Common Drug Review *



Submission Status

Product:	Abilify
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Generic Name:	aripiprazole
Manufacturer:	Bristol-Myers Squibb Canada
Submission Type:	New
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Date NOC Issued: Date Submission Received: 2009-Nov-06 2009-Jul-09 Targeted CEDAC Meeting: 2010-Mar-24 **Priority Review Granted:** Not Requested

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Phase		Target Time (Business Days)	Target Date**	Actual CDR Date	Comments		
	Submission Assessment	5	2009-Nov-13	2009-Nov-13			
1	Submission deemed complete			2009-Nov-13	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	2010-Feb-04	2010-Feb-12	Additional information requested December 8, 2009. Additional information requested December 9, 2009. Additional information received December 17, 2009. Additional information requested December 17, 2009. Additional information received December 21, 2009. Additional information received December 23, 2009. Additional information requested February 3, 2010. Additional information received February 9, 2010.		
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2010-Feb-16	2010-Feb-24	Due date for manufacturer's comment February 24, 2010.		
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2010-Feb-24	2010-Mar-05	Due date for reviewers' reply March 5, 2010.		
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2010-Mar-10	2010-Mar-10			
6	CEDAC Meeting		2010-Mar-24	2010-Mar-24			
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2010-Mar31	2010-Apr-05			
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	2010-Apr-15	2010-Apr-19			
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	2010-Apr-26	2010-Apr-27	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.