Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Myozyme
Generic Name: alglucosidase
Manufacturer: Genzyme Canada Inc.
Submission Type: New
Date Submission Received: 2006-Oct-10
Date NOC Issued: 2006-Aug-14
Targeted CEDAC Meeting: 2007-Feb-21
Priority Review Granted: Granted

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Oct-17	2006-Oct-17	ACP requested review. Priority review granted November 8, 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-Dec-15	2006-Dec-15	Additional information requested November 7, 2006. Additional information received November 17, 2006. Additional information requested November 21, 2006. Additional information requested November 27, 2006. Information requested on November 21, 2006 not yet available. Additional information received December 1, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2007-Jan-03	2007-Jan-05	Request for extension received December 22, 2006. Extension granted, new due date for manufacturer's comments is January 5, 2007.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2007-Jan-12	2007-Jan-16	Due date for reviewers replies January 16, 2007.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Feb-07	2007-Feb-07	
6	CEDAC Meeting		2007-May-16	2007-May-16	Discussed at the February 21, 2007 CEDAC meeting, Recommendation deferred pending further information. Additional information requested February 26, 2007. Additional information received March 12, 13, 20, 2007. Additional information received March 22, 2007. Discussed at the April 18, 2007 CEDAC meeting, Recommendation deferred to May 16, 2007 CEDAC.
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-May-24	2007-May-24	
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-Jun-07	2007-Jun-07	
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	2007-Jun-14	2007-Jun-14	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.
Reflects updates as of Thursday noon.