CADTH

Common Drug Review

Project Status Report

Brand Name: Harvoni

Non-proprietary Name: ledipasvir/sofosbuvir

Applicant: CDR-participating drug plans

Indication(s): Hepatitis C, chronic

Project Type: Request for advice

Date Received : 2016-Jan-06

Key Milestone[1]	Target Date	Actual CDR Date	Comments
CADTH request for advice approach detemined	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 *CDR Request for Advice* report sent to manufacturer	2016-Apr-06	2016-Mar-01	- New target date: 2016-Mar-01
Comments from manufacturer on draft *CDR Request for Advice* report received by CADTH	2016-Apr-15	2016-Mar-09	- New target date: 2016-Mar-10
Redaction requests from manufacturer on draft *CDR Request for Advice* report received by CADTH	2016-Apr-22	2016-Mar-09	- New target date: 2016-Mar-17
CDR review team's comments on draft CDR Request for Advice report sent to manufacturer	2016-Apr-08		
Canadian Drug Expert Committee (CDEC) meeting[2]	2016-Apr-20	2016-Apr-20	
CDEC recommendation & redacted *CDR Request for Advice* report sent to drug plans and manufacturer	2016-Apr-27 to 2016-Apr-29	2016-Apr-27	
Embargo period[4] and validation of redacted *CDR Request for Advice* report	2016-May-11	2016-May-11	
CDEC Final Recommendation issued to drug plans and manufacturer if: - no request for clarification is made AND - no request for reconsideration is made	2016-May-18	2016-May-18	
CDEC Final Recommendation posted [3]	2016-May-20	2016-May-20	
Final *CDR Request for Advice* report posted [3]		2018-May-23	

[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.