



Common Drug Review *

Submission Status

Product:
Generic Name:
Manufacturer:
Submission Type:
Date Submission Received: **Date NOC Issued:**
Targeted CEDAC Meeting: **Priority Review Granted:**

| Phase | Target Time <small>(Business Days)</small> | Target Date** | Actual CDR Date | Comments |
|-----------|---|---------------|-----------------|--|
| 1 | 5 | 2009-Oct-30 | | Not Applicable: This submission is a continuation of the review of Forteo Resubmission #3. The manufacturer had requested on September 29, 2009 for a voluntary withdrawal of the Forteo resubmission #3. However, ACP requested on October 23, 2009 that the review be continued. |
| | | | | Submission deemed complete |
| 2 | 45 | 2010-Jan-21 | 2009-Dec-10 | |
| | | | | CDR Reviewers' Reports Completed • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmacoeconomic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer |
| 3 | 7 | 2010-Feb-01 | 2009-Dec-21 | Due date for manufacturer's comments December 21, 2009. |
| 4 | 7 | 2010-Feb-09 | 2009-Dec-23 | Due date for reviewers' reply January 5, 2010. |
| 5 | 5 | 2010-Mar-10 | 2010-Jan-06 | |
| 6 | | 2010-Jan-20 | 2010-Jan-20 | CEDAC meeting date changed from March 24, 2010 to January 20, 2010. |
| 7 | 5 | 2010-Jan-27 | 2010-Jan-27 | |
| | | | | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer |
| 8 | 10 | 2010-Feb-10 | 2010-Feb-10 | |
| | | | | Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation |
| 9 (a) | 5 | 2010-Mar-17 | 2010-Mar-17 | Notice of Final Recommendation issued. |
| OR | | | | |
| 9 (b) | 5 | | | |
| | | | | Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made) |
| OR | | | | |
| 9 (c) | 25 Depends on Meeting Dates | | | |
| | | | | Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request) |
| 10 | 5 | | | |
| | | | | Final Recommendation sent to Drug Plans, ACP, and Manufacturer |

* 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.