### Common Drug Review Submission Status

**Product:** Genotropin  
**Generic Name:** somatropin  
**Manufacturer:** Pfizer Canada Inc.  
**Indication:** Growth hormone deficiency, pediatric

**Submission Type:** Initial  
**Date Submission Received:** 2013-May-27  
**Date NOC Issued:** 2013-Feb-07  
**Priority Review Granted:** Not Requested  
**Orginal Targeted CDEC Meeting:** 2013-Oct-16

<table>
<thead>
<tr>
<th>Phase</th>
<th>Target Time (Business Days)</th>
<th>Target Date</th>
<th>Actual CDR Date</th>
<th>Comments</th>
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</thead>
</table>
- 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-Jul-12 |
| Patient group input submission received | 2013-Jun-18 |
| Patient group input summary comments received | 5 | 2013-Aug-19 | 2013-Oct-02 | - Summary comments not required as patient input was not received |
| CADTH Reviewers' Reports sent to Manufacturer | 45 | 2013-Sep-03 | 2013-Oct-09 | - New target date: 2013-Sep-03  
- New target date: 2013-Oct-02 |
| Comments from Manufacturer on Reviewers' Reports Received by CADTH | 7 | 2013-Aug-28 | 2013-Oct-11 | - New target date: 2013-Oct-09  
- New target date: 2013-Oct-11  
- Manufacturer waived the opportunity to provide comments on the Reviewer's Reports |
| Redaction response from Manufacturer on Reviewers' Reports Received by CADTH | 3 | 2013-Sep-03 | 2013-Oct-17 | - New target date: 2013-Oct-17 |
- New target date: 2013-Nov-29 |
| Embargo Period and Validation of Redacted CDR Review Reports  
Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation | 10 | 2013-Nov-06 | 2013-Dec-13 | - New target date: 2013-Dec-11  
- New target date: 2013-Dec-13 |
| 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-Nov-13 | 2013-Dec-20 | - New target date: 2013-Dec-20  
- Notice of Final Recommendation issued |
| Clarification and Final Recommendation sent to Drug Plans and Manufacturer  
(Clarification Requested, no Request for Reconsideration made) | 5 | 2013-Dec-20 | |
| CDEC recommendation posted | 2 | 2013-Dec-20 | |
| Final CDR review reports posted | variable | 2014-Jan-17 | |

**OR**

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<tr>
<th>Phase</th>
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</table>
| 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 | variable | |

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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. The timing of the posting of CDR reviewer's reports depends on several factors, including the need for consultation with the manufacturer in case of disagreement with regard to redactions made.

This Submission Status Report reflects status as of Thursday noon.  
2014-Jan-24  
SR0333-000