Common Drug Review *



Submission Status

Product:	Xarelto
Generic Name:	rivaroxaban
Manufacturer:	Baver Inc.

Submission Type: Request for Advice

Date Submission Received: 2011-Jun-24 **Date NOC Issued:** 2008-Sep-15

Targeted CEDAC Meeting: 2011-Nov-16 **Priority Review Granted:** Not Requested

	Targeted CEDAC Meeting:	2011-Nov-16 Priority Review Granted:		Not Requested				
Phase		Target Time (Business Days)	Target Date**	Actual CDR Date	Comments			
1	CADTH Request for Advice Assessment complete	10	2011-Jul-11		- 2011-Jun-27: Manufacturer informed of request for advice - Information or comments due 2011-Jul-13 - 2011-Jul-12: Manufacturer information or comments received			
2	CADTH Reviewers' reports or other document sent to Manufacturer	45	2011-Sep-26	2011-Sep-26				
3	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Oct-05	2011-Oct-05				
4	CEDAC Meeting		2011-Nov-16	2011-Nov-16				
5	CEDAC Recommendation or Response to Request for Advice sent to Drug Plans, FWG and Manufacturer	5	2011-Nov-23	2011-Nov-23	- Record of Advice issued.			
	OR							
6 (a)	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10						
OR								
6 (b)	No Embargo Period if Request for Advice does not result in a Revised Recommendation							
7 (a)	Final Recommendation sent to Drug Plans, FWG, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5						
	OR							
7 (b)	Clarification and Final Recommendation sent to Drug Plans, FWG, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5						
	OR							
7 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates						
8	Final Recommendation sent to Drug Plans, FWG, 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.