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

## 1.0 Product Summary

***EFFIENT***

1.1 EFFIENT (prasugrel hydrochloride), co-administered with acetylsalicylic acid (**ASA**), is indicated for the early and long-term secondary prevention of atherothrombotic events in patients with acute coronary syndrome (**ACS**) as follows:

a) unstable angina (**UA**) or non-ST-segment elevation myocardial infarction (**NSTEMI**) managed with percutaneous coronary intervention (**PCI**)

b) ST-segment elevation myocardial infarction (**STEMI**) managed with primary or delayed PCI.

1.2 EFFIENT is marketed in one strength: 10 mg/tablet.

1.3 Health Canada issued a Notice of Compliance (**NOC**) for EFFIENT 10 mg tablets on April 16, 2010. Eli Lilly Canada Inc. (**Lilly**) began selling EFFIENT 10 mg tablets in Canada on May 17, 2010.

1.4 Canadian Patents No. 2,263,983, 2,322,171, 2,415,558, 2,432,644, and 2,611,668 are the current Canadian Patents that pertain to EFFIENT. The last reported patent pertaining to EFFIENT expires on June 6, 2026. Lilly is the patentee for purposes of the Patented Medicine Prices Review Board (**PMPRB**).

***ADCIRCA***

1.5 ADCIRCA (tadalafil) is indicated for the treatment of idiopathic ("primary") pulmonary arterial hypertension (**PAH**) or PAH associated with connective tissue disease, congenital heart disease or anorexigen use in patients with WHO functional class II or III who have not responded to conventional therapy.

1.6 ADCIRCA is marketed in one strength: 20 mg/tablet.

1.7 Health Canada issued an NOC for ADCIRCA 20 mg tablets on November 25, 2009. Lilly began selling ADCIRCA 20 mg tablets in Canada on January 19, 2010.

1.8 Canadian Patents No. 2,371,684, 2,379,948, 2,380,087, and 2,492,540 are the current Canadian Patents that pertain to ADCIRCA. The last reported patent pertaining to ADCIRCA expires on July 14, 2023. Lilly is the patentee for purposes of the PMPRB.

## 2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel (**HDAP**) identified EFFIENT as providing moderate improvement.

2.2 The HDAP identified ADCIRCA as providing slight to no improvement.

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

2.3 The prices of EFFIENT and ADCIRCA were within the PMPRB Guidelines at introduction and in all subsequent periods up to and including 2014.

2.4 In 2015, the National Average Transaction Prices (**N-ATPs**) of EFFIENT and ADCIRCA exceeded their respective National Non-Excessive Average Prices (**N-NEAPs**) by amounts that triggered the investigation criteria in the Guidelines. The N-ATPs of EFFIENT and ADCIRCA were within their respective N-NEAPs in 2016. As of December 31, 2016, cumulative excess revenues were $56,411.79 for EFFIENT and $392,943.53 for ADCIRCA for a total of $449,355.32.

## 3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (**VCU**) constitutes no admission by Lilly that the prices of EFFIENT or ADCIRCA are now, or were at any time since the date of first sale, excessive for purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the Patent Act.

## 4.0 Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Lilly undertakes:

4.1.1 To agree that the N-NEAPs for EFFIENT and ADCIRCA are as follows:

| Product | 2015 N-NEAP | 2016 N-NEAP | 2017 N-NEAP |
|---|---|---|---|
| EFFIENT | $2.5934 | $2.6712 | $2.6091 |
| ADCIRCA | $13.3533 | $13.5865 | $13.5135 |

4.1.2 To ensure the 2017 N-ATPs of EFFIENT and ADCIRCA do not exceed the respective 2017 N-NEAPs as stated in 4.1.1 above, and that the prices of EFFIENT and ADCIRCA are within the thresholds set out in the Guidelines in each market where they are sold;

4.1.3 To offset the excess revenues accrued by Lilly in respect of EFFIENT and ADCIRCA in 2015 by further reducing the 2017 N-ATPs for both EFFIENT and ADCIRCA below their respective 2016 N-NEAPs. The reduction in price for both products will be applied to offset the cumulative excess revenues as between them totalling $449,355.32;

4.1.4 To offset any remaining cumulative excess revenues for EFFIENT and ADCIRCA at the end of the period from January 1 to December 31, 2017, by making a payment to Her Majesty in right of Canada, within 30 days of receiving Board Staff's notification of remaining excess revenues calculated based on the semi-annual price and sales data filed by Lilly, as required by the *Patented Medicines Regulations* and the 2017 N-NEAPs set out in 4.1.1 above; and

4.1.5 To ensure that the prices of EFFIENT and ADCIRCA remain within the thresholds set out in the Guidelines in all future periods during which they are under the PMPRB's jurisdiction.

Name: Lauren Fischer

Position: VP Corporate Affairs

Patentee: Eli Lilly Canada Inc.

Date: August 15, 2017