



## Common Drug Review \*

### Submission Status

<b>Product:</b>	<input type="text" value="Daxas"/>		
<b>Generic Name:</b>	<input type="text" value="roflumilast"/>		
<b>Manufacturer:</b>	<input type="text" value="Nycomed Canada Inc."/>		
<b>Indication:</b>	<input type="text" value="Chronic obstructive pulmonary disease (COPD)"/>		
<b>Submission Type:</b>	<input type="text" value="Initial"/>		
<b>Date Submission Received:</b>	<input type="text" value="2010-Nov-30"/>	<b>Date NOC Issued:</b>	<input type="text" value="2010-Nov-23"/>
<b>Targeted CEDAC Meeting:</b>	<input type="text" value="2011-May-18"/>	<b>Priority Review Granted:</b>	<input type="text" value="Not Requested"/>

Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments	
1	Submission deemed complete	5	2010-Dec-07	2010-Dec-07	- Submission deemed complete. - Submission placed in queue in accordance with CDR procedures. Review to be initiated pending the availability of resources. - Submission initiated on 2011-Jan-10
2	Patient group input submission received		2011-Jan-24	2011-Jan-24	- 2011-Jan-24 - New target date based on submission initiated. - Patient group submissions received
3	CADTH Reviewers' Reports sent to Manufacturer	45	2011-Mar-25	2011-Mar-29	- New date: 2011-Mar-29
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Apr-05	2011-Apr-08	- New date: 2011-Apr-07
5	CEDAC Meeting		2011-May-18	2011-May-18	
6	CEDAC Recommendation *** Sent to Drug Plans, ACP and Manufacturer	5 to 7	2011-May-26	2011-May-26	
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Jun-09	2011-Jun-09	- Request for reconsideration received 2011-Jun-10 - Request for reconsideration granted 2011-Jun-16
8 (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			
<b>OR</b>					
8 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
<b>OR</b>					
8 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2011-Jul-20	2011-Jul-20	
9	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2011-Jul-27	2011-Jul-27	

\* 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.

\*\* The Formulary 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.cadth.ca](http://www.cadth.ca).

\*\*\* The Procedure for Common Drug Review, section 8.3.3a, states "...the CEDAC recommendation will be sent to the Manufacturer, ACP and to the drug plans within five (5) to seven (7) business days following the CEDAC meeting...". The original target date is based on five (5) business days.

\*\*\*\* The Recommendation is held in confidence and not acted upon until after CADTH has issued the notice of Final Recommendation.

This submission status report reflects updates as of Thursday noon.