CADTH

Common Drug Review

Project Status Report

Brand Name: Lixiana

Non-proprietary Name: edoxaban

Applicant: Daiichi Sankyo, Inc.

Indication(s): Venous thromboembolism, treatment and recurrence prevention

Project Type: Submission

Date Received: 2016-Sep-09

Date NOC Issued[1]: Pending

Application Fee Schedule[2]: Schedule B

Key Milestone[3]	Target Date	Actual Date	Comments
Application accepted for review	2016-Sep-23	2016-Sep-23	- Review has been initiated 2016-Sep-26
Patient group input received[4]	2016-Jul-28	2016-Jul-28	- Call for patient input posted on 2016-Jun-08 - Patient group input deadline: 2016-Jul-28 - No patient input submission received
Patient group comments on input summary received			
Draft CDR review report(s) sent to applicant	2016-Dec-08	2017-Jan-04	- New target date: 2016-Dec-16 - New target date: 2017-Jan-04
Comments from applicant on draft CDR review report(s) received by CADTH	2016-Dec-19	2017-Jan-10	- New target date: 2017-Jan-04 - New target date: 2017-Jan-10
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2017-Jan-03	2017-Jan-17	- New target date: 2017-Jan-11 - New target date: 2017-Jan-17
CDR review team's comments on draft CDR review report(s) sent to applicant	2017-Feb-03	2017-Feb-03	
Canadian Drug Expert Committee (CDEC) meeting	2017-Feb-15	2017-Feb-15	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2017-Feb-28 to 2017-Mar-02	2017-Feb-28	
Embargo period[5] and validation of redacted CDR review report(s)	2017-Mar-14	2017-Mar-14	
Applicant's request for reconsideration placed on CDEC agenda[7]	2017-May-17	2017-May-17	- Reconsideration requested - Target CDEC reconsideration meeting date: 2017-May-17
CDEC Final Recommendation issued to drug plans and applicant	2017-May-25	2017-May-25	
CDEC Final Recommendation posted[6]		2017-May-29	
Final CDR review report(s)[6] and patient input posted		2017-Jun-07	

[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.

[7] The time frame required to address a request for clarification at the drug plans' request or request for reconsideration at the applicant's request depends on the amount of work required to address the request and the available dates for CDEC meetings.

This CDR Project Status Report is posted every other week, reflecting status as of the end of day Wednesday (4:00 pm ET) of that week.