Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product:	Pradax
Generic Name:	dabigatran etexilate
Manufacturer:	Boehringer Ingelheim
Indication:	Prevention of stroke and systemic embolism in patients with atrial fibrillation
Submission Type:	New Indication
Date Submission Received:	2010-Oct-28
Date NOC Issued:	2010-Oct-26
Targeted CEDAC Meeting:	2011-Mar-23
Priority Review Granted:	Not Requested

	Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments
1	Submission deemed complete	5	2010-Nov-04	2010-Nov-04	Submission deemed complete.
2	Patient group input submission received		2010-Nov-18	2010-Nov-18	Patient group submissions received.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2011-Jan-26	2011-Feb-01	New due date to send to manufacturer 2011-Feb-01.
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Feb-04	2011-Feb-10	New due date for manufacturers comments 2011-Feb-10. Manufacturer's comments received.
5	CEDAC Meeting		2011-Mar-23	2011-Mar-23	
6	CEDAC Recommendation *** Sent to Drug Plans, ACP and Manufacturer	5 to 7	2011-Mar-30	2011-Apr-01	New date: 2011-Apr-1. In accordance with the Procedure for Common Drug Review recommendation released 7 business days after CEDAC.
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Apr-13	2011-May-13	- New date: 2011-Apr-15. - Request for extension to embargo period received from manufacturer on 2011-Apr-11. - Extension to embargo period granted. - Embargo period extended to 2011-May-13 - Request for clarification received 2011-Apr-15 - Request for reconsideration received 2011-May-09 - Request for reconsideration granted 2011-May-17
8 (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				
8 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
8 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2011-Jun-15	2011-Jun-15	
9	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2011-Jun-22	2011-Jun-22	

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

** The Formulary 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 Procedure for Common Drug Review, section 8.3.3a, states "…the CEDAC recommendation will be sent to the Manufacturer, ACP and to the drug plans within five (5) to seven (7) business days following the CEDAC meeting…". The original target date is based on five (5) business days.

**** The Recommendation is held in confidence and not acted upon until after CADTH has issued the notice of Final Recommendation.

This submission status report reflects updates as of Thursday noon.