Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Aptivus
Generic Name: tipranavir
Manufacturer: Boehringer Ingelheim (Canada) Inc.
Submission Type: New
Date Submission Received: 2005-Dec-15
Date NOC Issued: 2005-Nov-21
Targeted CEDAC Meeting: 2006-Apr-19
Priority Review Granted: Denied

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2005-Dec-22	2005-Dec-22	Priority review requested. Priority review denied January 5, 2006.
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	2006-Mar-03	2006-Mar-03	Additional information requested January 12, 2006. Additional information received January 20, 2006. Additional information requested February 3, 2006. Additional information received February 13, 2006. Additional information received February 15, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Mar-14	2006-Mar-14	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Mar-23	2006-Mar-23	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Apr-05	2006-Apr-05	
6	CEDAC Meeting		2006-Apr-19	2006-Apr-19	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Apr-26	2006-Apr-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	2006-May-10	2006-May-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	2006-May-17	2006-May-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.