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

1. Product Summary

1.1 DuoTrav® PQ is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins, or other IOP lowering agents and when the use of DuoTrav® PQ (the fixed combination drug) is considered appropriate.

1.2 Health Canada issued a Notice of Compliance for DuoTrav® PQ to Alcon Canada Inc. (Alcon) on March 17, 2006. DuoTrav® PQ was first sold in Canada on April 11, 2006.

1.3 The marketing authorization for DuoTrav® PQ was transferred from Alcon to Novartis Pharmaceuticals Canada Inc. ("Novartis") on February 1, 2017.

1.4 The last reported patent pertaining to DuoTrav® PQ expires on March 13, 2029. Novartis is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2. Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel identified DuoTrav® PQ as a Category 3 drug product.

2.2 DuoTrav® PQ triggered the investigation criteria in the Guidelines in 2016. The National Average Transaction Price (N-ATP) of DuoTrav® PQ continued to exceed the thresholds in the Guidelines during 2017.

3. Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Novartis that the price of DuoTrav® PQ in Canada 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. Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Novartis undertakes:

4.1.1 To agree that the 2018 N-NEAP for DuoTrav® PQ is $11.8176;

4.1.2 To reduce the list price of DuoTrav® PQ to $11.8176 per milliliter or lower by January 26, 2018, and to take no list price increase in 2018;

4.1.3 To ensure that the 2018 N-ATP does not exceed the NEAP outlined in section 4.1.1 above;

4.1.4 To offset excess revenues accrued by Novartis in respect of DuoTrav® PQ by making a payment of $275,000 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU;

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

4.1.6 To ensure that the price of DuoTrav® PQ remains within the thresholds set out in the Guidelines, as well as the requirements of section 4.1.4 above, in all future reporting periods during which it is under the jurisdiction of the PMPRB.

Signature: Original signed by

Name: Lison Prévost

Position: Vice President, Health Policy and Patient Access

Patentee: Novartis Pharmaceuticals Canada Inc.

Date: January 4th, 2018