Common Drug Review *

Submission Status

Product: Enablex

Generic Name: darifenacin hydrobromide

Manufacturer: Novartis Pharmaceuticals Canada Inc.

Submission Type: New

Date Submission Received: 2006-Apr-26 **Date NOC Issued:** 2005-Nov-14

Targeted CEDAC Meeting: 2006-Sep-20 **Priority Review Granted:** Not requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-May-03	2006-May-18	Submission incomplete - missing information requested May 16, 2006. Requested information received May 17, 2006. 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	2006-Jul-24	2006-Jul-25	
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Aug-02	2006-Aug-03	Due date for manufacturer's comments August 3, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Aug-14	2006-Aug-15	Due date for reviewers' Reply August 15, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Sep-06	2006-Sep-06	
6	CEDAC Meeting		2006-Sep-20	2006-Sep-20	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Sep-27	2006-Sep-27	
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-Oct-12	2006-Oct-12	
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-Oct-19	2006-Oct-19	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.