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

1.0 Product Summary

1.1. Neoral 50 mg capsule is indicated in the prevention of graft rejection following solid organ transplantation and in the treatment of transplant rejection in patients previously receiving other immunosuppressive agents.

1.2. The first patent pertaining to Neoral was granted on May 2, 1978 and the last patents pertaining have expired on September 26, 2014.

1.3. Health Canada issued a Notice of Compliance (NOC) for Neoral 50 mg capsule on January 13, 1995. Novartis Pharmaceuticals Canada Inc. ("Novartis") commenced sales in Canada on February 16, 1995.

1.4. Novartis was the patentee for purposes of the Patented Medicine Prices Review Board ("PMPRB").

2.0 Application of the Excessive Price Guidelines

2.1 The price of Neoral 50 mg capsule was within the Guidelines from introduction until 2014. In 2014, the price exceeded the Guidelines by an amount which triggered the investigation criteria based on the Highest International Price Comparison. Cumulative excess revenues are calculated to be $96,466.51.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Novartis that the price of Neoral 50mg is or was excessive for purposes of the *Patent Act.*

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Novartis agrees to undertake the following:

4.1 To agree that the 2014 N-NEAP for Neoral 50 mg capsule was $2.4673.

4.2 To make a payment to Her Majesty in right of Canada in the amount of $96,466.51 within 30 days of the acceptance of this VCU;

4.3 To notify the PMPRB in the event that other patents pertaining to Neoral are issued in any future periods.

Signature:	[Original signed by]
Name:	Lison Prévost
Position:	Vice-President Health Policy and Patient Access
Patentee:	Novartis Pharmaceuticals Canada Inc.
Date:	2-FEB-2016