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

1.0 Product Summary

1.1. Onreltea (brimonidine gel, 0.33%) is indicated for the topical treatment of facial erythema of rosacea in adults 18 years of age or older.

1.2. The first Canadian Patent (No. 2,530,938) pertaining to Onreltea was issued to Galderma Pharma S.A. (Switzerland) on December 13, 2011, and the last issued Canadian Patent No. 2,567,401 will expire on May 25, 2025.

1.3. Health Canada issued a Notice of Compliance ("NOC") for Onreltea on February 26, 2014. Sales in Canada commenced March 24, 2014.

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

2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel ("HDAP") recommended Onreltea be reviewed as a Slight/No improvement and identified azelaic acid, metronidazole and brimonidine ocular drops as the most appropriate comparators.

2.2 In accordance with the Board's Guidelines, a Therapeutic Class Comparison ("TCC") test and a Highest International Price Comparison ("HIPC") test were conducted. The results of these tests indicated that the March to June 2014 introductory price exceeded the Guidelines at a level that triggered the investigation criteria. Specifically, the Market Specific Average Transaction Price ("MS-ATP") for the Wholesaler class of customer was 6.6% above the Maximum Average Potential Price ("MAPP").

2.3 In subsequent reporting periods up to the January to December 2016 reporting period, the MS-ATP exceeded its respective Market-Specific Non-Excessive Average Price (MS-NEAP) for the Wholesaler class of customer. Collectively, five of ten markets in which Onreltea was sold had MS-ATPs above their respective MS-NEAPs in 2015, while eight of ten MS-ATPs in these markets exceeded their respective MS-NEAPs in 2016.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Galderma that the price of Onreltea is 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

In order to comply with the Guidelines, Galderma Canada Inc. undertakes:

4.1 To agree that the MAPP and N-NEAPs for Onreltea are as follows:

2014	$3.3000
2015	$3.0383
2016	$3.0985
2017	$3.0999

4.2 To reduce the individual Canadian list price of Onreltea to no greater than $3.4485per gram;

4.3 To ensure the 2018 N-ATP of Onreltea is below the calculated 2018 N-NEAP and to ensure that the price in each market where Onreltea is sold is within the thresholds set out in the Guidelines;

4.4 To offset any excess revenues received from January 1, 2017, to the date of implementation of this VCU, by making a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of excess revenues calculated based on the semi-annual price and sales data filed by Galderma, as required by the *Patented Medicines Regulations* and the 2017 N-NEAP set out in 4.1 above;

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

Name: Vifican Pham

Position: Director, Finance, IT & Analytics

Patentee: Galderma Canada Inc.

Date: February 2, 2018