Common Drug Review [1]

Submission Status

Product: Remsima (Subsequent Entry Biologic for infliximab)

Generic Name: infliximab

Manufacturer/Applicant: Fresenius Kabi Canada

Indication(s): Ankylosing spondylitis, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis

Submission Type: Initial

Date Submission Received: 2014-May-30 **Date NOC Issued:** 2014-Jan-15

Orginal Targeted CDEC Meeting: 2014-Oct-15 **Priority Review Status:** Granted

Phase	Target Time (Business Days)	Target Date [2]	Actual Date	Comments
Submission deemed complete	5	2014-Jun-06	2014-Jun-06	- Priority review request under assessment and due 2014-Jun-27 - Additional time is required to complete the priority review assessment. - Priority review granted - Submission will be removed from the queue and review will be initiated pending availability of resources and target dates will be updated. - Review has been initiated 2014-Jul-14
Patient group input submission received [3]		2014-Sep-04	2014-Sep-04	- Call for patient input posted on 2014-Jul-15 - Patient group input deadline: 2014-Sep-04 - Patient input submission received
Patient group input summary comments received	5	2014-Oct-01	2014-Oct-01	- Patient input summary sent for review on 2014-Sep-24 - Patient input summary feedback deadline: 2014-Oct-01 - Patient input summary feedback received
CDR review reports sent to manufacturer[4]	45	2014-Aug-22	2014-Oct-08	- New target date: 2014-Sep-26 - New target date: 2014-Oct-02 - New target date: 2014-Oct-08
Comments from manufacturer on CDR review reports received by CADTH	7	2014-Sep-03		- New target date: 2014-Oct-07 - New target date: 2014-Oct-14 - New target date: 2014-Oct-20 - Manufacturer has waived the opportunity to provide comments - Submission voluntarily withdrawn by the manufacturer on 2014-Oct-21
Redaction response from manufacturer on CDR review reports received by CADTH	5	2014-Sep-08		- New target date: 2014-Oct-10 - New target date: 2014-Oct-15 - New target date: 2014-Oct-21 - New target date: 2014-Oct-27
CDEC meeting		2014-Oct-15		- New target date: 2014-Nov-19
CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7	2014-Oct-22		- New target date: 2014-Nov-26
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-Nov-05		- New target date: 2014-Dec-10
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			
CDEC final recommendation posted [6]	Variable			
Final CDR review reports and patient input posted [7]	Variable			
OR				
Clarification and final recommendation sent to drug plans and manufacturer (Clarification requested, no request for reconsideration made)	5			
CDEC final recommendation posted [6]	Variable			
Final CDR review reports and patient input posted [7]	Variable			
OR				
Placed on CDEC agenda for reconsideration (At manufacturer's request)	25 Depends on Meeting Dates			
Final recommendation sent to drug plans and manufacturer	5			
CDEC final recommendation posted [6]	Variable			
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 submission status report reflects status as of Thursday noon.