

# Ontario Public Drug Programs

## Drug Submission Status

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**Generic Name:** dabrafenib mesylate

**Brand Name:** Tafinlar

**Strength:** 50mg and 75mg capsule

**Manufacturer:** GlaxoSmithKline Inc.

**Indication:** For the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation

**Rapid Review:** Not requested

| Submission Type:                     | Date Submission Received: | Date Submission Deemed Complete: | Review Status:       | Funding Decision:   |
|--------------------------------------|---------------------------|----------------------------------|----------------------|---|
| First Review<br>(Initial Submission) | 11/09/2013                | 05/11/2013                       | EO decision rendered | Funding considered through the Exceptional Access Program (EAP) |

### 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](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](http://www.health.gov.on.ca/en/pro/programs/drugs/ced_rec_table.aspx)

Updated: August 21, 2014