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

1.0 Product Summary

1.1 Pataday® (olopatadine hydrochloride) is indicated for the treatment of ocular itching associated with seasonal allergic conjunctivitis.

1.2 Health Canada issued a Notice of Compliance for Pataday® to Alcon Canada Inc. ("Alcon") on January 21 , 2011. Pataday® was first sold in Canada on April 14, 2011.

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

1.4 The last reported patent pertaining to Pataday®, Canadian Patent No. 2447924, expires on June 19, 2022. Novartis is the patentee for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Price *Guidelines*

2.1 Pataday® was classified as a Slight or No level of therapeutic improvement.

2.2 In 2016, the National Average Transaction Price (N-ATP) for Pataday® began to exceed the National Non-Excessive Average Price (N-NEAP) and as of 2018 had generated sufficient calculated excess revenues to trigger the investigation criteria set out in the *Compendium of Policies, Guidelines and Procedures* ("*Guidelines*"). As of December 31, 2018, cumulative excess revenues for Pataday® were calculated to be $72,691.53.

3.0 Positions of the Patentee and Board Staff

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Novartis that the price of Pataday® 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, Novartis undertakes:

4.1.1 To agree that the 2016, 2017, 2018 and 2019 N-NEAPs for Pataday® are as follows:

Year	N-NEAP
2016	$11.9443
2017	$11.9956
2018	$12.1182
2019	$12.4090

4.1.2 To ensure that the 2019 N-ATP for Pataday® does not exceed its 2019 N-NEAP and that the price of Pataday® is within the thresholds set out in the *Guidelines* in each market in which it is sold;

4.1.3 To offset the cumulative excess revenues accrued by Novartis in respect of Pataday® by making a payment of $72,691.53 to Her Majesty in right of Canada within 30 days of acceptance of this VCU;

4.1.4 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 semi-annual price and sales data filed by Novartis; and

4.1.5 To ensure that the price of Pataday® remains within the PMPRB's *Guidelines* in all future periods in which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Lison Prévost

Position: Vice-President, Health Policy and Patient Access

Patentee: Novartis Pharmaceuticals Canada Inc.

Date: June 10, 2019_____