Common Drug Review *

Submission Status

Product: Sebivo
Generic Name: telbivudine
Manufacturer: Novartis Pharmaceuticals Canada Inc.
Submission Type: New
Date Submission Received: 2006-Dec-04
Date NOC Issued: 2006-Nov-28
Targeted CEDAC Meeting: 2007-Apr-18
Priority Review Granted: Denied

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Assessment	5	2006-Dec-11	2006-Dec-11	Submission incomplete.
	Submission deemed complete			2006-Dec-13	Outstanding requirement received December 12, 2006. Priority Review Request denied December 14, 2006. Submission placed in queue in accordance with CDR procedures. Review to be initiated pending availability of resources. Review initiated January 12, 2007.
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	2007-Mar-05	2007-Mar-05	Additional information requested January 12, 2007. Additional information requested January 16, 2007. Additional information received January 23, 2007. Additional information received January 24, 2007. Additional information requested January 26, 2007. Clarification of information required February 9, 2007. Additional information received February 13, 2007. Clarification received February 16, 2007. Clarification of information required February 19, 2007. Clarification received February 20, 2007.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2007-Mar-14	2007-Mar-14	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2007-Mar-23	2007-Mar-23	Clarification of information requested March 23, 2007. Clarification received March 28, 2007.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Apr-03	2007-Apr-03	
6	CEDAC Meeting		2007-Apr-18	2007-Apr-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Apr-25	2007-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	2007-May-09	2007-May-10	Embargo Period ends May 10, 2007. Request for Reconsideration received May 10, 2007.
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			
	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	2007-Sep-19	2007-Sep-19	Discussed at June 20, 2007 CEDAC meeting. Recommendation deferred to September 19, 2007 CEDAC meeting.
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2007-Sep-26	2007-Sep-26	Notice of Final Recommendation issued.

* 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.
Reflects updates as of Thursday noon.