Common Drug Review [1]

Submission Status

Product: Onglyza
Generic Name: Saxagliptin
Manufacturer: Bristol-Myers Squibb / AstraZeneca
Indication: Diabetes mellitus, type 2
Submission Type: Pre-NOC - New Indication
Date Submission Received: 2013-May-09 **Date NOC Issued:** 2013-May-13
Orginal Targeted CDEC Meeting: 2013-Sep-18 **Priority Review Granted:** Not Requested

Phase	Target Time (Business Days)	Target Date [2]	Actual CDR Date	Comments
Submission deemed complete	5	2013-May-16	2013-May-16	- 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-Jun-11
Patient group input submission received [3]		2013-May-31		- Call for patient input posted on 2013-May-09 - Patient input deadline: 2013-May-31 - No patient input submission received
Patient group input summary comments received	5			- Summary comments not required as patient input was not received
CADTH Reviewers' Reports sent to Manufacturer[4]	45	2013-Aug-01	2013-Aug-26	- New target date: 2013-Aug-26
Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2013-Aug-13	2013-Sep-05	- New target date: 2013-Sep-05
Redaction response from Manufacturer on Reviewers' Reports Received by CADTH	3	2013-Aug-16	2013-Sep-10	- New target date: 2013-Sep-10
CDEC Meeting		2013-Sep-18	2013-Oct-16	- New target date: 2013-Oct-16
CDEC Recommendation & Redacted CDR Review Reports Sent to Drug Plans and Manufacturer	5 to 7	2013-Sep-25	2013-Oct-25	- New target date: 2013-Oct-23 - New target date: 2013-Oct-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	2013-Oct-09	2013-Nov-08	- New target date: 2013-Nov-06 - New target date: 2013-Nov-08
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	2013-Oct-17	2013-Nov-15	- New target date: 2013-Nov-15
CDEC recommendation posted	2	2013-Oct-21	2013-Nov-19	- New target date: 2013-Nov-19
Final CDR review reports posted [6]		2013-Oct-21	2013-Nov-29	- New target date: 2013-Nov-19 - Posting of reports is postponed
OR				
Clarification and Final Recommendation sent to Drug Plans and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
CDEC recommendation posted	2			
Final CDR review reports posted [6]				
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 recommendation posted	2			
Final CDR review reports posted [6]				

[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] CDR Reviewers' Reports will generally be posted at the same time as the Final CDEC Recommendation. However, in the case of disagreement expressed by the Manufacturer regarding redactions in the CDR Reports, additional time may be required to publish the CDR review reports.

This Submission Status Report reflects status as of Thursday noon.