



Common Drug Review Project Status Report

Brand Name:
Non-proprietary Name:
Applicant:
Indication(s):
Project Type:
Date Received :

Key Milestone ¹	Target Date	Actual CDR Date	Comments
CADTH request for advice approach determined	2016-Jan-20	2016-Jan-20	- 2016-Jan-20: Manufacturer informed of request for advice - 2016-Jan-06: Relevant patient groups informed of request for advice - 2016-Feb-25: Patient groups' information/comments due - Patient input submission received
Draft <i>CDR Request for Advice</i> report sent to manufacturer	2016-Apr-06	2016-Mar-02	- New target date: 2016-Mar-02
Comments from manufacturer on draft <i>CDR Request for Advice</i> report received by CADTH	2016-Apr-15	2016-Mar-11	- New target date: 2016-Mar-11
Redaction requests from manufacturer on draft <i>CDR Request for Advice</i> report received by CADTH	2016-Apr-22	2016-Mar-18	- New target date: 2016-Mar-18
Canadian Drug Expert Committee (CDEC) meeting ²	2016-Apr-20	2016-Apr-20	
CDEC recommendation & redacted <i>CDR Request for Advice</i> report sent to drug plans and manufacturer	2016-Apr-27 to 2016-Apr-29	2016-Apr-28	
Embargo period ⁴ and validation of redacted <i>CDR Request for Advice</i> report	2016-May-12	2016-May-12	
<i>CDEC Final Recommendation</i> issued to drug plans and manufacturer if: - no request for clarification is made AND - no request for reconsideration is made	2016-May-19	2016-May-19	
<i>CDEC Final Recommendation</i> posted ³	2016-May-26	2016-May-26	
Final <i>CDR Request for Advice</i> report posted ³		2018-May-31	

¹ 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 request for advice process and targeted time frames for key milestones.

² A request for advice may result in a revised CDEC recommendation that would supersede a previous CEDAC or *CDEC Final Recommendation*, or a *CDEC Record of Advice* document containing additional context and/or clarifications regarding a previous CEDAC or *CDEC Final Recommendation*.

³ The timing for posting the *CDEC Record of Advice*, *CDEC Final Recommendation* and *CDR Request for Advice* report depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

⁴ 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 manufacturer may make a request for reconsideration and the drug plans may make a request for clarification. The manufacturer may request an extension of up to 20 extra business days solely for the purpose of preparing and filing a request for reconsideration (i.e., a total of 30 business days).

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.