

Approved by the Chairperson on January 17, 2012

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
LEO PHARMA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Dovobet is a patented medicine sold in Canada by LEO Pharma Inc. since December 27, 2001 for the topical treatment of psoriasis. It is supplied in the form of an ointment containing 50 mcg/g of calcipotriol and 0.5 mg/g of betamethasone dipropionate (DIN 02244126).
- 1.2 There are 3 patents pertaining to Dovobet;
- Patent No. 2151730 was issued on January 4, 2005 and will expire on January 7, 2014.
 - Patent No. 2561590 was issued on November 18, 2008 and will expire on March 23, 2025.
 - Patent No. 2370565 was issued on November 25, 2008 and will expire on January 27, 2020.
- 1.3 LEO Pharma Inc. is the Canadian patentee for all purposes relating to the *Patent Act* and the *Patented Medicines Regulations* in respect of the jurisdiction of the Patented Medicine Prices Review Board (PMPRB).

2.0 Background

- 2.1 Following a price hearing, which was the subject of a judicial review by the Federal Court of Canada, the Board ordered on September 17, 2007 that LEO Pharma pay the sum of \$3,736,398.71 and ensure that the price of Dovobet remains below the Maximum Non-Excessive (MNE) price for all future periods in which it remains under the Board's jurisdiction.
- 2.2 During the January to December 2010 period, the price of Dovobet was excessive. In particular, the price of \$1.3800 was 0.7% above the MNE price of \$1.3710, resulting in excess revenues of \$32,019.28. During the subsequent reporting period, the price of Dovobet was within the Guidelines.

3.0 Terms of the Voluntary Compliance Undertaking

- 3.1 In order to resolve this matter LEO Pharma Inc. agrees to undertake as follows:
- 3.1.1 To agree that the National Non-Excessive Average Price (N-NEAP) for Dovobet in 2010 and 2011 are \$1.3710 and \$1.4038, respectively.

- 3.1.2 To offset the cumulative excess revenues as calculated by Board Staff and received by LEO Pharma Inc. during the period of January 1, 2010 to December 31, 2010, by making a payment to Her Majesty in right of Canada, within 30 days of acceptance of this VCU, in the amount of \$32,019.98.
- 3.1.3 To ensure that the price of Dovobet remains within the Guidelines in all future reporting periods in which Dovobet remains under the PMPRB's jurisdiction.

LEO Pharma Inc.

Signature: Original signed by

Company Officer: Adam R. Coote

Position: VP, Market Access & Business Intelligence

Date: January 11, 2012