Common Drug Review [1]

Submission Status

Product: Afinitor

Generic Name: everolimus

Manufacturer: Novartis Pharmaceuticals Canada Inc.

Indication: subependymal giant cell astrocytoma associated with tuberous sclerosis complex

Submission Type: New Indication

Date Submission Received: 2014-Mar-19 **Date NOC Issued:** 2011-Jun-30

Orginal Targeted CDEC Meeting: 2014-Sep-17 **Priority Review Status:** Not Granted

Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
Submission deemed complete	5	2014-Mar-26	2014-Mar-26	- Submission placed in queue in accordance with CDR procedures. Review to be initiated pending the availability of resources and target dates will be updated. - Priority review request under asssessment - Priority review not granted - Review has been initiated 2014-Sep-18
Patient group input submission received [3]		2014-Aug-28	2014-Sep-19	- Patient Input invitations will be posted at a later date (please refer to CDR Update 95) - Call for patient input posted on 2014-Jul-09 - Patient group input deadline: 2014-Aug-28 - New target date: 2014-Sep-19 - Patient input submission received
Patient group input summary comments received	5	2014-Oct-08	2014-Oct-08	- Patient input summary sent for review on 2014-Oct-01 - Patient input summary feedback deadline: 2014-Oct-08 - Patient input summary feedback received
CDR review reports sent to manufacturer[4]	45	2014-Jun-11	2014-Dec-02	- New target date: 2014-Dec-02
Comments from manufacturer on CDR review reports received by CADTH	7	2014-Jun-20	2014-Dec-11	- New target date: 2014-Dec-11
Redaction response from manufacturer on CDR review reports received by CADTH	5	2014-Jun-27	2014-Dec-18	- New target date: 2014-Dec-18
CDEC meeting		2014-Sep-17	2015-Feb-18	- New target date: 2015-Feb-18
CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7	2014-Sep-24	2015-Feb-25	- New target date: 2015-Feb-25
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-Oct-08	2015-Mar-11	- New target date: 2015-Mar-11
Placed on CDEC agenda for reconsideration (At manufacturer's request)	25 Depends on Meeting Dates	2015-Apr-08	2015-Apr-08	- The April 2015 Canadian Drug Expert Committee (CDEC) meeting will be held on April 8, to accommodate for the 2015 CADTH Symposium from April 12 to 14, 2015, in Saskatoon, SK.
Final recommendation sent to drug plans and manufacturer	5	2015-Apr-15	2015-Apr-15	- Notice of final recommendation issued
CDEC final recommendation posted [6]	variable	2015-Apr-17	2015-Apr-17	
Final CDR review reports and patient input posted [7]	variable			

[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 35 business days if advance notice (20 business days maximum) 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 additional electronic copies (5 business days) and time allocated for distribution of electronic copies 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.