth hormone deficiency

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