



Common Drug Review *

Submission Status

Product:	<input type="text" value="Remicade"/>		
Generic Name:	<input type="text" value="Infliximab"/>		
Manufacturer:	<input type="text" value="Centocor Inc."/>		
Submission Type:	<input type="text" value="New"/>		
Date Submission Received:	<input type="text" value="2008-Sep-29"/>	Date NOC Issued:	<input type="text" value="2006-Mar-10"/>
Targeted CEDAC Meeting:	<input type="text" value="2009-Feb-18"/>	Priority Review Granted:	<input type="text" value="Not Requested"/>

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission deemed complete	5	2008-Oct-06	2008-Oct-06	ACP requested review.
2	CDR Reviewers' Reports Completed <ul style="list-style-type: none"> • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmaco-economic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer 	45	2008-Dec-19	2009-Jan-06	Additional information requested October 20, 2008. Additional information requested October 23, 2008. Additional information received November 12, 2008. Additional information received November 14, 2008. Additional information requested November 21, 2008. Additional information requested November 24, 2008. Additional information received November 28, 2008. Additional information requested November 28, 2008. Additional information received December 1, 2008. Additional information received December 3, 2008. Additional information received December 4, 2008.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2009-Jan-07	2009-Jan-15	Due date for manufacturer's comments January 15, 2009.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2009-Jan-16	2009-Jan-26	Due date for reviewer's reply January 26, 2009.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2009-Feb-03	2009-Feb-03	
6	CEDAC Meeting		2009-Feb-18	2009-Feb-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2009-Feb-25	2009-Feb-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	2009-Mar-11	2009-Mar-11	Request for Reconsideration received March 11, 2009.
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	2009-Apr-15	2009-Apr-15	Additional information requested April 2, 2009. Additional information received April 6, 2009. Additional information received April 7, 2009.
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2009-Apr-22	2009-Apr-22	Notice of Final Recommendation issued.

* 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.