Common Drug Review *

Submission Status

Product: Humira
Generic Name: adalimumab
Manufacturer: Abbott Laboratories, Limited
Submission Type: Resubmission
Date Submission Received: 2006-Jun-21
Date NOC Issued: 2006-Jun-20
Targeted CEDAC Meeting: 2006-Oct-18
Priority Review Granted: Not requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Jun-28	2006-Jun-29	Required information requested June 28, 2006. Required information received June 29, 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-Sep-05	2006-Sep-08	Additional information requested June 30, 2006. Additional information received July 5, 2006. Additional information requested July 20, 2006. Additional information received July 31, 2006. Additional information requested August 2, 2006. Additional information received August 2, 2006. Additional information requested August 11, 2006. Additional information received August 23, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Sep-14	2006-Sep-15	New due date for manufacturer's comments is September 15, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Sep-25	2006-Sep-25	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Oct-03	2006-Oct-03	
6	CEDAC Meeting		2006-Oct-18	2006-Oct-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Oct-25	2006-Oct-25	
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-Nov-08	2006-Nov-08	Request for clarification received November 2, 2006.
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	2006-Nov-29	2006-Nov-29	Placed on the November 22, 2006 CEDAC agenda in response to the ACP request for clarification. Notice of Final Recommendation issued.
	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.