VOLUNTARY COMPLIANCE UNDERTAKING OF SANOFI-AVENTIS CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Praluent (alirocumab) is human monoclonal antibody indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults 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 granted a Notice of Compliance to Sanofi-Aventis Canada Inc. (Sanofi-Aventis) for Praluent on April 11, 2016.

1.3. Praluent is available in four pre-filled presentations. The 75 mg/milliliter (DIN 02453819) and 150 mg/milliliter (DIN 02453835) pens were first sold in Canada on May 18, 2016 and April 29, 2016, respectively. The 75 mg/milliliter (DIN 02453754) and 150 mg/milliliter (DIN 02453762) syringes were first sold in Canada on August 13, 2016.

1.4. The first reported patent pertaining to Praluent was laid open on July 8, 2010, and was granted on January 9, 2018. The last reported patent pertaining to Praluent will expire on December 15, 2029. Sanofi-Aventis is the patentee for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board.

2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel (HDAP) classified Praluent as a Slight or No Level of Therapeutic Improvement and identified Repatha (evolocumab) as the most appropriate comparator for the purposes of conducting Therapeutic Class Comparison (TCC) tests. The TCC tests established the Maximum Average Potential Prices (MAPPs).

2.2 The introductory National Average Transaction Prices (N-ATPs) of Praluent exceeded the MAPPs by 13.6%, triggering the investigation criteria in the Guidelines. As of December 31, 2018, cumulative excess revenues were determined to be $426,955.62.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Sanofi-Aventis that the prices of Praluent are now, or were 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*.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Sanofi-Aventis will undertake:

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.

4.1.1 To agree that the MAPP and Non-Excessive Average Prices (NEAPs) for each strength of Praluent are as follows:

Year	MAPP/NEAP
2016	$245.8845
2017	$248.5892
2018	$252.2775
2019	$256.2116

4.1.2 To reduce the list prices of Praluent to the 2019 NEAPs of $256.2116 per pen/syringe or lower within 30 days of the acceptance of this VCU;

4.1.3 To file evidence with Board Staff within 30 days of the price reduction that customers have received notification that the prices have been reduced;

4.1.4 To offset the excess revenues accrued by Sanofi-Aventis in respect of Praluent by making a payment of $426,955.62 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU;

4.1.5 To ensure that the 2019 N-ATPs do not exceed the 2019 NEAPs of $256.2116 per pen/syringe;

4.1.6 To make a further payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining cumulative excess revenues as of December 31, 2019, as calculated based on the total 2019 price and sales data filed by Sanofi-Aventis; and

4.1.7 To ensure that the prices of Praluent remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Name:	Michael Mullette	Name:	Pat Papillo
Position:	President	Position:	CFO Canada
Patentee:	Sanofi-Aventis Canada Inc.	Patentee:	Sanofi-Aventis Canada Inc.
Date:	2019-04-01	Date:	2019-04-01

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