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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Zavesca

Generic Name: miglustat

Manufacturer: Actelion Pharmaceutiques Canada Inc.

Submission Type: NEW

Date Submission Received: 2004-May-13

Date NOC Issued: 2004-Mar-31

Targeted CEDAC Meeting: 2004-Sep-15

Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2004-May-20	2004-May-19	
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	2004-Jul-30	2004-Jul-30	Additional information requested on June 1/04. Additional information received on June 16/04. Additional information requested June 22, 2004, still pending. Additional information requested June 24, 2004. All requested information received July 5, 2004.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2004-Aug-11	2004-Aug-11	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2004-Aug-20	2004-Aug-18	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2004-Aug-27	2004-Sep-02	
6	CEDAC Meeting		2004-Sep-15	2004-Sep-15	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, CDRC and Manufacturer	5	2004-Sep-22	2004-Sep-22	
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	2004-Oct-06	2004-Oct-06	Request for reconsideration received October 6, 2004.
9 (a)	Final Recommendation sent to Drug Plans, CDRC, 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, CDRC, 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	2004-Nov-17	2004-Nov-17	
10	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer	5	2004-Nov-24	2004-Nov-24	Notice of Final Recommendation Issued.

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.ccohta.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.ccohta.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.