| Common Drug Review 1<br>Submission Status |   |                                   |                             |                    |   |  |
|---|---|-----------------------------------|-----------------------------|--------------------|---|--|
|   | Canadian Agency for<br>Drugs and Technologies   | Effient                           |                             |                    |   |  |
|   | Canadian Agency for<br>Drugs and Technologies<br>in Health Generic Name: prasugrel  |                                   |                             |                    |   |  |
|   | Manufacturer: Eli Lily Canada Inc.  |                                   |                             |                    |   |  |
| Indication: Acute Coronary Syndrome (ACS) |   |                                   |                             |                    |   |  |
| Submission Type: Resubmission             |   |                                   |                             |                    |   |  |
| Date Submission Received:                 |   | 2011-Dec-12 Date NOC Issued:      |                             | te NOC Issued:     | 2010-Mar-16   |  |
| Targeted CDEC Meeting:                    |   | 2012-May-16                       | Priority Review Granted:    |                    | Not Requested   |  |
|   | Phase   | Target<br>Time<br>(Business Days) | Target<br>Date <sup>2</sup> | Actual<br>CDR Date | Comments  |  |
| 1   | Submission deemed complete  | 10                                | 2012-Jan-03                 | 2012-Jan-04        |   |  |
| 2   | Patient group input submission received <sup>3</sup>  |                                   |                             |                    | - No patient group input requested on this Resubmission |  |
| 3   | CADTH Reviewers' Reports sent to Manufacturer <sup>4</sup>  | 45                                | 2012-Mar-19                 | 2012-Mar-19        |   |  |
| 4   | Comments from Manufacturer on Reviewers' Reports Received by CADTH  | 7                                 | 2012-Mar-28                 | 2012-Mar-28        |   |  |
| 5   | CDEC Meeting  |                                   | 2012-May-16                 | 2012-May-16        |   |  |
| 6   | CDEC Recommendation<br>Sent to Drug Plans and Manufacturer  | 5 to 7                            | 2012-May-24                 | 2012-May-24        |   |  |
|   | Embargo Period <sup>5</sup><br>Manufacturers may make a Request for<br>Reconsideration and Drug Plans may make a<br>Request for Clarification of the Recommendation                                 | 10                                | 2012-Jun-07                 | 2012-Jun-07        |   |  |
| 8 (a)                                     | Final Recommendation sent to Drug Plans and<br>Manufacturer<br>(No Requests for Clarification are made AND no<br>Request for Reconsideration is made or Request for<br>Reconsideration is Resolved) | 5                                 | 2012-Jun-14                 | 2012-Jun-14        | - Notice of Final Recommendation issued                 |  |
|   | OR  |                                   |                             |                    |   |  |
| 8 (b)                                     | Clarification and Final Recommendation sent to Drug<br>Plans and Manufacturer<br>(Clarification Requested, no Request for<br>Reconsideration made)  | 5                                 |                             |                    |   |  |
| OR  |   |                                   |                             |                    |   |  |
| 8 (c)                                     | Placed on CDEC Agenda For Reconsideration<br>(At Manufacturer's request)  | 25<br>Depends on<br>Meeting Dates |                             |                    |   |  |
| 9   | Final Recommendation sent to Drug Plans and Manufacturer  | 5                                 |                             |                    |   |  |

<sup>1</sup> Refer to the Procedure for Common Drug Review on the Common Drug Review section of <u>www.cadth.ca</u> for more details.

<sup>2</sup> The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.

<sup>3</sup> The deadline for Patient Group Input is 15 business days after CADTH receives the Submission or up to 25 business days if advance notice of a Submission is received from the Manufacturer.

<sup>4</sup> 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 binders (5 business days) and time allocated for distribution of binders to reviewers (3 business days).

<sup>5</sup> The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of Final Recommendation.

This Submission Status Report reflects status as of Thursday noon.