Conseil d'examen du prix des médicaments brevetés

Decision: PMPRB-04-D4-Dovobet

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c.P-4 as amended

AND IN THE MATTER OF LEO Pharma Inc. (the "Respondent") and the medicine "Dovobet"

ORDER

Pursuant to the provisions of section 83 of the *Patent Act*, the Patented Medicine Prices Review Board issued a Notice of Hearing on November 29, 2004 to determine whether LEO Pharma Inc. ("LEO Pharma") 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.

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, the Board Orders 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.

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- 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.

Board Members: Robert G. Elgie

Réal Sureau

Thomas (Tim) Armstrong

Board Counsel: Gordon Cameron

Original signed by
Sylvie Dupont
Secretary of the Board

September 17, 2007