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

1.0 Product Summary

1.1 Repatha (evolocumab) 140 mg/syringe (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 (NOC) for Repatha on September 10, 2015. Repatha was first sold in Canada on September 28, 2015 and is marketed by Amgen Canada Inc. (Amgen).

1.3 Canadian Patent No. 2,790,018 is the first patent identified by Amgen in its Form 1 that pertains to Repatha and was issued on February 3, 2015. The last patent pertaining to Repatha (Canadian Patent No. 2,696,252) identified by Amgen in its Form 1 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 15.9%, triggering the investigation criteria in the PMPRB's Compendium of Policies, Guidelines and Procedures – Updated February 2017 (the *"Guidelines")*. As of June 30, 2017, cumulative excess revenues for Repatha were calculated to be $1,340,400.97.

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 MAPP for 2015 and National Non-Excessive Average Prices (N-NEAPs) for 2016 and 2017 for Repatha are as follows:

Year	MAPP/N-NEAP
2015	$241.0632
2016	$245.8845
2017	$248.5362

4.1.2 To agree that the 2018 and 2019 N-NEAPs of Repatha will be set by the lower of:

a) the Non-Excessive Average Price derived from the ordinary application of the CPI-Adjustment Methodology of Schedule 9 of the current Guidelines; and
b) the lowest international price of the seven countries currently set out in the *Patented Medicines Regulations* as of the end of the second reporting period of the previous year;

4.1.3 To ensure that the 2018 and 2019 N-ATPs do not exceed the N-NEAPs determined in section 4.1.2 above, and that the price of Repatha is within the thresholds set out in the current *Guidelines* in each market where it is sold;

4.1.4 To offset the excess revenues accrued by Amgen in respect of Repatha from its introduction 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 cumulative excess revenues calculated based on the semi-annual price and sales data filed by Amgen for the July to December 2017 reporting period, as required by the *Patented Medicines Regulations* and the N-NEAPs set out in 4.1.1 above; and

4.1.5 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: Executive Director, Value, Access & Policy

Patentee: Amgen Canada Inc.

Date: December 11, 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.