Common Drug Review *

Submission Status

Product: Pradax
Generic Name: dabigatran etexilate
Manufacturer: Boehringer Ingelheim (Canada) Ltd.
Submission Type: Pre-NOC - New Indication
Date Submission Received: 2010-May-31
Date NOC Issued:
Targeted CEDAC Meeting:
Priority Review Granted: Not granted

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2010-Jun-07	2010-Jun-07	
	Submission deemed complete			2010-Jun-07	Submission deemed complete, however, the Pre-NOC Priority Review request was not granted (June 9, 2010). The Pradax review will not proceed at this time.
2	Patient group input submission received		2010-Jun-25		
3	CDR Reviewers' Reports Completed • Reviewers selected and contracted • Literature search and selection completed • Patient group input reviewed • 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			
4	Comments from Manufacturer on Reviewers' Reports Received by CDR	7			
5	Reviewers' Reply to Manufacturer's Comments Completed	7			
6	CEDAC Brief Completed and Sent to CEDAC Members	5			
7	CEDAC Meeting				
8	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5			
9	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			
10 (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				
10 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
10 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates			
11	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.