Common Drug Review *

Submission Status

Product: Pradax
Generic Name: dabigatran etexilate
Manufacturer: Boehringer Ingelheim (Canada) Ltd.
Submission Type: New
Date Submission Received: 2008-Jul-08
Date NOC Issued: 2008-Jun-10
Targeted CEDAC Meeting: 2008-Nov-19
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2008-Jul-15	2008-Jul-15	
	Submission deemed complete			2008-Jul-15	Submission deemed complete.
2	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	45	2008-Sep-30	2008-Oct-03	Additional information requested July 15, 2008. Additional information received July 16, 2008. Additional information received July 22, 2008. Additional information requested July 24, 2008. Additional information received July 28, 2008. Revised information received July 30, 2008. Additional information requested August 12, 2008. Additional information received August 13, 2008. Additional information requested August 19, 2008. Additional information requested August 27, 2008. Additional information received September 5, 2008. Revised information received September 18, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2008-Oct-09	2008-Oct-15	Due date for manufacturer's comments October 15, 2008.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2008-Oct-21	2008-Oct-21	Due date for reviewers' comments October 24, 2008. Additional information requested October 20, 2008. Additional information received October 23, 2008. Additional information requested October 23, 2008. Additional information received October 24, 2008.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2008-Nov-05	2008-Nov-05	
6	CEDAC Meeting		2008-Nov-19	2008-Nov-19	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2008-Nov-26	2008-Nov-26	
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-Dec-10	2008-Dec-10	Request for Reconsideration received December 9, 2008.
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			
	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	2009-Jan-21	2009-Jan-21	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2009-Jan-28	2009-Jan-28	Notice of Final Recommendation issued.

* 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.