



## Common Drug Review Submission Status

<b>Product:</b>	Ofev	<b>Date NOC Issued:</b>	2015-Jun-25
<b>Generic Name:</b>	nintedanib	<b>Application Fee Schedule<sup>1</sup>:</b>	Schedule A
<b>Manufacturer/Applicant:</b>	Boehringer Ingelheim (Canada) Ltd	<b>Priority Review Status:</b>	Not Requested
<b>Indication(s):</b>	Idiopathic pulmonary fibrosis (IPF)		
<b>Submission Type:</b>	Pre-NOC - Initial		
<b>Date Submission Received:</b>	2015-Apr-23		
<b>Original Targeted CDEC Meeting:</b>	2015-Sep-16		

Key Milestone <sup>2</sup>	Target Date	Actual Date	Comments
Submission/resubmission accepted for review	2015-May-07	2015-May-07	- Review has been initiated 2015-May-08
Patient group input submission received <sup>3</sup>	2015-May-04	2015-May-04	- Call for patient input posted on 2015-Mar-13 - Patient group input deadline: 2015-May-04 - Patient input submission received
Patient group input summary comments received	2015-May-28	2015-May-28	- Patient input summary sent for review on 2015-May-21 - Patient input summary feedback deadline: 2015-May-28 - Patient input summary feedback received
Draft CDR review report(s) sent to manufacturer	2015-Jul-23	2015-Jul-23	
Comments from manufacturer on draft CDR review report(s) received by CADTH	2015-Aug-04	2015-Aug-04	
Redaction response from manufacturer on draft CDR review report(s) received by CADTH	2015-Aug-11	2015-Aug-11	
CDEC meeting	2015-Sep-16	2015-Sep-16	
CDEC recommendation & redacted CDR review report(s) sent to drug plans and manufacturer	2015-Sep-25	2015-Sep-23	- New target date: 2015-Sep-23
Embargo period <sup>4</sup> and validation of redacted CDR review report(s) Manufacturer may make a request for reconsideration and drug plans may make a request for clarification of the recommendation	2015-Oct-09	2015-Oct-07	- New target date: 2015-Oct-07
Final recommendation issued to drug plans and manufacturer (No request for clarification is made AND no request for reconsideration is made or request for reconsideration is resolved)	2015-Oct-19	2015-Oct-15	- New target date: 2015-Oct-15 - Notice of final recommendation issued
CDEC Final Recommendation posted <sup>5</sup>	2015-Oct-19	2015-Oct-19	
Final CDR review report(s) and patient input posted <sup>5</sup>		2018-Jul-09	

<sup>1</sup> Refer to Appendix 1 of the Procedure for the CADTH Common Drug Review in the Common Drug Review section of [www.cadth.ca](http://www.cadth.ca) for details regarding fee schedules.

<sup>2</sup> Please refer to the *Procedure for the CADTH Common Drug Review* in the Common Drug Review section of [www.cadth.ca](http://www.cadth.ca) for complete details regarding the CDR process and targeted time frames for key milestones.

<sup>3</sup> The call for patient group input is posted 20 business days in advance of the manufacturer's anticipated date of filing the application. Patient groups have a total of 35 business days for preparing and submitting patient input.

<sup>4</sup> The embargoed CDEC recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of *CDEC Final Recommendation*.

<sup>5</sup> The timing for posting the *CDEC Final Recommendation* and CDR review report(s) depends on several factors including the need for consultation with the manufacturer regarding redaction issues.

**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.**