### Common Drug Review *

**Submission Status**

**Product:** Humira

**Generic Name:** adalimumab injection

**Manufacturer:** Abbott Laboratories, Limited

**Submission Type:** NEW

**Date Submission Received:** 2004-Sep-24  
**Date NOC Issued:** 2004-Sep-24  
**Targeted CEDAC Meeting:** 2005-Jan-19  
**Priority Review Granted:** Denied

<table>
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<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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| 1     | Submission Deemed Complete  | 5             | 2004-Oct-01     | 2004-Sep-28  
Priority review requested.  
| 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  
Additional information received October 14, 2004.  
Additional information requested October 14, 2004.  
Additional information received October 18, 2004. |
| 3     | Comments from Manufacturer on Reviewers’ Reports Received by CDR | 7 | 2004-Dec-08 | 2004-Dec-10 | Due date for manufacturer’s comments December 10, 2004. |
| 4     | Reviewers’ Reply to Manufacturer’s Comments Completed | 7 | 2004-Dec-17 | 2004-Dec-21 |
| 5     | CEDAC Brief Completed and Sent to CEDAC Members | 5 | 2004-Dec-24 | 2005-Jan-04 |
| 6     | CEDAC Meeting | 2005-Jan-19 | 2005-Jan-19 |
| 7     | CEDAC Recommendation and Reasons for Recommendation Sent to Drug Plans, CDRC and Manufacturer | 5 | 2005-Jan-26 | 2005-Jan-26 |
| 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-Feb-09 | 2005-Feb-08 |
| 9 (a) | Final Recommendation sent to Drug Plans, CDRC, and Manufacturer  
(No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved) | 5 | 2005-Feb-11 | Notice of Final Recommendation issued. |
| 9 (b) | Clarification and Final Recommendation sent to Drug Plans, CDRC, and Manufacturer (Clarification Requested, no Request for Reconsideration made) | 5 |             |           |
| 9 (c) | Placed on CEDAC Agenda For Reconsideration (At Manufacturer’s request) | 25 | Depends on Meeting Dates |           |
| 10    | Final Recommendation sent to Drug Plans, CDRC, and Manufacturer | 5 |             |           |


** 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.