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

1.0 Product Summary

1.1 Patanol® (olopatadine hydrochloride) and Pataday® (olopatadine hydrochloride) are indicated for the treatment of allergic conjunctivitis and the treatment of ocular itching associated with seasonal allergic conjunctivitis, respectively.

1.2 Health Canada first issued a Notice of Compliance to Alcon Canada Inc. ("Alcon") for Patanol® 1 mg/milliliter (DIN 02233143) on September 16, 1997, and Pataday® 2 mg/milliliter (DIN 02362171) on January 21, 2011. Patanol® and Pataday® were first sold in Canada on January 26, 1998, and April 14, 2011, respectively.

1.3 The marketing authorization for Patanol® and Pataday® was transferred from Alcon to Novartis Pharmaceuticals Canada Inc. ("Novartis") on February 2, 2017.

1.4 The last reported patent pertaining to Patanol® and Pataday®, Canadian Patent No. 2,447,924, expired on June 19, 2022. Novartis is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Guidelines

2.1 Patanol® was classified by the Human Drug Advisory Panel as a Category 3 new medicine. As a new strength of an existing medicine, Pataday® was classified as a Slight or No Improvement.

2.2 In 2020, the National Average Transaction Prices (N-ATPs) for Patanol® and Pataday® began to exceed the National Non-Excessive Average Prices (N-NEAPs) by an amount which triggered the investigation criteria set out in the *Compendium of Policies, Guidelines, and Procedures* ("*Guidelines*").

3.0 Position of the Rights Holder

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Novartis that the prices of Patanol® and Pataday® 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 Novartis agrees to undertake the following:

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a rights holder to comply with the terms of the VCU to close an investigation initiated by PMPRB Staff. Consideration of a VCU is an administrative procedure and does not constitute an admission or determination by the PMPRB that the price submitted by the Rights Holder, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.

PATANOL and PATADAY are registered trademarks.

4.1.1 To offset cumulative excess revenues accrued by Novartis in respect to Patanol® and Pataday® by making a payment of $393,194.00 to Her Majesty in right of Canada, within 30 days of acceptance of this VCU:

4.1.2 In the event that a new patent is issued, to ensure that the prices of Patanol® and Pataday® comply with the PMPRB's Guidelines in all future periods in which they are under the PMPRB's jurisdiction.

Signature: _____

Name: Pedro Miguel Ferreira

Position: Country Chief Financial Officer

Rights Holder: Novartis Pharmaceuticals Canada Inc.

Date: 29 August 22

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