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

1.0 Product Summary

1.1 Cyramza (ramucirumab) is indicated as a single agent, or in combination with paclitaxel, for the treatment of patients with advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma, with disease progression on or after prior platinum and fluoropyrimidine chemotherapy.

1.2 Cyramza is marketed in one strength: 10 mg/mL.

1.3 Health Canada issued a Notice of Compliance (**NOC**) for Cyramza on July 16, 2015. Lilly Canada Inc. (**Lilly**) commenced sales in Canada on September 10, 2015.

1.4 Canadian Patent No 2,478,169 pertaining to Cyramza was issued to ImClone LLC on April 16, 2013 and will expire on March 4, 2023. Lilly is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (**PMPRB**).

2.0 Application of the Excessive Price Guidelines

2.1 The HDAP classified Cyramza as a Slight/No Level of Therapeutic Improvement.

2.2 In accordance with the Guidelines, a Therapeutic Class Comparison (**TCC**) test and Highest International Price Comparison (**HIPC**) test were conducted. The result of the TCC test indicated that the introductory price of Cyramza exceeded the thresholds set out in the Guidelines by an amount which triggered the investigation criteria. The introductory prices in each market were also found to exceed the thresholds set out in Guidelines.

2.3 The National Average Transaction Price (**N-ATP**) of Cyramza was above the Maximum Average Potential Price (**MAPP**) of $62.6679, resulting in cumulative excess revenues of $335,531.56 as of December 31, 2016.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking (**VCU**) constitutes no admission by Lilly that the price of Cyramza is now, or was 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 2015 MAPP, 2016 N-NEAP and 2017 N-NEAP for Cyramza are as follows:

2015	$62.6679
2016	$63.9213
2017	$64.6106

4.1.2 To ensure that the 2017 N-ATP of Cyramza does not exceed the 2017 N-NEAP as stated in 4.1.1 above, and that the price of Cyramza is within the thresholds set out in the Guidelines in each market where it is sold;

4.1.3 To offset the excess revenues accrued by Lilly in respect of Cyramza by further reducing the 2017 N-ATP for Cyramza below its 2016 N-NEAP. The reduction in price will be applied to offset the cumulative excess revenues totalling $335,531.56;

4.1.4 To offset any remaining cumulative excess revenues for Cyramza 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-NEAP set out in 4.1.1 above; and

4.1.5 To ensure that the price of Cyramza remains within the thresholds set out in the Guidelines in all future periods during which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Lauren Fischer

Position: Vice President, Corporate Affairs

Patentee: Eli Lilly Canada Inc.

Date: August 15, 2017

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.