Common Drug Review [1]

Submission Status

Product: Esbriet

Generic Name: Pirfenidone

Manufacturer/Appliacant: Hoffmann-La Roche Limited

Indication(s): Pulmonary fibrosis (idiopathic, mild to moderate)

Submission Type: Resubmission

Date Submission Received: 2014-Aug-29 **Date NOC Issued:** 2012-Oct-02

Orginal Targeted CDEC Meeting: 2014-Feb-18 **Priority Review Status:** Granted

Phase	Target Time (Business Days)	Target Date [2]	Actual Date	Comments
Submission deemed complete	10	2014-Sep-15	2014-Sep-15	- Ten business days are allotted for assessing resubmissions for completeness as opposed to five business days for submissions - Priority review request under assessment and due 2014-Sep-22 - Priority review granted - Review has been initiated 2014-Sep-23
Patient group input submission received [3]		2014-Sep-22	2014-Sep-22	- Call for patient input posted on 2014-Jul-31 - Patient group input deadline: 2014-Sep-22 - Patient input submission received
Patient group input summary comments received	5	2014-Oct-09		- Patient input summary sent for review on 2014-Oct-02 - Patient input summary feedback deadline: 2014-Oct-09 - No patient input summary feedback received
CDR review reports sent to manufacturer[4]	45	2014-Nov-28	2014-Dec-05	- New target date: 2014-Dec-05
Comments from manufacturer on CDR review reports received by CADTH	7	2014-Dec-09	2014-Dec-16	- New target date: 2014-Dec-16
Redaction response from manufacturer on CDR review reports received by CADTH	5	2014-Dec-16	2014-Dec-23	- New target date: 2014-Dec-23
CDEC meeting		2014-Feb-18	2015-Feb-18	
CDEC recommendation & redacted CDR review reports sent to drug plans and manufacturer	5 to 7	2014-Feb-25	2015-Feb-25	
Embargo period and validation of redacted CDR review reports [5] Manufacturers may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	10	2014-Mar-11	2015-Mar-11	
Placed on CDEC agenda for reconsideration (At manufacturer's request)	25 Depends on Meeting Dates	2015-Apr-08	2015-Apr-08	- The April 2015 Canadian Drug Expert Committee (CDEC) meeting will be held on April 8, to accommodate for the 2015 CADTH Symposium from April 12 to 14, 2015, in Saskatoon, SK.
Final recommendation sent to drug plans and manufacturer	5	2015-Apr-15	2015-Apr-15	- Notice of final recommendation issued
CDEC final recommendation posted [6]	Variable	2015-Apr-17	2015-Apr-17	
Final CDR review reports and patient input posted [7]	Variable		2018-Dec-04	

[1] Refer to the Procedure for Common Drug Review on the Common Drug Review section of 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 35 business days if advance notice (20 business days maximum) 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 additional electronic copies (5 business days) and time allocated for distribution of electronic copies 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 target date for posting the CDEC final recommendation depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

[7] The timing of the posting of CDR review reports depends on several factors, including the need for consultation with the manufacturer in case of disagreement with regard to redactions made.

This CDR Project Status Report is posted every other week, reflecting status as of the end of day Wednesday (4:00 pm ET) of that week.