Common Drug Review *

Submission Status

Product: Aclasta
Generic Name: zoledronic acid
Manufacturer: Novartis Pharmaceuticals Canada Inc.
Submission Type: Request for Advice
Date Submission Received: 2011-Jul-20 **Date NOC Issued:** 2007-Oct-29
Targeted CDEC Meeting: 2012-Jan-18 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	CADTH Request for Advice Assessment complete	10	2011-Aug-04		
2	CADTH Reviewers' reports or other document sent to Manufacturer	45	2011-Oct-20	2011-Sep-09	- New due date for CADTH Reviewers' reports or other document sent to Manufacturer: 2011-Sep-09
3	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Oct-31	2011-Sep-15	- New due date for Comments from Manufacturer on Reviewers' Reports Received by CADTH: 2011-Sep-20
4	CDEC Meeting		2012-Jan-18	2011-Oct-19	- New date: October 19, 2011
5	CDEC Recommendation or Response to Request for Advice sent to Drug Plans, FWG and Manufacturer	5	2012-Jan-25	2011-Oct-26	- New date: October 26, 2011
	OR				
6 (a)	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2012-Feb-08	2011-Nov-09	- New date: November 9, 2011
	OR				
6 (b)	No Embargo Period if Request for Advice does not result in a Revised Recommendation				
7 (a)	Final Recommendation sent to Drug Plans, FWG, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5	2012-Feb-15	2011-Nov-16	- Notice of Final Recommendation issued.
	OR				
7 (b)	Clarification and Final Recommendation sent to Drug Plans, FWG, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
7 (c)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates			
8	Final Recommendation sent to Drug Plans, FWG, 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 CDEC 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.