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Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

Common Drug Review *

Submission Status

Product: Adderall XR

Generic Name: mixed amphetamine salts

Manufacturer: Shire BioChem Inc.

Submission Type: NEW

Date Submission Received: 2004-Apr-13 **Date NOC Issued:** 2004-Jan-21

Targeted CEDAC Meeting: 2004-Aug-18 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2004-Apr-20	2004-Apr-14	
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-Jul-05	2004-Jul-06	Additional information requested on May 11/04. All information received by June 1/04. Additional information requested on June 4/04. Received information on June 11/04.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2004-Jul-14	2004-Jul-15	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2004-Jul-23	2004-Jul-27	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2004-Jul-30	2004-Aug-04	
6	CEDAC Meeting		2004-Aug-18	2004-Aug-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, CDRC and Manufacturer	5	2004-Aug-25	2004-Aug-25	
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-Sep-09	2004-Sept-09	Embargo period extended to September 28, 2004. Request for reconsideration received September 28, 2004.
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			
	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	2004-Nov-17	2004-Nov-17	
10	Final Recommendation sent to Drug Plans, CDRC, and Manufacturer	5	2004-Nov-24	2004-Nov-24	Notice of Final Recommendation Issued.

* 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.