VOLUNTARY COMPLIANCE UNDERTAKING
OF
Merck Canada Inc.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

1.1 Bridion (sugammadex) is indicated for the reversal of moderate or deep neuromuscular blockade (NMB) induced by rocuronium or vecuronium.

1.2 Health Canada issued a Notice of Compliance for Bridion to Merck Canada Inc. (Merck) on February 5, 2016. Bridion was first sold in Canada on February 19, 2016.

1.3 The last reported patent pertaining to Bridion expires on November 23, 2020. Merck is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2. Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel (HDAP) classified Bridion as a moderate level of therapeutic improvement based on primary factors.

2.2 Bridion is available in 2 milliliter and 5 milliliter vials, which are priced non-linearly.

2.3 At introduction, the price of the 2 milliliter vial ($53.5000 per milliliter) was above the Maximum Average Potential Price (MAPP), resulting in certain Market Specific Average Transaction Prices (MS-ATPs) triggering the investigation criteria set out in the Guidelines.

2.4 The 2 milliliter vial continued to be sold at this price in subsequent reporting periods.

2.5 At introduction, the price of the 5 milliliter vial ($42.8000 per milliliter) was below the MAPP.

3. Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Merck that the price of Bridion in Canada is now, or was at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act.*

4. Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Merck undertakes:

4.1.1 To agree that the MAPP and Non-Excessive Average Prices (NEAPs) for 2016, 2017, and 2018 are as follows:

Year	MAPP/NEAP
2016	$46.7514
2017	$47.2657
2018	$47.9669

4.1.2 To reduce the list price of the 2 milliliter vial size of Bridion to $47.9669 per milliliter or lower by November 1, 2017, and to take no list price increase in 2018;

4.1.3 To ensure that the 2018 National Average Transaction Price (N-ATP) and MS-ATPs do not exceed the NEAPs outlined in section 4.1.1 above;

4.1.4 To ensure, beginning January 1, 2019, that the N-ATP and MS-ATPs do not exceed the lower of the application of the CPI-Adjustment Methodology and the Median International Price Comparison test;

4.1.5 To file evidence with Board Staff within 30 days of the price reduction that customers have received notification that the price has been reduced for the purposes of adherence to the Guidelines and this VCU;

4.1.6 To ensure that the price of Bridion remains within the thresholds set out in the Guidelines, as well as the requirements of section 4.1.4 above, in all future reporting periods during which Bridion is under the jurisdiction of the PMPRB.

Signature: _____

Name: Chirfi Guindo

Position: President & Managing Director

Patentee: Merck Canada Inc.

Date: Oct 26, 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.