## Common Drug Review *

### Submission Status

| Product: | Strattera (atomoxetine hydrochloride) |
| Manufacturer: | Eli Lilly Canada Inc. |

### Date Submission Received: 2005-Jan-25  
### Date NOC Issued: 2004-Dec-24  
### Targeted CEDAC Meeting: 2005-May-18  
### 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>
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<tr>
<td>1</td>
<td>Submission Deemed Complete</td>
<td>5</td>
<td>2005-Feb-01</td>
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</table>
| 2     | CDR Reviewers’ Reports Completed  
- Reviewers selected and contracted  
- Literature search and selection completed  
- Systematic review of clinical data completed  
- Critical appraisal of pharmacoeconomic (PE) data completed  
- Clinical and PE reports written  
- Reports edited and finalized  
- Reviewers’ reports sent to manufacturer | 45            | 2005-Apr-06     | 2005-Apr-18  
** Due to additional information received after the initial targets, the CDR review process extended by 45 days.  
** 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.ccohta.ca. |
| 3     | Comments from Manufacturer on Reviewers’ Reports Received by CDR | 7             | 2005-Apr-15     | 2005-Apr-25  
** Due to additional information received after the initial targets, the CDR review process extended by 7 days.  
** Due date for manufacturer's comments April 25, 2005. |
| 4     | Reviewers’ Reply to Manufacturer’s Comments Completed | 7             | 2005-Apr-26     | 2005-Apr-28  
** Due to additional information received after the initial targets, the CDR review process extended by 7 days.  
** Due date for reviewer's reply April 28, 2005. |
| 5     | CEDAC Brief Completed and Sent to CEDAC Members | 5             | 2005-May-04     | 2005-May-05  
** Due to additional information received after the initial targets, the CDR review process extended by 5 days. |
| 6     | CEDAC Meeting | 5             | 2005-May-18     | 2005-May-18  
** Due to additional information received after the initial targets, the CDR review process extended by 5 days. |
| 7     | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, ACP and Manufacturer | 5             | 2005-May-26     | 2005-May-26  
** Due to additional information received after the initial targets, the CDR review process extended by 5 days. |
| 8     | Embargo Period***  
- Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation and Reasons for Recommendation | 10            | 2005-Jun-09     | 2005-Jun-09  
** Due to additional information received after the initial targets, the CDR review process extended by 10 days.  
** Request for reconsideration received June 9, 2005.  
** Additional information received July 8, 2005. |
| 9 (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             | 2005-Sep-21     | 2005-Sep-21  
** Final recommendation sent to Drug Plans, ACP, and Manufacturer after receiving no additional information. |
| 9 (b) | Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made) | 5             | 2005-Sep-21     | 2005-Sep-21  
** Final recommendation sent to Drug Plans, ACP, and Manufacturer after receiving a clarification. |
| 9 (c) | Placed on CEDAC Agenda For Reconsideration (At Manufacturer’s request)  
** Discussed at July 27, 2005 CEDAC.  
** Depending on Meeting Dates, the CDR review process extended by 25 days.  
** Final recommendation sent to Drug Plans, ACP, and Manufacturer after receiving a clarification. |
| 10    | Final Recommendation sent to Drug Plans, ACP, and Manufacturer | 5             | 2005-Sep-28     | 2005-Sep-28  
** Final recommendation sent to Drug Plans, ACP, and Manufacturer after receiving a clarification. |

** 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.ccohta.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.  

September 30, 2005