CADTH

Common Drug Review

Project Status Report

Brand Name: Cosentyx

Non-proprietary Name: secukinumab

Applicant: Novartis Pharmaceuticals Canada Inc.

Indication(s): Ankylosing spondylitis

Project Type: Submission

Date Received: 2016-Feb-19

Date NOC Issued[1]: 2016-Apr-20

Application Fee Schedule[2]: Schedule B

Key Milestone[3]	Target Date	Actual Date	Comments
Application accepted for review	2016-Mar-04	2016-Mar-04	- Review has been initiated 2016-Mar-07
Patient group input received[4]	2016-Mar-11	2016-Mar-11	- Call for patient input posted on 2016-Jan-21 - Patient group input deadline: 2016-Mar-11 - Patient input submission received
Patient group comments on input summary received	2016-Mar-29	2016-Mar-29	- Patient input summary sent for review on 2016-Mar-21 - Patient input summary feedback deadline: 2016-Mar-29 - Patient input summary feedback received
Draft CDR review report(s) sent to applicant	2016-May-19	2016-Jun-02	- New target date: 2016-May-26 - New target date: 2016-Jun-02
Comments from applicant on draft CDR review report(s) received by CADTH	2016-May-31	2016-Jun-13	- New target date: 2016-Jun-06 - New target date: 2016-Jun-13
Redaction requests from applicant on draft CDR review report(s) received by CADTH	2016-Jun-07	2016-Jun-20	- New target date: 2016-Jun-13 - New target date: 2016-Jun-20
CDR review team's comments on draft CDR review report(s) sent to applicant	2016-Jul-08	2016-Jul-08	
Canadian Drug Expert Committee (CDEC) meeting	2016-Jul-20	2016-Jul-20	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and applicant	2016-Aug-02 to 2016-Aug-04	2016-Aug-02	
Embargo period[5] and validation of redacted CDR review report(s)	2016-Aug-16	2016-Aug-16	
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-Aug-23	2016-Aug-23	
CDEC Final Recommendation posted[6]	2016-Aug-25	2016-Aug-25	
Final CDR review report(s)[6] and patient input posted		2018-Dec-03	

[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 Wednesday 4:00 pm EasternTime.