

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

1 Product Summary

- 1.1 Differin Pledget (adapalene) is a patented medicine sold in Canada by Galderma Canada Inc. (Galderma).
- 1.2 Adapalene is used for the topical treatment of acne vulgaris. Adapalene 0.1% is supplied in a cream, gel and solution.
- 1.3 Canadian Patent 1,266,646 pertaining to Differin Topical Liquid was granted to C.I.R.D., France (now Galderma R&D, France) on March 13, 1990 and will expire on March 13, 2007. Galderma is the patentee for purposes of the Patented Medicine Prices Review Board (the Board).
- 1.4 Health Canada issued a Notice of Compliance to Galderma for Differin Pledget Solution 1mg/ml (DIN 02148757) on January 24, 1995. Galderma began selling Differin Pledget on July 1, 2001 at a price of \$0.7774 per ml.

2 Application of the Excessive Price Guidelines

- 2.1 Board Staff conducted its review of the price of Differin Pledget Solution in accordance with the Board's Excessive Price Guidelines. Differin Pledget was classified as a category 1 new medicine in that it is a new DIN of a comparable dosage form of an existing medicine. A Reasonable Relationship (RR) Test and International Price Comparison (IPC) Test were conducted.
- 2.2 By applying the Board's Excessive Price Guidelines, Board Staff concluded that the price of Differin Pledget Solution exceeded the 2001 Maximum Non-Excessive (MNE) price of \$0.5780 per ml by 34.5% with resulting excess revenues of \$17,575.12 during the introductory period July 1, 2001 to December 31, 2001.

3 Terms of the Voluntary Compliance Undertaking

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Galderma that the price of Differin Pledget Solution is or was excessive for purposes of the Patent Act.
- 3.2 In order to comply with the Excessive Price Guidelines and policies of the Board, Galderma undertakes as follows:
 - 3.2.1 To reduce the average selling price within 30 days of acceptance of this VCU so that the average price for 2002 does not exceed the 2002 MNE.
 - 3.2.2 To advise customers that price reductions have been implemented as a result of this undertaking.
 - 3.2.3 To offset excess revenues received by Galderma for the sale of Differin Pledget during the period July 1, 2001 to December 31, 2001 by making a payment to Her Majesty the Queen in the right of Canada, within 30 days of the acceptance of this undertaking, in the amount of \$17,575.
 - 3.2.4 To ensure that the price of Differin Pledget remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction.

Galderma Canada Inc.

Signature: Denis Roy
(original signed by)

Title: Director of Marketing

Date: August 12, 2002