Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Vesicare
Generic Name: solifenacin succinate
Manufacturer: Astellas Pharma Canada Inc.
Submission Type: NEW
Date Submission Received: 2006-Jul-24
Date NOC Issued: 2006-Feb-20
Targeted CEDAC Meeting: 2006-Nov-15
Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Jul-31	2006-Jul-31	
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 writt	45	2006-Oct-04	2006-Oct-06	Additional information requested September 7, 2006. Additional information requested September 8, 2006. Additional information received September 14, 2006. Additional information received September 20, 2006.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2006-Oct-16	2006-Oct-18	Due date for manufacturer's comments October 18, 2006.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2006-Oct-25	2006-Oct-27	Due date for reviewers' replies is October 27, 2006.
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2006-Nov-08	2006-Nov-08	
6	CEDAC Meeting		2006-Nov-22	2006-Nov-22	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2006-Nov-29	2006-Nov-29	
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-Dec-13	2006-Dec-13	Request for Reconsideration received December 13, 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	2007-Jan-17	2007-Jan-17	
10	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2007-Jan-24	2007-Jan-24	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.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.