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Canadian Coordinating Office for  
Health Technology Assessment  
(CCOHTA)

## Common Drug Review \*

### Submission Status

<b>Product:</b>	Adderall XR		
<b>Generic Name:</b>	mixed amphetamine salts		
<b>Manufacturer:</b>	Shire BioChem Inc.		
<b>Submission Type:</b>	NEW		
<b>Date Submission Received:</b>	2004-Apr-13	<b>Date NOC Issued:</b>	2004-Jan-21
<b>Targeted CEDAC Meeting:</b>	2004-Aug-18	<b>Priority Review Granted:</b>	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	<ul style="list-style-type: none"> <li>CDR Reviewers' Reports Completed</li> <li>Reviewers selected and contracted</li> <li>Literature search and selection completed</li> <li>Systematic review of clinical data completed</li> <li>Critical appraisal of pharmacoeconomic (PE) data completed</li> <li>Clinical and PE reports written</li> <li>Reports edited and finalized</li> <li>Reviewers' reports sent to manufacturer</li> </ul>	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](http://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](http://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.