## Common Drug Review <sup>1</sup>



**Orginal Targeted CDEC Meeting:** 

**Submission Status** 

<b>Product:</b>	Rebif
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Generic Name: Interferon beta-1a

Manufacturer: EMD Serono

Indication: Clinically Isolated Syndrome

**Priority Review Granted:** 

Not Requested

Submission Type: Initial

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2013-Jul-17

 Date Submission Received:
 2013-Mar-08

 Date NOC Issued:
 2013-Jun-07

**Target Target** Actual **Phase** Comments **Time** Date <sup>2</sup> **CDR Date** (Business Days) Submission deemed complete 5 2013-Mar-15 2013-Mar-15 Call for patient input posted on 2012-Nov-22 2 Patient group input submission received <sup>3</sup> 2013-Jan-15 Patient group input deadline: 2013-Jan-15 No patient group input submission received CADTH Reviewers' Reports sent to Manufacturer<sup>4</sup> 2013-May-31 2013-May-31 45 Comments from Manufacturer on Reviewers' 7 2013-Jun-11 4 2013-Jun-11 Reports Received by CADTH 2013-Jul-17 2013-Jul-17 5 **CDEC Meeting** CDEC Recommendation 5 to 7 2013-Jul-24 2013-Jul-24 Sent to Drug Plans and Manufacturer Embargo Period 5 Manufacturers may make a Request for 10 2013-Aug-08 2013-Aug-08 Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation Final Recommendation sent to Drug Plans and Manufacturer (No Requests for Clarification are made AND no 2013-Aug-15 2013-Aug-15 Notice of final recommendation issued on 2013-Aug-15 5 Request for Reconsideration is made or Request for Reconsideration is Resolved) OR Clarification and Final Recommendation sent to Drug Plans and Manufacturer 8 (b) 5 (Clarification Requested, no Request for Reconsideration made)

OR

(At Manufacturer's request)

Manufacturer

8 (c)

9

Placed on CDEC Agenda For Reconsideration

Final Recommendation sent to Drug Plans and

25

Depends on

**Meeting Dates** 

5

<sup>&</sup>lt;sup>1</sup> Refer to the Procedure for Common Drug Review on the Common Drug Review section of www.cadth.ca for more details.

<sup>&</sup>lt;sup>2</sup> The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> 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).

<sup>&</sup>lt;sup>5</sup> 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.