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

1.0 Product Summary

1.1 Cialis (tadalafil) is indicated for the treatment of erectile dysfunction (ED) and/or benign prostatic hyperplasia (BPH). Cialis is marketed in four (4) strengths:

Cialis	10 mg tablets	"On-demand" Dosing
	20 mg tablets	
Cialis	2.5 mg tablets	"Once-a-day" Use
	5.0 mg tablets	

1.2 Health Canada issued a Notice of Compliance ("NOC") for Cialis 10 & 20 mg tablets on September 17, 2003. Eli Lilly Canada Inc. ("Lilly") began selling Cialis 10 & 20 mg tablets in Canada on November 28, 2003.

1.3 Health Canada issued a Notice of Compliance ("NOC") for Cialis 2.5 & 5.0 mg tablets on June 27, 2007. Eli Lilly Canada Inc. ("Lilly") began selling Cialis 2.5 and 5.0 mg tablets in Canada on January 18, 2008.

1.4 Canadian Patent Nos. 2,226,784, 2,371,684, 2,379,948, and 2,380,087 are the current Canadian Patents that pertain to Cialis. The last patent pertaining to Cialis expires on August 1, 2020. Lilly is the patentee for purposes of the Patented Medicine Prices Review Board ("PMPRB").

2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel (HDAP) identified Cialis 10 & 20 mg tablets as Category 3 new medicines (moderate, slight or no improvement). Cialis 2.5 and 5.0 mg tablets were reviewed as Category 1 new medicines.

2.2 The prices of all strengths of Cialis were within the PMPRB Guidelines at introduction (in 2003 and 2007) and in all subsequent periods up to and including 2013.

2.2 In 2014, the National Average Transaction Prices (N-ATPs) of three strengths of Cialis (5 mg, 10 mg and 20 mg) exceeded their respective National Non-Excessive Average Prices ("N-NEAP") by amounts that triggered the investigation criteria; the N-ATP of the 2.5 mg strength exceeded the Guidelines by an amount that triggered the investigation criteria in 2015. As of December 31, 2015, cumulative excess revenues totalled $8,329,915.78.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Lilly that the prices of Cialis are or were at any time since the date of first sale of the medicine excessive for purposes of the *Patent Act.*

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Lilly agrees to undertake the following:

4.1. To agree that the National-Non-Excessive Average Prices (N-NEAP) of Cialis are as follows:

Strengths	2014	2015	2016
2.5 mg	$3.9858	$4.0416	$4.0400
5 mg	$4.0311	$4.0875	$4.1661
10 mg	$13.1854	$13.3700	$13.6240
20 mg	$13.6772	$13.8687	$14.1345

4.2 To ensure the 2016 N-ATPs of all strengths of Cialis do not exceed the 2016 N-NEAPs outlined in 4.1 above.

4.3 To offset the cumulative excess revenues received by Lilly by further reducing the 2016 N-ATPs for all strengths of Cialis below their respective 2015 N-NEAPs.

4.4 To offset any remaining excess revenues at the end of the July 1 to December 31, 2016 period, 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 2016 N-NEAPs set out in 4.1.1above.

4.5 To ensure that the prices of all strengths of Cialis remain within the PMPRB's Guidelines in all future periods in which Cialis remains under the PMPRB's jurisdiction.

Signature: (Original signed by)

Name: Lauren Fischer

Position: Vice President, Corporate Affairs

Patentee: Eli Lilly Canada Inc.

Date: May 31, 2016