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

1.0 Product Summary

1.1. Apprilon (doxycycline monohydrate) modified-release capsule is indicated for the treatment of only inflammatory lesions (papules and pustules) or rosacea in adult patients. No meaningful effect demonstrated for generalized erythema (redness) of **rosacea.**

1.2. Canadian Patent 2440472 pertaining to Apprilon was granted to Galderma Pharma S.A. (Switzerland) on January 18, 2011, and will expire on April 5, 2022.

1.3. Health Canada issued a Notice of Compliance (NOC) for Apprilon on November 14, 2011. Sales in Canada commenced November 29, 2012.

1.4. Galderma Canada Inc. is the patentee for purposes of the *Patent Act* and the Patented Medicines Prices Review Board (PMPRB).

2.1 Application of the Excessive Price Guidelines

2.2 Board Staff recommended Apprilon be reviewed as a Slight/No improvement and identified doxycycline as the most appropriate comparator.

2.3 In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the November to December 2012 introductory price at the national and market levels exceeded the Guidelines at a level that triggered the investigation criteria. The N-ATP and the Market Specific ATPs (MS-ATPs) continued to exceed the Guidelines in subsequent reporting periods.

3.1 Position of Patentee

3.2 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Galdenma Canada Inc. that the price of Apprilon is or was excessive for purposes of the *Patent Act.*

4.1 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Galderma Canada Inc. agrees to undertake the following:

4.2 To agree that the 2012 MAPP and subsequent 2013 – 2016 N-NEAPs for Apprilon are as follows:

2012	$2.3000
2013	$2.3207
2014	$2.3667
2015	$2.3998
2016	$2.4228

4.2 To ensure from the date of the implementation of this VCU that the 2016 N-ATP of Apprilon and the average transaction price within each market in which Apprilon is sold remains within the 2016 N-NEAP as stated in 4.1 above;

4.3 To ensure that the price of Apprilon remains within the Guidelines in all future periods in which Apprilon is under the PMPRB's jurisdiction.

Name: Wendy Adams

Position: General Manager

Patentee: Galderma Canada Inc.

Date: February 4, 2016