

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

**1.0 Product Summary**

- 1.1 Levemir<sup>®</sup> Penfill<sup>®</sup> (Levemir) is the brand name of a medicine known generically as insulin detemir. Levemir is a patented medicine sold in Canada by Novo Nordisk Canada Inc. (Novo Nordisk Canada).
- 1.2 Levemir is a soluble, long-acting basal insulin analogue with a flat and predictable action profile with a prolonged duration of action for blood glucose control. It is supplied as an injectable solution in a 3 mL cartridge in a strength of 100 IU/mL of insulin detemir in pack sizes of 5 cartridges.
- 1.3 Health Canada issued a Notice of Compliance (NOC) for the sale of Levemir on September 29, 2005 (DIN 02271842) for the treatment of adult patients with type 1 or type 2 diabetes mellitus who require a long-acting (basal) insulin for the maintenance of normal glucose homeostasis.
- 1.4 Canadian Patent No. 2,171,424 pertaining to Levemir was granted to Novo Nordisk A/S, Denmark (Novo Nordisk Denmark) on June 4, 2002 and will expire on September 16, 2014. Novo Nordisk Canada is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB), and first sold Levemir in Canada on January 3, 2006.

**2.0 Application of the Excessive Price Guidelines**

- 2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Levemir should be classified as a category 3 new medicine and identified Lantus (insulin glargine), Humulin N (NPH insulin) and Novolin ge NPH (NPH insulin) as comparator drug products.
- 2.2 Board Staff and Novo Nordisk Canada agree that the introductory maximum non-excessive (MNE) price is \$5.7772.
- 2.3 Based on the above, the price of Levemir during the introductory period (January 3 to June 30, 2006) exceeded the introductory MNE price, resulting in excess revenues of \$124,767.80.
- 2.4 As Levemir continued to be sold at a price that exceeded the Guidelines, cumulative excess revenues in the amount of \$6,035,903.54 have accrued to the period ending December 31, 2009.

**3.0 Position of the Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Novo Nordisk Canada that the price of Levemir in Canada is now or was excessive for purposes of the Patent Act.
- 3.2 In order to comply with the Guidelines, Novo Nordisk Canada has lowered the price of Levemir effective April 1, 2010.

#### 4.0 Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Novo Nordisk Canada agrees to undertake the following:

4.1.1 To agree that the MNE prices are as follows:

2006 \$5.7772  
2007 \$5.8985  
2008 \$6.0372  
2009 \$6.0603

4.1.2 To ensure that the average price of Levemir from April 1, 2010 to December 31, 2010 does not exceed the 2010 National Non-Excessive Average Price (N-NEAP) of \$6.1934 in any market in Canada in which it is sold;

4.1.3 To offset the cumulative excess revenues received from January 3, 2006 to December 31, 2009 by making a payment to Her Majesty in right of Canada in the amount of \$6,035,903.54 within 30 days of the acceptance of this VCU;

4.1.4 To offset any excess revenues received from January 1, 2010 to March 31, 2010 by making a further payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU based on the company's filing of price and sales data for January to March 2010 in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Levemir at a price higher than the MNE price;

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers that the April 1, 2010 price reduction of Levemir was for purposes of ensuring adherence to the Guidelines, include a reference to the PMPRB Web site for the complete text of this VCU, and provide copies of such notifications to Board Staff;

4.1.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Levemir has been reduced in a manner consistent with the terms of this VCU; and,

4.1.7 To ensure that the price of Levemir remains within the Guidelines in all future periods in which Levemir is under the PMPRB's jurisdiction.

#### Novo Nordisk Canada Inc.

Signature:

Original signed by

Company Officer:

VINCE LAMMANNA

Position:

PRESIDENT

Date:

30 - APRIL - 2010