Common Drug Review *

Submission Status

Canadian Agency for Drugs and Technologies in Health

Product: BuTrans

Generic Name: buprenorphine transdermal patch

Manufacturer: Purdue Pharma

Indication: Pain, persistent (moderate intensity)

Submission Type: Resubmission

Date Submission Received: 2011-May-09 **Date NOC Issued:** 2010-Mar-05

Targeted CDEC Meeting: 2011-Oct-19 **Priority Review Granted:** Not Requested

	Phase	Target Time (Business Days)	Target Date **	Actual CDR Date	Comments
1	Submission deemed complete	10	2011-May-24	2011-May-24	
2	Patient group input submission received				- Patient group submissions received with Initial Submission.
3	CADTH Reviewers' Reports sent to Manufacturer	45	2011-Aug-09	2011-Jun-01	- New due date for reports to manufacturer: 2011-Jun-01
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2011-Aug-18	2011-Jun-10	- New due date for Comments from Manufacturer on Reviewers' Reports Received by CADTH: 2011-Jun-10
5	CDEC Meeting		2011-Oct-19	2011-Jul-20	- New CDEC meeting date: 2011-Jul-20
6	CDEC Recommendation *** Sent to Drug Plans, FWG and Manufacturer	5 to 7	2011-Oct-26	2011-Jul-27	- New due date for CDEC Recommendation sent to Drug Plans, FWG and Manufacturer: 2011-Jul-27
7	Embargo Period **** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2011-Nov-09	2011-Aug-11	- New due date for Embargo Period: 2011-Aug-11 - Request for Reconsideration received: 2011-Aug-11 - Request for Reconsideration granted: 2011-Aug-16
8 (a)	Final Recommendation sent to Drug Plans, FWG, and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made or Request for Reconsideration is Resolved)	5			
	OR				
8 (b)	Clarification and Final Recommendation sent to Drug Plans, FWG, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
	OR				
8 (c)	Placed on CDEC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2012-Jan-18	2011-Sep-21	- New due date for Placed on CDEC Agenda For Reconsideration (At Manufacturer's request): 2011-Sep-21
9	Final Recommendation sent to Drug Plans, FWG, and Manufacturer	5	2012-Jan-25	2011-Sep-28	- New date: 2011-Sep-28. - Notice of Final Recommendation issued.

***** Refer to the Procedure for Common Drug Review on the Common Drug Review section of 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 CDEC meeting schedule, which is posted on www.cadth.ca.

*** The Procedure for Common Drug Review, section 8.3.3a, states "…the CDEC recommendation will be sent to the Manufacturer, FWG and to the drug plans within five (5) to seven (7) business days following the CDEC 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.