# Common Drug Review *

## Submission Status

**Product:** Isentress
**Generic Name:** raltegravir
**Manufacturer:** Merck Frosst Canada Ltd.
**Submission Type:** New
**Date Submission Received:** 2007-Nov-29
**Date NOC Issued:** 2007-Nov-27
**Targeted CEDAC Meeting:** 2008-May-21
**Priority Review Granted:** Denied

| | Phase | Target Time (Business Days) | Target Date** | Actual CDR Date | Comments |
|---|---|---|---|---|---|
| 1 | Submission Assessment | 5 | 2007-Dec-06 | 2007-Dec-06 | Category 1 submission requirements deemed incomplete December 6, 2007.<br>Priority Review request denied December 11, 2007. |
| | Submission deemed complete | | | 2007-Dec-10 | Submission deemed complete. |
| 2 | CDR Reviewers' Reports Completed<br>• Reviewers selected and contracted<br>• Literature search and selection completed<br>• Systematic review of clinical data completed<br>• Critical appraisal of pharmacoeconomic (PE) data completed<br>• Clinical and PE reports written<br>• Reports edited and finalized<br>• Reviewers' reports sent to manufacturer | 45 | 2008-Mar-04 | 2008-Mar-05 | Additional information requested December 19, 2007.<br>Response to request for additional information received January 11, 2008.<br>Additional information requested February 8, 2008.<br>Additional information received February 12, 2008.<br>CEDAC date advanced to April 16, 2008. |
| 3 | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2008-Mar-13 | 2008-Mar-14 | Due date for manufacturer's comments March 14, 2008. |
| 4 | Reviewers' Reply to Manufacturer's Comments Completed | 7 | 2008-Mar-25 | 2008-Mar-26 | Due date for Reviewer's reply March 26, 2008. |
| 5 | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2008-Apr-02 | 2008-Apr-02 | |
| 6 | CEDAC Meeting | | 2008-Apr-16 | 2008-Apr-16 | |
| 7 | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2008-Apr-23 | 2008-Apr-23 | |
| 8 | Embargo Period***<br>Manufacturers may make a Request for Reconsideration and Drug Plans may make a Reques for Clarification of the Recommendation and Reasons for Recommendation | 10 | 2008-May-07 | 2008-May-07 | |
| 9 (a) | Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved) | 5 | 2008-May-14 | 2008-May-14 | Notice of Final Recommendation issued. |
| | **OR** | | | | |
| 9 (b) | Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(Clarification Requested, no Request for Reconsideration made) | 5 | | | |
| | **OR** | | | | |
| 9 (c) | Placed on CEDAC Agenda For Reconsideration<br>(At Manufacturer's request) | 25<br>Depends on Meeting Dates | | | |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5 | | | |

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.
** The CDR review process is initiated AFTER a submission is deemed complete. The target dates for this report are based on the CEDAC meeting schedule, which is posted on www.cadth.ca.
*** The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the notice of Final Recommendation.
Reflects updates as of Thursday noon.