

Ontario Public Drug Programs Drug Submission Status

Generic Name: dabigatran etexilate mesilate
Brand Name: Pradaxa
Strength: 75mg and 110mg capsule
Manufacturer: Boehringer Ingelheim Canada Ltd.
Indication: Venous thromboembolism prevention
Rapid Review: Not requested

| Submission Type: | Date Submission Received: | Date Submission Deemed Complete: | Review Status: | Funding Decision: |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review (Initial Submission) | 26/08/2008 | 26/09/2008 | EO decision rendered | Funding not considered through Ontario Public Drug Programs |
| Second Review (Resubmission #1) | 02/07/2009 | 14/09/2009 | EO decision rendered | Funding not considered through Ontario Public Drug Programs |

Rapid Review:

Details of the Rapid Review process can be found at:
www.health.gov.on.ca/english/providers/program/drugs/drug_submissions/rapid_review_process.html

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: www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html

Updated: May 2, 2013