Common Drug Review [1]

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Xarelto
Generic Name: rivaroxaban
Manufacturer: Bayer Inc.
Indication: Deep-Vein Thrombosis (treatment), without Symptomatic Pulmonary Embolism
Submission Type: Request for Advice
Date Submission Received: 2012-Oct-10 **Date NOC Issued:** 2012-Feb-16
Targeted CDEC Meeting: 2013-Mar-20 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
1	CADTH Request for Advice Assessment complete	10	2012-Oct-24	2012-Oct-24	- 2012-Oct-10: Manufacturer informed of request for advice - Information or comments due 2012-Oct-24 - Manufacture information/comments received: 2012-Oct-24
2	CADTH Reviewers' reports or other document sent to Manufacturer [3]	45	2013-Jan-15		- New target date: 2013-Jan-31
3	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2013-Jan-24		- New target date: 2013-Feb-11
4	CDEC Meeting		2013-Mar-20		
5	CDEC Recommendation or Response to Request for Advice sent to Drug Plans, ACP and Manufacturer	5	2013-Mar-27		
	OR				
6 (a)	Embargo Period [4] Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2013-Apr-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, ACP, 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, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
7 (c)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates			
8	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5			

[1] Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.

[2] The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

[3] Target time is calculated, based on the date the Reviewers receive copies of the Manufacturer's Submission. Target time does not include the time allocated for receipt of Manufacturer's binders (5 business days) and time allocated for distribution of binders to reviewers (3 business days).

[4] The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of Final Recommendation.

This Submission Status Report reflects status as of Thursday noon.