

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

1.0 Product Summary

1.1 Tactuo (adapalene/benzoyl peroxide) is a patented medicine sold in Canada by Galderma Canada Inc. (Galderma). It is Indicated for the treatment of acne vulgaris, characterized by comedones, inflammatory papules/pustules with or without occasional nodules in patients 12 years of age and older.

1.2 Health Canada issued a Notice of Compliance (NOC) for the sale of Tactuo 1/25 on March 21, 2011 (DIN 02365871). Sales in Canada commenced May 3, 2011.

1.3 Canadian Patent No. 2,466,321 pertaining to Tactuo was granted to Galderma R&D, France on November 8, 2011 and will expire December 9, 2022. The patent was laid open for public inspection in July 2003. As a result, the Board's jurisdiction commences as of date of first sale in May 2011. Galderma is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended a moderate level of therapeutic improvement, based on secondary factors. The HDAP further recommended that Tactuo (a fixed drug combination) be compared to the Individual components: adapalene and benzoyl peroxide for purposes of conducting a Therapeutic Class Comparison (TCC) test.

2.2 In accordance with the Guidelines, a TCC test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the introductory price of Tactuo exceeded the Guidelines based on the TCC test. Specifically, the 2011 introductory price of Tactuo of \$1.4300 exceeded the maximum allowable potential price (MAPP) of \$1.2534 by 14.1% resulting in excess revenues of \$419,468.12 as of December 31, 2012.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Galderma that the price of Tactuo in Canada is now, or was at any time since date of first sale, excessive for purposes of the Patent Act.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

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

4.1.1 To agree that the 2011 MAPP and the 2012, 2013 National Non- Excessive Average Prices (N-NEAPs) of Tactuo are as follows:

2011	\$1.2534
2012	\$1.2722
2013	\$1.3048

4.1.2 To ensure the national average transaction price of Tactuo in 2013 does not exceed the 2013 N-NEAP of \$1.3048;

4.1.3 To offset the cumulative excess revenues received by Galderma from May 2011 to December 31, 2012 by making a payment to Her Majesty In right of Canada in the amount of \$419,468.12 within 30 days of the acceptance of this VCU;

4.1.4 In the event that the national average transaction price of Tactuo is not within the Guidelines as per 4.1.1, to offset any excess revenues received during the period January 1, 2013 to December 31, 2013 by making a further payment to Her Majesty in right of Canada within 30 days of the filing of the July to December 2013 price and sales data in accordance with the Patented Medicines Regulations for such further amounts, to be calculated by Board Staff;

4.1.5 To ensure that the national average transaction prices of Tactuo remains within the Guidelines in all future periods during which Tactuo is under the PMPRB's jurisdiction.

Galderma Canada Inc.

Signature

Company Officer:

Title:

Date:

Francis Fournier
President
April 15, 2013