Common Drug Review [1]

Submission Status

Product: Galexos

Generic Name: simeprevir

Manufacturer: Janssen Inc.

Indication: Hepatitis C, chronic

Submission Type: Pre-NOC - Initial

Date Submission Received: 2013-Aug-22 **Date NOC Issued:** 2013-Nov-18

Orginal Targeted CDEC Meeting: 2014-Jan-15 **Priority Review Granted:** Not Requested

Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
Submission deemed complete	5	2013-Aug-29	2013-Aug-29	- Submission placed in queue in accordance with CDR procedures. Review to be initiated pending availability of resources and target dates will be updated. - Review has been initiated 2013-Dec-10
Patient group input submission received [3]		2013-Sep-13	2013-Sep-13	- Call for patient input posted on 2013-Aug-22 - Patient input deadline: 2013-Sep-13 - Patient input submission received
Patient group input summary comments received	5	2013-Dec-20	2014-Jan-08	- Patient input summary sent for review on 2013-Dec-12 - Patient input summary feedback deadline: 2013-Dec-20 - New target date: 2014-Jan-08 - Patient input summary feedback received
CDR review reports sent to manufacturer[4]	45	2013-Nov-14	2014-Mar-03	- New target date: 2014-Mar-03
Comments from manufacturer on review reports received by CADTH	7	2013-Nov-25	2014-Mar-12	- New target date: 2014-Mar-12
Redaction response from manufacturer on review reports received by CADTH	3	2013-Nov-28	2014-Mar-17	- New target date: 2014-Mar-17
CDEC meeting		2014-Jan-15	2014-May-21	- New target date: 2014-May-21
CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7	2014-Jan-22	2014-May-28	- New target date: 2014-May-28
Embargo period and validation of redacted CDR review reports [5] Manufacturers may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	10	2014-Feb-05	2014-Jun-11	- New target date: 2014-Jun-11
Final recommendation sent to drug plans and manufacturer (No requests for clarification are made AND no request for reconsideration is made or request for reconsideration is resolved)	5	2014-Feb-12	2014-Jun-18	- New target date: 2014-Jun-18 - Notice of final recommendation issued
CDEC final recommendation posted [6]	variable	2014-Jun-20	2014-Jun-20	
Final CDR review reports posted [7]	variable	2016-Nov-11	2016-Nov-11	

[1] Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.

[2] The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

[3] The deadline for Patient Group Input is 15 business days after CADTH receives the Submission or up to 25 business days if advance notice of a Submission is received from the Manufacturer.

[4] Target time is calculated, based on the date the Reviewers receive copies of the Manufacturer's Submission. Target time does not include the time allocated for receipt of Manufacturer's binders (5 business days) and time allocated for distribution of binders to reviewers (3 business days).

[5] The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of Final Recommendation.

[6] The target date for posting the CDEC final recommendation depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

[7] The timing of the posting of CDR review reports depends on several factors, including the need for consultation with the manufacturer in case of disagreement with regard to redactions made.

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.