Common Drug Review *

Submission Status

Product: Gilenya

Generic Name: fingolimod

Manufacturer: Novartis Pharmaceuticals Canada Inc.

Indication: Multiple Sclerosis, relapsing remitting

Submission Type: Initial

Date Submission Received: 2011-May-10 **Date NOC Issued:** 2011-Mar-09

Targeted CDEC Meeting: 2011-Sep-21 **Priority Review Granted:** Not Granted

	Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments
1	Submission deemed complete	5	2011-May-17	2011-May-20	- Priority review requested - Submission deemed incomplete 2011-May-17 - Priority review not granted 2011-Jun-17
2	Patient group input submission received				- Pending submission notification posted on 2011-Mar-11 - Patient input deadline 2011-May-09 - Patient group submissions received.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2011-Aug-03	2011-Aug-24	- New due date for CADTH Reviewers' Reports sent to Manufacturer: 2011-Aug-24
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Aug-12	2011-Sep-02	- New due date for Comments from Manufacturer on Reviewers' Reports Received by CADTH: 2011-Sep-02
5	CDEC Meeting		2011-Sep-21	2011-Oct-19	- New Target date: 2011-Oct -19
6	CDEC Recommendation *** Sent to Drug Plans, FWG and Manufacturer	5 to 7	2011-Sep-28	2011-Oct-26	- New Target date: 2011-Oct -26
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Oct-13	2011-Nov-09	- New Target date: 2011-Nov-09
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	2011-Oct-20	2011-Nov-16	- Notice of Final Recommendation issued.
	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			
9	Final Recommendation sent to Drug Plans, FWG, and Manufacturer	5			

***** 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.