



## 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-Mar-03	2006-Mar-07	
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 pharmaco-economic (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-May-10	2006-May-10	Additional information requested April 6, 2006. Additional information requested April 17, 2006. Additional information received April 24, 2006. Additional information requested April 26, 2006. Additional information received May 3, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-May-19	2006-May-19	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-May-31	2006-May-31	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Jun-07	2006-Jun-07	
6	CEDAC Meeting		2006-Jun-21	2006-Jun-21	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Jun-28	2006-Jun-28	
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-Jul-13	2006-Jul-13	
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	2006-Jul-20	2006-Jul-20	Notice of Final Recommendation issued.
<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			
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](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.