

Common Drug Review *

Submission Status



Canadian Agency for
Drugs and Technologies
in Health

Product:	Effient		
Generic Name:	prasugrel hydrochloride		
Manufacturer:	Eli Lilly Canada Inc.		
Indication:	Acute Coronary Syndrome (ACS)		
Submission Type:	Initial		
Date Submission Received:	2010-May-05	Date NOC Issued:	2010-Apr-16
Targeted CEDAC Meeting:	2010-Sep-15	Priority Review Granted:	Not Requested

	Phase	Target Time (Business Days)	Target Date**	Actual CDR Date	Comments
1	Submission deemed complete	5	2010-May-12	2010-May-12	Submission deemed complete.
2	Patient group input submission received	na	na	na	Not applicable
3	CADTH Reviewers' Reports sent to Manufacturer	45	2010-Jul-28	2010-Jul-28	
4	Comments from Manufacturer on Reviewers' Reports Received by CADTH	7	2010-Aug-09	2010-Aug-09	
5	CEDAC Meeting		2010-Sep-15	2010-Sep-15	
6	CEDAC Recommendation Sent to Drug Plans, ACP and Manufacturer	5	2010-Sep-22	2010-Sep-22	
7	Embargo Period*** Manufacturers may make a Request for Reconsideration and Drug Plans may make a Request for Clarification of the Recommendation	10	2010-Oct-06	2010-Oct-06	Request for reconsideration received on 2010-Oct-06.
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			
OR					
8 (b)	Clarification and Final Recommendation sent to Drug Plans, ACP, and Manufacturer (Clarification Requested, no Request for Reconsideration made)	5			
OR					
8 (c)	Placed on CEDAC Agenda For Reconsideration (At Manufacturer's request)	25 Depends on Meeting Dates	2010-Nov-17	2010-Nov-17	
9	Final Recommendation sent to Drug Plans, ACP, and Manufacturer	5	2010-Nov-24	2011-Feb-16	Notice of Final Recommendation delayed. Review suspended on 2010-Dec-23. Suspension lifted on 2011-Feb-10. Notice of Final Recommendation 2011-Feb-16.

* 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 CEDAC meeting schedule, which is posted on www.cadth.ca.

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

Reflects updates as of Thursday noon.