Common Drug Review *

Submission Status

Product: Viread

Generic Name: tenofovir disoproxil fumarate

Manufacturer: Gilead Sciences Canada Inc.

Submission Type: Request for Advice

Date Submission Received: 2008-Jul-07 **Date NOC Issued:** 2005-Jul-20

Targeted CEDAC Meeting: 2008-Nov-19 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	CDR Request for Advice Assessment - Review team formed and determines approach for responding to Request for Advice	10	21-Jul-08	2008-Aug-05	ACP request for advice.
2	CDR Reviewers' reports or other document completed as determined by CDR team i) Reviewers' Report sent to Manufacturer for comment ii) Documentation completed as required and sent to manufacturer for information only. (no comments required)	45	2008-Sep-24	2008-Oct-07	Information requested August 12, 2008. Information received August 13, 2008. Additional information requested September 4, 2008. Additional information received September 16, 2008. Additional information received September 18, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2008-Oct-03	2008-Oct-10	Due date for manufacturer's comments October 17, 2008.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2008-Oct-15	2008-Oct-22	Due date for reviewers' comments October 22, 2008.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2008-Nov-05	2008-Nov-05	
6	CEDAC Meeting		2008-Nov-19	2008-Nov-19	
7	Recommendation and Reasons for Recommendation **or** Response to Request for Advice sent to Drug Plans, ACP and Manufacturer	5	2008-Nov-26	2008-Nov-26	Response to Request for Advice sent to Drug Plans, ACP and Manufacturer on November 26, 2008. No CEDAC recommendation issued in response to this Request for Advice.
8 (a)	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	2008-Dec-10		
	OR				
8 (b)	No Embargo Period if Request for Advice does not result in a Revised Recommendation or Reasons for Recommendation				
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			
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 submission is assessed. 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.