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

1. Product Summary

1.1 Zepatier (elbasvir/grazoprevir) is indicated for the treatment of chronic hepatitis C (CHC) genotypes 1, 3, or 4 infection in adults with or without ribavirin, or with sofosbuvir.

1.2 Health Canada issued a Notice of Compliance for Zepatier to Merck Canada Inc. (Merck) on January 19, 2016. Zepatier was first sold in Canada on January 25, 2016.

1.3 The last reported patent pertaining to Zepatier expires on March 25, 2030. 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 Zepatier as a slight or no level of therapeutic improvement.

2.2 In accordance with the Guidelines, Board Staff conducted Therapeutic Class Comparison (TCC) and Highest International Price Comparison (HIPC) tests. The HIPC test established the Maximum Average Potential Price (MAPP) of $666.9408 per tablet.

2.3 The introductory National Average Transaction Price (N-ATP) exceeded the MAPP by an amount which triggered the investigation thresholds set out in the Guidelines. As of December 31, 2016, cumulative excess revenues for Zepatier were calculated to be $427,557.00.

2.4 The list price of Zepatier was reduced to $666.9400 per tablet in all provinces in Canada effective April 1, 2017.

3. Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Merck that the price of Zepatier 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 Price (NEAP) for 2016 and 2017 respectively are as follows:

Year	MAPP/NEAP
2016	$666.9408
2017	$674.2771

4.1.2 To ensure that the 2017 N-ATP does not exceed the NEAP outlined in section 4.1.1 above, and that the price of Zepatier 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 Merck in respect of Zepatier by making a payment of $427,557.00 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU;

4.1.4 To offset any remaining cumulative excess revenues for Zepatier at the end of the period from January 1, 2017 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 Merck, as required by the *Patented Medicines Regulations* and the 2017 NEAP set out in 4.1.1 above;

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

Signature: _____

Name: CHRIS GUINDO

Position: President & Managing Director

Patentee: Merck Canada Inc.

Date: Oct 27, 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.