# Common Drug Review *

## Submission Status

**Product:** Omnitrope

**Generic Name:** somatropin (rDNA origin)

**Manufacturer:** Sandoz Canada Inc.

**Submission Type:** New

**Date Submission Received:** 2009-Jun-12 **Date NOC Issued:** 2009-Apr-20

**Targeted CEDAC Meeting:** 2009-Nov-18 **Priority Review Granted:** Not Requested

| | Phase | Target Time (Business Days) | Target Date** | Actual CDR Date | Comments |
|---|---|---|---|---|---|
| 1 | Submission Assessment | 5 | 2009-Jun-19 | 2009-Jun-19 | Category 1 & 2 requirements deemed incomplete. |
| | Submission deemed complete | | | 2009-Jul-13 | Submission deemed complete. |
| 2 | CDR Reviewers' Reports Completed<br>• Reviewers selected and contracted<br>• Literature search and selection completed<br>• Systematic review of clinical data completed<br>• Critical appraisal of pharmacoeconomic (PE) data completed<br>• Clinical and PE reports written<br>• Reports edited and finalized<br>• Reviewers' reports sent to manufacturer | 45 | 2009-Sep-28 | 2009-Oct-01 | Additional information requested July 24, 2009.<br>Additional information received July 27, 2009.<br>Additional information requested July 29, 2009.<br>Additional information received August 4, 2009. |
| 3 | Comments from Manufacturer on Reviewers' Reports Received by CDR | 7 | 2009-Oct-07 | 2009-Oct-13 | Due date for manufacturer's comments October 13, 2009. |
| 4 | Reviewers' Reply to Manufacturer's Comments Completed | 7 | 2009-Oct-16 | 2009-Oct-22 | Due date for reviewers' reply October 22, 2009. |
| 5 | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2009-Nov-04 | 2009-Nov-04 | Subsequent Entry Biologics (SEBs) pilot project became effective October 23, 2009. (CDR Update - Issue 62) Omnitrope submission is being reviewed under the SEB pilot project. |
| 6 | CEDAC Meeting | | 2009-Nov-18 | 2009-Nov-18 | |
| 7 | CEDAC Recommendation Sent to Drug Plans, ACP and Manufacturer | 5 | 2009-Nov-25 | 2009-Nov-25 | CEDAC Advice - Subsequent Entry Biologic Document sent to Drug Plans, ACP and Manufacturer. |
| 8 | Embargo Period***<br>Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation | 10 | 2009-Dec-09 | 2009-Dec-09 | Request for Clarification received December 9, 2009. |
| 9 (a) | Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved) | 5 | | | |
| | OR | | | | |
| 9 (b) | Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer<br>(Clarification Requested, no Request for Reconsideration made) | 5 | | | |
| | OR | | | | |
| 9 (c) | Placed on CEDAC Agenda For Reconsideration<br>(At Manufacturer's request) | 25<br>Depends on Meeting Dates | | | |
| 10 | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5 | 2009-Dec-16 | 2009-Dec-16 | Final CEDAC Advice - Subsequent Entry Biologic Document sent to Drug Plans, ACP and Manufacturer. |

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

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

*** The Recommendation and Reasons for Recommendation are to be held in confidence and not acted upon until after the CDR Directorate has issued the notice of Final Recommendation.

Reflects updates as of Thursday noon.