# Common Drug Review

**Submission Status**

**Product:** Esbriet  
**Generic Name:** pirfenidone  
**Manufacturer:** InterMune Canada Inc.  
**Indication:** Pulmonary fibrosis (idiopathic), mild to moderate  
**Date NOC Issued:** 2012-Oct-01  
**Priority Review Granted:** Not Requested  
**Original Targeted CDEC Meeting:** 2013-Feb-20

<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>
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</table>
| 1     | Submission deemed complete  | 5           | 2012-Oct-15     | 2012-Oct-16  
- Submission deemed incomplete: 2012-Oct-15  
- Submission deemed complete: 2012-Oct-16  
- Submission placed in queue in accordance with CDR procedures. Review to be initiated pending availability of resources and target dates will be updated.  
- Submission is now out of queue and the review has been initiated: 2012-Nov-07 |
| 2     | Patient group input received | 45          | 2012-Oct-26     | 2012-Oct-26  
- Call for patient input posted on 2012-Oct-04  
- Patient group input deadline: 2012-Oct-26  
- Patient group input submission received |
| 3     | CADTH Reviewers' Reports sent to Manufacturer | 45          | 2013-Jan-04     | 2013-Jan-29  
- New Target date: 2013-Jan-29 |
| 4     | Comments from Manufacturer on Reviewers' Reports Received by CADTH | 7           | 2013-Jan-15     | 2013-Feb-07  
- New Target date: 2013-Feb-07 |
| 5     | CDEC Meeting                |             | 2013-Feb-20     | 2013-Mar-20  
- New Target date: 2013-Mar-20 |
| 6     | CDEC Recommendation          | 5 to 7      | 2013-Feb-27     | 2013-Mar-27  
- New Target date: 2013-Mar-27 |
| 7     | Embargo Period              | 10          | 2013-Mar-13     | 2013-Apr-11  
- New Target date: 2013-Apr-11 |
| 8 (a) | Final Recommendation sent to Drug Plans and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Reconsideration is Resolved) | 5           | 2013-Apr-18     | 2013-Apr-18  
- Notice of Final Recommendation issued |
| 8 (b) | Clarification and Final Recommendation sent to Drug Plans and Manufacturer (Clarification Requested, no Request for Reconsideration made) | 5           |                 |           |
| 8 (c) | Placed on CDEC Agenda For Reconsideration (At Manufacturer’s request) | 25          |                 | Depends on Meeting Dates |
| 9     | Final Recommendation sent to Drug Plans and Manufacturer | 5           |                 |           |

1. Refer to the Procedure for Common Drug Review on the Common Drug Review section of [www.cadth.ca](http://www.cadth.ca) for more details.  
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. This Submission Status Report reflects status as of Thursday noon.