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

1.0 Product Summary

1.1. Dupixent (dupilumab) is an interleukin inhibitor indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

1.2. Health Canada granted a Notice of Compliance to Sanofi-Aventis Canada Inc. (Sanofi-Aventis) for Dupixent 300 mg per syringe (DIN 02470365) on November 30, 2017. Dupixent was first sold in Canada on February 7, 2018.

1.3. The last reported patent pertaining to Dupixent will expire on October 27, 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 introductory National Average Transaction Price (N-ATP) of Dupixent exceeded the MAPP by 3.6%, generating excess revenues of $353,928.44 and triggering the investigation criteria in the Guidelines. As of December 31, 2018, cumulative excess revenues were determined to be $1,654,520.73.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Sanofi-Aventis that the price of Dupixent 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*.

4.0 Terms of the Voluntary Compliance Undertaking

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

4.1.1 To agree that the 2018 MAPP for Dupixent is $923.5799 per syringe, and that the 2019 NEAP for Dupixent is $938.3572 per syringe;

4.1.2 To reduce the list price of Dupixent to the 2019 NEAP of $938.3572 per 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 price has been reduced;

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.

4.1.4 To offset the excess revenues accrued by Sanofi-Aventis in respect of Dupixent in 2018 by making a payment of $1,654,520.73 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-ATP does not exceed the 2019 NEAP of $938.3572 per 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 price of Dupixent remains 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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