

# Ministry of Health and Long-Term Care

## Ontario Public Drug Programs

### Drug Submission Status

|                      |   |
|----------------------|---|
| <b>Generic Name:</b> | telmisartan / amlodipine besylate   |
| <b>Brand Name:</b>   | Twynsta   |
| <b>Strength:</b>     | 40mg/5mg, 40mg/10mg, 80mg/5mg and 80mg/10mg tablet  |
| <b>Manufacturer:</b> | Boehringer Ingelheim Canada Ltd.  |
| <b>Indication:</b>   | For the treatment of mild to moderate essential hypertension where combination therapy is appropriate |
| <b>Rapid Review:</b> | Requested & Denied  |

| Submission Type:   | Date Submission Received: | Date Submission Deemed Complete: | Review Status:       | Funding Decision: |
|--|---------------------------|----------------------------------|----------------------|-------------------|
| First Review, <b>Pre-Notice of Compliance</b> (Initial Submission) | 15/06/2011                | N/A                              | Submission withdrawn | File closed       |

#### **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](http://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 Decision:**

The Committee to Evaluate Drugs (CED) recommendation and the Executive Officer (EO) decision can be found at: [www.health.gov.on.ca/english/providers/program/drugs/ced\\_rec\\_table.html](http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html)

Updated: August 12, 2011