Common Drug Review *

Submission Status

Product: Enablex

Generic Name: darifenacin hydrobromide

Manufacturer: Novartis Pharmaceuticals Canada Inc.

Submission Type: Resubmission #1

Date Submission Received: 2008-Oct-01 **Date NOC Issued:** 2005-Nov-14

Targeted CEDAC Meeting: 2009-Mar-18 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	10	2008-Oct-16	2008-Oct-16	
	Submission deemed complete			2008-Oct-16	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	2009-Jan-07	2009-Jan-14	Additional information requested November 7, 2008. Additional information received November 11, 2008. Additional information requested November 14, 2008. Additional information received November 18, 2008. Additional information requested November 25, 2008. Additional information received December 12, 2008. Additional information received December 18, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2009-Jan-16	2009-Jan-29	Due date for manufacturer's comment January 23, 2009.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2009-Jan-27	2009-Feb-09	Due date for reviewers' reply February 9, 2009.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2009-Mar-04	2009-Mar-04	
6	CEDAC Meeting		2009-Mar-18	2009-Mar-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2009-Mar-25	2009-Mar-25	
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	2009-Apr-08	2009-Apr-08	Request for Clarification received April 8, 2009.
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	2009-Apr-16	2009-Apr-16	Clarification and Notice of Final Recommendation issued.
	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.