CADTH

Common Drug Review

Project Status Report

Brand Name: Repatha

Non-proprietary Name: evolocumab

Applicant: Amgen Canada Inc.

Indication(s): Primary hyperlipidemia and mixed dyslipidemia

Project Type: Submission

Date NOC Issued[1]: 2015-Sep-10

Date Received: 2015-Jun-30

Application Fee Schedule[2]: Schedule A

Key Milestone[3]	Target Date	Actual Date	Comments
Application accepted for review	2015-Jul-15	2015-Jul-15	- Review has been initiated 2015-Jul-16
Patient group input received[4]	2015-Jul-24	2015-Jul-24	- Call for patient input posted on 2015-Jun-04 - Patient group input deadline: 2015-Jul-24 - Patient input submissions received
Patient group comments on input summary received	2015-Aug-07	2015-Aug-07	- Patient input summary sent for review on 2015-Jul-30 - Patient input summary feedback deadline: 2015-Aug-07 - Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2015-Sep-30	2015-Nov-17	- 2015-Sep-16: Received finalized information following NOC being issued. Information is being assessed by the CDR review team. Revised anticipated timelines for the review are to be determined. - New target date: 2015-Nov-05 - New target date: 2015-Nov-17
Comments from applicant on draft CDR review report(s) received by CADTH	2015-Oct-09	2015-Nov-26	- New target date: 2015-Nov-16 - New target date: 2015-Nov-26
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2015-Oct-19	2015-Dec-03	- New target date: 2015-Nov-23 - New target date: 2015-Dec-03
Canadian Drug Expert Committee (CDEC) meeting	2015-Nov-18	2016-Jan-20	- New target date: 2016-Jan-20
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2015-Nov-25 to 2015-Nov-27	2016-Jan-28	- New target date: 2016-Jan-27 to 2016-Jan-29
Embargo period[5] and validation of redacted CDR review report(s)	2016-Feb-11	2016-Feb-11	
CDEC Final Recommendation issued to drug plans and applicant if: - no request for clarification is made AND - no request for reconsideration is made AND - no request for resubmission based on a reduced price during embargo period is made	2016-Feb-19		
CDEC Final Recommendation posted[6]			
Final CDR review report(s)[6] and patient input posted			

[1] CDR applications for submissions can be filed on a pre-NOC basis. When such a submission is received, this field will indicate 'pending' until the NOC (or NOC/c) is issued by Health Canada.

[2] Refer to Appendix 1 of the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf) for details regarding CDR application fee schedules.

[3] Please refer to the *Procedure for the CADTH Common Drug Review* (https://www.cadth.ca/media/cdr/process/CDR_Procedure.pdf) for complete details regarding the CDR process and targeted time frames for key milestones.

[4] The call for patient group input is posted 20 business days inadvance of the applicant's anticipated date of filing the CDR application. Patient groups have a total of 35 business days for preparing and submitting patient input.

[5] The embargoed CDEC recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of *CDEC Final Recommendation.* The applicant may make a request for reconsideration or resubmission based on reduced price during the embargo period, and the drug plans may make a request for clarification, as applicable (see section 8 of the *Procedure for the CADTH Common Drug Review)* .

[6] The timing for posting the *CDEC Final Recommendation* and CDR review report(s) depends on several factors including the need for consultation with the applicant regarding redaction issues.

This *CDR Project Status Report* typically reflects status as of each Thursday at noon EasternTime.