Common Drug Review [1]

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Benlysta

Generic Name: belimumab

Manufacturer: GlaxoSmithKline

Indication: Systemic Lupus Erythematosus

Submission Type: Initial

Date Submission Received: 2011-Sep-19 **Date NOC Issued:** 2011-Jul-06

Targeted CDEC Meeting: 2012-Feb-15 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
1	Submission deemed complete	5	2011-Sep-26	2011-Sep-26	
2	Patient group input submission received [3]		2011-Oct-11	2011-Oct-11	- Call for patient input posted on 2011-Aug-30 - Patient input deadline 2011-Oct-11 - Patient group input submission received
3	CADTH Reviewers' Reports sent to Manufacturer[4]	45	2011-Dec-09	2012-Jan-09	- New Target date: 2012-Jan-9
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Dec-20	2012-Jan-18	- New Target date: 2012-Jan-18
5	CDEC Meeting		2012-Feb-15	2012-Feb-15	
6	CDEC Recommendation Sent to Drug Plans and Manufacturer	5 to 7	2012-Feb-23	2012-Feb-23	
7	Embargo Period [5] Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2012-Mar-08	2012-Mar-08	
8 (a)	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			
	OR				
8 (b)	Clarification and Final Recommendation sent to Drug Plans and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
8 (c)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2012-Apr-18	2012-Apr-18	
9	Final Recommendation sent to Drug Plans and Manufacturer	5	2012-Apr-25	2012-Apr-25	- Notice of Final Recommendation Issued

[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.

This Submission Status Report reflects status as of Thursday noon.