

Draft VCU attached to letter of June 24, 2011

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
ELI LILLY CANADA INC.  
TO THE  
PATENTED MEDICINE PRICES REVIEW BOARD**

**1. Product Summary**

- 1.1 Effient (prasugrel) 10 mg tablet is indicated for co-administration with acetylsalicylic acid (ASA) for early and long-term secondary prevention of atherothrombotic events in patients with acute coronary syndrome (ACS).
- 1.2 Canadian Patents No. 2,077,695, No. 2,263,983 and No. 2,322,171 pertaining to Effient were issued on August 20, 2002, March 21, 2006 and October 27, 2009 respectively, to the Sankyo Company Ltd. (Japan). The last patent will expire on February 26, 2019. Eli Lilly Canada Inc. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 A Notice of Compliance was granted to Eli Lilly Canada Inc. for Effient 10 mg tablet (DIN 2349124) on April 16, 2010. Effient was first sold in Canada on May 17, 2010.

**2. Application of the Guidelines**

- 2.1 At introduction, the Board's Human Drug Advisory Panel (HDAP) identified Effient as a new medicine providing a moderate level of therapeutic improvement. The National Average Transaction Price (N-ATP) exceeded the Maximum Average Potential Price (MAPP) by 20.51% and as such triggered the investigation criteria under the Board's Guidelines.
- 2.2 In the July to December 2010 reporting period, the N-ATP of Effient was reduced to below the MAPP.
- ~~2.3 In the May 17, 2010 to June 30, 2010 period, there were excess revenues of \$4,618.51.~~

**3. Position of Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Eli Lilly Canada Inc. that the price of Effient is or was excessive for purposes of the *Patent Act*.

**4. Terms of the Voluntary Compliance Undertaking**

In order to comply with the Guidelines, Eli Lilly Canada Inc. undertakes as follows:

4.1.1 To agree that the 2010 and 2011 N-NEAPs of Effient 10 mg tablet are as follows:

2010 \$2.5973  
2011 \$2.6504

4.1.2 To offset the cumulative excess revenues received from May 17, 2010 to June 30, 2010 by making a payment of \$4,618.51 to Her Majesty in right of Canada, within 30 days of the acceptance of this VCU.

4.1.3 To ensure that the price of Effient 10 mg tablet remains within the Guidelines in all future periods in which Effient is under the PMPRB's jurisdiction.

Signature: Original signed by

Name: TERRY McCool

Position: VP. CORPORATE AFFAIRS

Company: Eli Lilly Canada Inc.

Date: 07/18/11