Common Drug Review *

Submission Status

Product: Xarelto
Generic Name: rivaroxaban
Manufacturer: Bayer Inc.
Submission Type: NEW-PreNOC pilot project
Date Submission Received: 2008-May-07 **Date NOC Issued:** 2008-Sep-15
Targeted CEDAC Meeting: 2008-Sep-17 **Priority Review Granted:** Not requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2008-May-14	2008-May-14	Submission filed preNOC as a collaborative pilot project between CDR, Health Canada and manufacturer. Due to confidentiality, first web report posted September 19, 2008.
	Submission deemed complete			2008-May-14	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-Jul-28	2008-Sep-15	Information received from manufacturer April 17, 2008. Additional information requested May 16, 2008. Additional information received May 21, 2008. Additional information requested June 4, 2008. Additional information requested June 11, 2008. Additional information received June 11, 2008. Additional information requested June 13, 2008. Additional information received June 13, 2008. Additional information requested June 18, 2008. Additional information received June 18, 2008. Additional information received June 26, 2008. Additional information received July 7, 2008. Additional information received July 15, 2008. Additional information received July 21, 2008. Additional information received July 28, 2008. Additional information received August 15, 2008. Additional information received September 4, 2008. NOC received September 15, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2008-Aug-07	2008-Sep-16	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2008-Aug-18	2008-Sep-25	Due date for reviewers reply September 25, 2008.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2008-Sep-30	2008-Sep-30	
6	CEDAC Meeting		2008-Oct-15	2008-Oct-15	November CEDAC meeting date determined from NOC received date. October CEDAC meeting date determined from date manufacturer's comments received. Discussed at the October 15, 2008 CEDAC meeting. Recommendation deferred pending further discussion. Additional information requested October 17, 2008. Additional information received October 20, 2008. Additional information received October 21, 2008. Additional information requested October 22, 2008. Additional information received October 23, 2008. Additional information received October 24, 2008. To be discussed at the November 19, 2008 CEDAC meeting.
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	
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-Dec-17	2008-Dec-17	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.