WWW.CCOHTA.CA

Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Avodart

Generic Name: dutasteride

Manufacturer: GlaxoSmithKline Inc.

Submission Type: NEW

Date Submission Received: 2004-Aug-24

Date NOC Issued: 2003-Jul-22

Targeted CEDAC Meeting: 2004-Dec-15

Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2004-Aug-31	2004-Aug-26	
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	2004-Nov-02	2004-Nov-02	Additional information requested September 9, 2004. Additional information received September 21, 2004. Additional information requested October 15, 2004. Additional information received October 22, 2004.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2004-Nov-11	2004-Nov-11	Clarification of comments requested on November 12, 2004. Clarifications received on November 14, 2004.
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2004-Nov-22	2004-Nov-22	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2004-Nov-29	2004-Dec-03	
6	CEDAC Meeting		2004-Dec-15	2004-Dec-15	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, CDRC and Manufacturer	5	2004-Dec-22	2004-Dec-22	
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	2005-Jan-13	2005-Jan-13	
9 (a)	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5		2005-Jan-20	Notice of Final Recommendation issued.
	OR				
9 (b)	Clarification and Final Recommendation sent to Drug Plans, CDRC, 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, CDRC, and Manufacturer	5			

* Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.ccohta.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.