Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: Victoza

Generic Name: liraglutide

Manufacturer: Novo Nordisk Canada Inc.

Indication: Diabetes, Type 2

Submission Type: Initial

Date Submission Received: 2010-Nov-29 **Date NOC Issued:** 2010-May-21

Targeted CDEC Meeting: 2011-May-18 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments
1	Submission deemed complete	5	2010-Dec-06	2010-Dec-08	- Submission deemed complete. - Submission placed in queue in accordance with CDR procedures. Review to be initiated pending the availability of resources. Review initiated 2010-Dec-17.
2	Patient group input submission received		2011-Jan-10	2011-Jan-10	- 2010-Dec-20 - Target date tentative until submission initiated. - 2011-Jan-10 - New target date based on submission initiated. - Patient group submissions received.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2011-Apr-01	2011-Mar-09	- New due date for reports to manufacturer: 2011-Mar-09
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Apr-12	2011-Mar-30	- New date for manufacturer comments: 2011-Mar-18 - Extension to 2011-Mar-31 requested by manufacturer on 2011-Mar-10 - Extension granted on 2011-Mar-17 - New date for manufacturer comments: 2011-Mar-31 - Additional information received. CDEC date to be determined based on review of information.
5	CDEC Meeting		2011-May-18	2011-Jun-15	- New due date for CDEC meeting to be determined based on review of information (see above). - New CDEC meeting date: 2011-Jun-15
6	CDEC Recommendation *** Sent to Drug Plans, FWG and Manufacturer	5 to 7	2011-May-26	2011-Jun-24	- New due date for CDEC Recommendation Sent to Drug Plans, FWG and Manufacturer: 2011-Jun-24
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Jun-09	2011-Aug-01	- New due date for Embargo Period: 2011-July 11 - Request for extension to embargo period received from manufacturer on 2011-Jul-4 - Extension to embargo period granted. - Embargo period extended to 2011-Aug-01 - Request for reconsideration received 2011-Aug-01 - Request for reconsideration granted 2011-Aug-10
8 (a)	Final Recommendation sent to Drug Plans, FWG, 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, FWG, 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	2011-Sep-21	2011-Sep-21	
9	Final Recommendation sent to Drug Plans, FWG, and Manufacturer	5	2011-Sep-28	2011-Sep-28	- Notice of Final Recommendation issued.

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

** The Formulary review process is initiated AFTER a submission is deemed complete. The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

*** The Procedure for Common Drug Review, section 8.3.3a, states "…the CDEC recommendation will be sent to the Manufacturer, FWG and to the drug plans within five (5) to seven (7) business days following the CDEC meeting…". The original target date is based on five (5) business days.

******** The Recommendation is held in confidence and not acted upon until after CADTH has issued the notice of Final Recommendation.

This submission status report reflects updates as of Thursday noon.