Common Drug Review *

Submission Status

Product: Macugen
Generic Name: pegaptanib sodium
Manufacturer: Pfizer Canada Inc.
Submission Type: New
Date Submission Received: 2005-Oct-20
Date NOC Issued: 2005-May-02
Targeted CEDAC Meeting: 2006-Mar-08
Priority Review Granted: Denied

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2005-Oct-27	2005-Oct-27	Priority review requested. Priority review denied November 18, 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	2006-Jan-17	2006-Jan-17	Additional information requested November 3, 2005. Response received on November 7, 2005 from manufacturer that information requested November 3, 2005 is not available. Additional information requested November 25, December 6, 14 & 21, 2005 Additional information received December 2 & 7, 2005. Additional information requested January 4, 2006. Additional information received January 4 & 5, 2006. Response to request for additional information received January 13, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Jan-26	2006-Jan-25	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Feb-06	2006-Feb-03	New due date for Reviewer's Reply is February 3, 2006. Additional information requested February 15, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Feb-27	2006-Feb-24	Additional information received February 17, 2006. Additional information requested February 28, 2006. Additional information received March 1, 2006. Additional information received March 3, 2006.
6	CEDAC Meeting		2006-Mar-08	2006-Mar-08	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Mar-15	2006-Mar-15	
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-Mar-29	2006-Mar-29	Request for reconsideration received March 29, 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			
	OR				
9 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2006-May-17	2006-May-17	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2006-May-25	2006-May-25	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.