



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 Assessment	5	2008-Jan-17	2008-Jan-17	Category 1 requirements deemed incomplete January 17, 2008.
	Submission deemed complete			2008-Jan-21	Submission deemed complete January 21, 2008. Submission placed in queue in accordance with CDR procedures. Review to be initiated pending availability of resources. Review initiated February 12, 2008.
2	CDR Reviewers' Reports Completed <ul style="list-style-type: none"> • 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 	45	2008-Apr-17	2008-Apr-14	Additional information requested February 15, 2008. Additional information received February 21, 2008. Additional information requested February 25, 2008. Additional information received February 25, 2008. Additional information received February 26, 2008. Additional information received March 20, 2008. Additional information received March 26, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2008-Apr-28	2008-Apr-22	Due date for manufacturer's comments April 23, 2008.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2008-May-07	2008-May-01	Due date for reviewers' reply May 1, 2008.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2008-Jun-04	2008-Jun-04	
6	CEDAC Meeting		2008-Jun-18	2008-Jun-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2008-Jul-23	2008-Jul-23	Discussed at the June 18, 2008 CEDAC meeting. Recommendation deferred pending further discussion at the July 16, 2008 CEDAC meeting.
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	2008-Aug-07	2008-Aug-07	
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	2008-Aug-14	2008-Aug-14	Notice of Final Recommendation issued.
OR					
9 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
OR					
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 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.