Common Drug Review *



Submission Status

Product: Revatio	
Generic Name: sildenafil citrate	
Manufacturer: Pfizer Canada Inc.	

Submission Type: New

Date NOC Issued: Date Submission Received: 2006-Sep-20 2006-May-26 Targeted CEDAC Meeting: 2007-Jan-17 Priority Poviou Granted:

Targeted CEDAC Meeting: 2007-Jan-17		Priority Review Granted:		Not requested			
	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments		
1	Submission Deemed Complete	5	2006-Sep-27	2006-Sep-27			
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-Nov-29	2006-Nov-29	Additional information requested October 11, 2006, Response to request received October 11, 2006. Additional information requested November 7, 2006. Additional information requested November 16, 2006. Partial information received November 17, 2006 for November 7, 2006 request. Additional information received November 20, 2006.		
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Dec-08	2006-Dec-08			
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Dec-19	2006-Dec-19	Additional information requested December 13, 2006. Additional information received December 15, 2006. Additional information received December 19, 2006.		
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Jan-03	2007-Jan-03			
6	CEDAC Meeting		2007-Jan-17	2007-Jan-17			
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Jan-24	2007-Jan-24			
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	2007-Feb-07	2007-Feb-07			
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	2007-Feb-14	2007-Feb-14	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					
	to the Procedure for Common Drug Review on the Con	·		tel 6			

^{*} 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.