**Product:** Invega Sustenna  
**Generic Name:** paliperidone palmitate  
**Manufacturer:** Janssen Inc.  
**Indication:** Schizophrenia

**Submission Type:** Initial  
**Date Submission Received:** 2010-Jul-09  
**Date NOC Issued:** 2010-Jun-30  
**Targeted CEDAC Meeting:** 2010-Nov-17  
**Priority Review Granted:** Not Requested

<table>
<thead>
<tr>
<th>Phase</th>
<th>Target Time (Business Days)</th>
<th>Target Date **</th>
<th>Actual CDR Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>5</td>
<td>2010-Jul-16</td>
<td>Submission deemed complete.</td>
</tr>
<tr>
<td>2</td>
<td>Patient group input submission received</td>
<td>2010-Jul-30</td>
<td>2010-Jul-30</td>
<td>Patient group submissions received.</td>
</tr>
<tr>
<td>3</td>
<td>CADTH Reviewers' Reports sent to Manufacturer</td>
<td>45</td>
<td>2010-Oct-01</td>
<td>Reviewer's Reports Sent on 2010-Oct-08.</td>
</tr>
</tbody>
</table>
| 4     | Comments from Manufacturer on Reviewers' Reports Received by CADTH | 7             | 2010-Oct-13     | - Due date for Manufacturer’s Comments 2010-Oct-20.  
- Manufacturer's Comments received on 2010-Oct-20. |
| 5     | CEDAC Meeting |                            | 2011-Jan-19     | - Initial recommendation sent on 2011-Jan-19  
- Recommendation deferred to the January 19, 2011 CEDAC meeting. |
| 6     | CEDAC Recommendation ***  
S ent to Drug Plans, ACP and Manufacturer | 5 to 7         | 2011-Jan-26     | - CEDAC Recommendation based on reduced price expected on 2011-Mar-30 |
| 7     | Embargo Period ****  
Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation | 10            | 2011-Feb-09     | - Received request for resubmission based on reduced price during embargo period.  
- Resubmission based on reduced price during embargo period granted 2011-Feb-16. |
| 8 (a) | Final Recommendation sent to Drug Plans, ACP, and Manufacturer  
(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved) | 5             | 2011-Apr-20     | - New date: 2011-Apr-25.  
- Notice of Final Recommendation issued. |
| 8 (b) | Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer  
(Clarification Requested, no Request for Reconsideration made) | 5             |                |          |
| 8 (c) | Placed on CEDAC Agenda For Reconsideration  
(At Manufacturer’s request) | 25 Depends on Meeting Dates |                |          |
| 9     | Final Recommendation sent to Drug Plans, ACP, 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 CEDAC meeting schedule, which is posted on www.cadth.ca.  
*** The Procedure for Common Drug Review, section 8.3.3a, states “…the CEDAC recommendation will be sent to the Manufacturer, ACP and to the drug plans within five (5) to seven (7) business days following the CEDAC 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.