



## 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 (Business Days)	Target Date**	Actual CDR Date	Comments	
1	Submission Deemed Complete	5	2006-May-01	2006-May-09	Submission placed in queue on May 9, 2006 in accordance with CDR procedure. Review to be initiated pending availability of resources. Review initiated May 18, 2006. Priority review requested May 16, 2006. Priority review denied May 23, 2006.
2	CDR Reviewers' Reports Completed <ul style="list-style-type: none"> <li>• Reviewers selected and contracted</li> <li>• Literature search and selection completed</li> <li>• Systematic review of clinical data completed</li> <li>• Critical appraisal of pharmacoeconomic (PE) data completed</li> <li>• Clinical and PE reports written</li> <li>• Reports edited and finalized</li> <li>• Reviewers' reports sent to manufacturer</li> </ul>	45	2006-Jul-13	2006-Jul-28	Additional information requested June 1, 2006. Additional information received June 9, 2006. Additional information requested June 14, 2006. Additional information received June 22, 2006. Additional information requested June 23, 2006. Additional information received June 30, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Jul-24	2006-Aug-08	Comments from manufacturer due August 9, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Aug-02	2006-Aug-14	Due date for reviewers' reply August 17, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Sep-06	2006-Sep-06	
6	CEDAC Meeting		2006-Sep-20	2006-Sep-20	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Sep-27	2006-Sep-27	
8	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	10	2006-Oct-12	2006-Oct-12	Request for reconsideration received October 11, 2006.
9 (a)	Final Recommendation sent to Drug Plans, ACP, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5			
<b>OR</b>					
9 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
<b>OR</b>					
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2006-Nov-22	2006-Nov-22	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2006-Nov-29	2006-Nov-29	Notice of Final Recommendation issued.

\* Refer to the Procedure for Common Drug Review on the Common Drug Review section of [www.cadth.ca](http://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](http://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.