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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Remodulin

Generic Name: treprostinil sodium

Manufacturer: Northern Therapeutics Inc

Submission Type: Resubmission

Date Submission Received: 2004-Jul-14

Date NOC Issued: 2002-Oct-04

Targeted CEDAC Meeting: 2004-Oct-20

Priority Review Granted: Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2004-Jul-21	2004-Jul-20	Initial Submission: Deemed complete May 14, 2004. Resubmission: New information (new cost information) provided by manufacturer on July 14, 2004; resulted in resubmission. Scheduled for October 20, 2004 CEDAC meeting.
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-Sep-03	2004-Sep-02	Initial Submission: Additional information requested on June 4/04. Received information on June 10/04. Additional Information Requested June 24, 2004. Clarification of additional information received July 6, 2004. Resubmission: Additional information requested August 3, 2004. Additional information received August 10, 2004.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2004-Sep-15	2004-Sep-14	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2004-Sep-24	2004-Sep-27	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2004-Oct-01	2004-Oct-07	
6	CEDAC Meeting		2004-Oct-20	2004-Oct-20	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, CDRC and Manufacturer	5	2004-Oct-27	2004-Oct-27	
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	2004-Nov-10	2004-Nov-10	
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		2004-Nov-17	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.