

WITHOUT PREJUDICE
VOLUNTARY COMPLIANCE UNDERTAKING
OF
LEO PHARMA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

- 1.1 Dovobet (calcipotriol/betamethasone dipropionate) is a patented medicine which is sold in Canada by LEO Pharma Inc. since December 27, 2001.
- 1.2 Dovobet is indicated for the topical treatment of psoriasis. Dovobet is classified in the World Health Organization ("WHO") Anatomical Therapeutic Chemical ("ATC") index 2003 as D05AX - Other antipsoriatics for topical use. 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).
- 1.3 Canadian Patent No. 2,151,730 pertains to Dovobet. This patent was granted to LEO Pharmaceuticals Prod. Ltd., Denmark, on January 4, 2005 and expires on January 7, 2014. LEO Pharma Inc. is the Canadian patentee for all purposes relating to the *Patent Act* ("Act") and the *Patented Medicines Regulations, 1994* ("Regulations") in respect of the jurisdiction of the Patented Medicine Prices Review Board ("PMPRB").
- 1.4 Health Canada issued a Notice of Compliance ("NOC") for Dovobet on June 11, 2001. It was first sold in Canada in December 2001.

2.0 Notice of Hearing

- 2.1 Pursuant to the provisions of section 83 of the Act, the PMPRB issued a Notice of Hearing on November 29, 2004 to determine whether LEO Pharma Inc. is selling or has sold the medicine known as Dovobet in any market in Canada at a price that is or was excessive and if so, what order, if any, should be made.
- 2.2 Upon conducting its hearing and for the Reasons of the Board issued April 19, 2006 and August 21, 2007, and the Reasons of the Federal Court issued March 21, 2007, on September 17, 2007 the Board Ordered as follows:

1. The maximum non-excessive ("MNE") price of Dovobet for the introductory period January to June 2002 is \$1.2132 per gram. For the period July to December 2002, the MNE is \$1.1926 based on the highest international price of Dovobet.

2. The MNE price of Dovobet for subsequent years, to be calculated on a yearly basis, is equal to the lesser of:

a) the benchmark price of Dovobet, adjusted for increases in the consumer price index ("CPI") based on the methodology set out in Schedule 4 of the PMPRB's Compendium of Guidelines, Policies and Procedures ("Guidelines"); and

b) the highest price at which Dovobet is sold in any of the countries listed in Schedule 1 of the *Patented Medicines Regulations, 1994* based on the methodology set out in Schedule 3 of the Guidelines.

3. The MNE price of Dovobet was \$1.2206 for 2003, \$1.2536 for 2004 and \$1.2950 for 2005.

4. For the periods under review, the distribution of free Dovobet by LEO Pharma is to be included in the calculation of the Average Transaction Price (ATP) of Dovobet, and excess revenues shall be calculated on that basis.

5. LEO Pharma shall pay to the Crown, by cheque payable to the Receiver General of Canada and forwarded to the Secretary of the Board, the sum of \$3,736,398.71, representing excess revenues for the period from the introduction of Dovobet in Canada to the end of 2005 within 30 days of this Order, no later than October 18, 2007.

6. LEO Pharma shall ensure that the ATP of Dovobet remains below the MNE price, as calculated pursuant to paragraph 2, for all future periods in which it remains under the Board's jurisdiction.

2.3 For the period January 1, 2006 through December 31, 2006, Board Staff calculated the MNE price in accordance with the Board Order set out above. The 2006 MNE price is \$1.2963. In 2006, the ATP of Dovobet exceeded the 2006 MNE price, resulting excess revenues of \$870,425.68.

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 offset the cumulative excess revenues as calculated by Board Staff and received by LEO Pharma Inc. during the period of January 1, 2006 to December 31, 2006, by making a payment to Her Majesty in right of Canada, within 30 days of acceptance of this VCU, in the amount of \$870,425.68.

LEO Pharma Inc.

Signature:

Original signed by

Company Officer:

KEN JONES

Position:

PRESIDENT

Date:

09/01/08