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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Xolair

Generic Name: omalizumab

Manufacturer: Novartis Pharmaceuticals Canada Inc.

Submission Type: Resubmission

Date Submission Received: 2005-Oct-13 **Date NOC Issued:** 2004-Nov-18

Targeted CEDAC Meeting: 2006-Feb-07 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2005-Oct-20	2005-Oct-20	
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	2005-Dec-22	2005-Dec-14	
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Jan-09	2006-Jan-06	Due date for Manufacturer's comments is December 23, 2005 Request for extension received December 16, 2005. Extension granted, due date for manufacturer's comments January 6, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Jan-18	2006-Jan-17	Due date for Reviewers' Reply is January 17, 2006
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Jan-24	2006-Jan-26	
6	CEDAC Meeting		2006-Feb-07	2006-Feb-07	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Feb-14	2006-Feb-14	
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-Feb-28	2006-Feb-28	
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-Mar-07	2006-Mar-07	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.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.