Common Drug Review *

Submission Status

Product: Tramacet
Generic Name: tramadol hydrochloride / acetaminophen
Manufacturer: Janssen-Ortho Inc.
Submission Type: New
Date Submission Received: 2006-Oct-02
Date NOC Issued: 2005-Jul-20
Targeted CEDAC Meeting: 2007-Apr-18
Priority Review Granted: Not requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission Deemed Complete	5	2006-Oct-10	2006-Oct-10	ACP requested review.
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	2007-Jan-23	2007-Mar-01	Additional information requested December 8, 2006. Additional information requested December 14, 2006. Additional information received December 19, 2006. Additional information received December 21, 2006. Additional information requested January 12, 2007. Additional information received January 15, 2007. Additional information requested January 16, 2007. New due date for Reviewers' Reports to be determined after assessment of all relevant material received. Additional information requested January 26, 2007. Response to additional information request received February 1, 2007. Additional information received February 2, 2007. Assessment of all material complete and final reports sent for manufacturer's comment March 1, 2007.
3	Comments from Manufacturer on Reviewers' Reports Received by CDR	7	2007-Mar-12	2007-Mar-12	
4	Reviewers' Reply to Manufacturer's Comments Completed	7	2007-Mar-21	2007-Mar-21	
5	CEDAC Brief Completed and Sent to CEDAC Members	5	2007-Apr-03	2007-Apr-03	
6	CEDAC Meeting		2007-Apr-18	2007-Apr-18	
7	CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2007-Apr-25	2007-Apr-26	
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	2007-May-09	2007-May-10	Embargo Period ends May 10, 2007. Request for reconsideration received May 10, 2007. In consultation, issues raised were resolved with manufacturer May 16, 2007.
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	2007-May-17	2007-May-17	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.cadth.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.cadth.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.
Reflects updates as of Thursday noon.