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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: NEW
Date Submission Received: 2005-Apr-18
Date NOC Issued: 2004-Nov-18
Targeted CEDAC Meeting: 2005-Sep-21
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2005-Apr-25	2005-May-09	Submission Incomplete - Missing information requested April 25, 2005. Missing information supplied May 6, 2005. Submission deemed complete May 9, 2005.
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-Jul-13	2005-Jul-26	Additional information requested May 18, 2005. Additional information received May 19, 2005. Additional information requested May 31, 2005. Additional information received June 6, 2005. Additional information requested June 24, 2005. Additional information received June 28 & 30, 2005. Additional information received July 5, 2005. Additional information requested July 6, 2005. Additional information received July 12, 13 & 14 2005 Additional information received July 15 & 18, 2005. Delays in receipt of requested information.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2005-Jul-22	2005-Aug-08	Due date for Manufacturer's comments is August 5, 2005 Request for Extention received July 28, 2005. Extension granted, due date for manufacturer's comments August 8, 2005.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2005-Aug-03	2005-Aug-10	Due date for Reviewers' reply August 17, 2005 Additional information requested August 11, 2005 Additional information received August 15, 2005
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2005-Sep-07	2005-Sep-07	Additional information requested September 19 and 20, 2005 Additional information received September 19 and 20, 2005
6	CEDAC Meeting		2005-Sep-21	2005-Sep-21	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2005-Sep-28	2005-Sep-28	
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	2005-Oct-13	2005-Oct-13	Request for reconsideration received October 13, 2005. Request for reconsideration deemed to include "New Information", therefore drug will undergo review as a resubmission. A final recommendation will not be issued at this time.
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.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.