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

1.0 Background

1.1. This Voluntary Compliance Undertaking ("VCU") is for the drug products described in the table below.

DIN	Brand Name	Chemical Name	Strength	NOC Date
02243948	PUREGON	Follitropin beta solution for injection (cartridge)	833 unit/mL	11 May 2001
02242439	PUREGON	Follitropin beta solution for injection (50 IU vial)	50 unit/0.5 mL	11 May 2001
02242441	PUREGON	Follitropin beta solution for injection (100 IU vial)	100 unit/0.5 mL	11 May 2001
02446901	ZERBAXA	Ceftolozane/Tazobactam	1500 mg/vial	30 Sept. 2015

1.2 The first patent pertaining to Puregon was issued on March 5, 2013. Puregon came under the jurisdiction of the Patented Medicine Prices Review Board ("PMPRB") upon the date of first sale in October 2001 as this was after the date that the patent was laid open, February 3, 2000.

1.3 Zerbaxa came under the jurisdiction of the PMPRB when it was first sold on January 12, 2016. The last patent pertaining lapsed on October 27, 2016.

1.4 Merck Canada Inc. is the patentee for purposes of the *Patent Act* and the PMPRB.

2.0 Application of the Excessive Price Guidelines

2.1 All three strengths of Puregon were reviewed as Category 1 new drug products based on the pre-2010 Guidelines. An existing strength of Puregon was identified for comparison purposes. The introductory prices for all three strengths of Puregon exceeded the Maximum Average Potential Price ("MAPP") by an amount which triggered the investigation criteria set out in the Guidelines. These prices continued to exceed the National Non-Excessive Average Prices ("N-NEAP") in the subsequent reporting periods.

2.2 The Human Drug Advisory Panel recommended that Zerbaxa be reviewed as a Slight to No Improvement and identified ciprofloxacin, levofloxacin, ceftazidime, cefepime, piperacillin/tazobactam, imipenem and meropenem for comparison purposes. The introductory price exceeded the MAPP by an amount which triggered the investigation criteria. The price in the subsequent reporting period continued to exceed the thresholds set out in the Guidelines.

2.3 Total cumulative excess revenues for all three strengths of Puregon and Zerbaxa are calculated to be $750,000.00.

3.0 Position of Patentee

3.1 This VCU constitutes no admission by Merck Canada Inc. that the price of any of the drug products subject to this VCU are or were excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Merck Canada Inc. agrees to undertake:

4.1 To agree that the 2016 and 2017 N-NEAPs are as follows:

DIN	Brand Name	2016 N-NEAP	2017 N-NEAP
02243948	PUREGON 833 unit/mL	$0.9700	$0.9700
02242439	PUREGON 50 unit/0.5 mL	$48.5000	$48.5000
02242441	PUREGON 100 unit/0.5 mL	$97.0000	$97.0000
02446901	ZERBAXA	$136.6300	No longer patented

4.2 To ensure that the 2017 N-ATP of each of the three strengths of Puregon does not exceed its respective 2017 N-NEAP as specified in 4.1 above;

4.3 To make a payment to Her Majesty in right of Canada in the amount of $750,000.00;

4.4 To advise the PMPRB in the event that other patents pertaining to Zerbaxa are issued in any future period; and

4.5 To ensure that the price of the drug products subject to this VCU remain within the thresholds set out in the Guidelines in all future periods during which they are under the PMPRB's jurisdiction.

Signature: _____

Name: C. GUINDO

Position: President & Managing Director

Patentee: Merck Canada Inc.

Date: June 16, 2019

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.