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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review * Submission Status

Product: Myfortic
Generic Name: mycophenolate sodium
Manufacturer: Novartis Pharmaceuticals Canada Inc.
Submission Type: NEW
Date Submission Received: 2005-Mar-03 **Date NOC Issued:** 2005-Feb-04
Targeted CEDAC Meeting: 2005-Jul-27 **Priority Review Granted:** Not Requested

Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments	
1	Submission Deemed Complete	5	2005-Mar-10	2005-Mar-10	
2	CDR Reviewers' Reports Completed <ul style="list-style-type: none"> • Reviewers selected and contracted • Literature search and selection completed • Systematic review of clinical data completed • Critical appraisal of pharmaco-economic (PE) data completed • Clinical and PE reports written • Reports edited and finalized • Reviewers' reports sent to manufacturer 	45	2005-May-13	2005-May-13	Additional information requested April 22, 2005. Additional information received April 25 & 26, 2005. Additional information requested April 29, 2005. Additional information received May 3, 2005.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2005-May-25	2005-May-25	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2005-Jun-03	2005-May-26	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2005-Jul-13	2005-Jun-02	
6	CEDAC Meeting		2005-Jul-27	2005-Jun-15	Review advanced to June 15, 2005 CEDAC.
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2005-Aug-04	2005-Jun-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-Aug-18	2005-Jul-05	Deadline for Embargo Period: July 7, 2005, due to advanced CEDAC date.
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		2005-Jul-08	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			

* 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.