

**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.

