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

1.0 Product Summary

1.1 Repatha (evolocumab) 120 mg/mL (Repatha) is indicated as an adjunct to diet and maximally tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C).

1.2 Health Canada issued a Notice of Compliance for Repatha on December 15, 2016. Repatha was first sold in Canada on April 4, 2017 and is marketed by Amgen Canada Inc. (Amgen).

1.3 Canadian Patent No. 2,790,018 is the first reported patent that pertains to Repatha and was issued on February 3, 2015. The last reported patent pertaining to Repatha (Canadian Patent No. 2,696,252) expires on August 22, 2028. Amgen 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 introductory National Average Transaction Price (N-ATP) of Repatha exceeded its Maximum Average Potential Price (MAPP) by 12.4%, triggering the investigation criteria in the Guidelines. As of December 31, 2017, cumulative excess revenues were calculated to be $40,070.73.

3.0 Positions of the Patentee and Board Staff

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Amgen that the price of Repatha 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 Pursuant to this VCU, Amgen will undertake:

4.1.1 To agree that the 2017 MAPP for 2017 for Repatha is $538.4951;

4.1.2 To ensure that the 2018 N-ATP for Repatha does not exceed its 2018 NEAP and that the price of Repatha 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 Amgen in respect of Repatha by making a payment of $40,070.73 to Her Majesty in right of Canada within 30 days of acceptance of this VCU; and

4.1.4 To ensure that the price of Repatha remains within the PMPRB's Guidelines in all future periods in which Repatha is under the PMPRB's jurisdiction.

Signature: Original signed by

Name: GEOFF SPRANG

Position: EXEC DIRECTOR, VALUE, ACCESS & POLICY

Patentee: Amgen Canada Inc.

Date: MAY 1st, 2018

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.