This 4th day of March, 2008

Without Prejudice
For purposes of discussion
VOLUNTARY COMPLIANCE UNDERTAKING
OF
SANOFI-AVENTIS CANADA INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 LANTUS® (insulin glargine), a patented medicine sold in Canada by sanofi-aventis Canada Inc. (sanofi-aventis), is indicated for once-daily subcutaneous administration in the treatment of adult patients with Type 1 or Type 2 diabetes mellitus and pediatric patients (age 6-17 years) with Type 1 diabetes mellitus who require basal (long-acting) insulin for the control of hyperglycemia.

1.2 LANTUS is classified in the 4th level of the World Health Organisation (WHO) Anatomical Therapeutic Chemical (ATC) classification index as Al0AE, *Drugs used in Diabetes, Insulins and analogues, Insulins and analogues, long-acting*.

1.3 LANTUS is supplied in 10 mL vials and 3 mL cartridges in packages of 5, for use with pens suitable for LANTUS cartridges.

1.4 Health Canada issued a Notice of Compliance (NOC) for the sale of LANTUS vial (DIN 02245689) on April 3, 2002 and LANTUS cartridge (DIN 02251930) on March 31, 2004. LANTUS vial has been sold in Canada since November 28, 2004 and LANTUS cartridge since September 18, 2006.

1.5 Canadian Patents 2,050,644, 1,340,237 & 1,339,044 pertaining to LANTUS were granted to the sanofi-aventis German sister corporation respectively on November 27, 2001, December 15, 1998 & April 1, 1997 and will respectively expire on September 4, 2011, December 15, 2015 & April 1, 2014. Sanofi-aventis is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.6 The results of the introductory price review of LANTUS vial are available on the PMPRB's Web site. The price of LANTUS cartridge is the subject of this Voluntary Compliance Undertaking (VCU).

2.0 Application of the Excessive Price Guidelines

2.1 LANTUS cartridge was reviewed as a category 1 new medicine as it is a new DIN of an existing dosage form of an existing medicine.

2.2 In accordance with the Board's *Excessive Price Guidelines* (Guidelines), a Reasonable Relationship (RR) test and an International Price Comparison (IPC) test were conducted for the introductory period (September 18 to December 31, 2006) and it was concluded by Board Staff that the price of LANTUS cartridge was higher than the maximum non-excessive (MNE) price of $5.4807/mL determined by the RR test. Sales of LANTUS cartridge during this period resulted in excess revenues of $694,239.50.

2.3 The price of LANTUS cartridge continued to exceed the CPI adjusted MNE price of $5.5958/mL in the subsequent year (January to December 2007), such that cumulative excess revenues as of December 31, 2007 totalled $3,969,554.83.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by sanofi-aventis that the price of LANTUS cartridge in Canada is or has been at any time sold at a price that is excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 Sanofi-aventis agrees to undertake the following:

4.1.1 To agree that the MNE price of LANTUS cartridge was $5.4807/mL at introduction in 2006, $5.5958 for 2007 and $5.6780 for 2008.

4.1.2 To reduce the average transaction price (ATP) of LANTUS cartridge within 30 days of the acceptance of this VCU so that it does not exceed the 2008 MNE price of $5.6780/mL.

4.1.3. To offset the cumulative excess revenues received from September 18, 2006 to December 31, 2006 of $694,239.50 by making a payment to Her Majesty in Right of Canada within 30 days of acceptance of the VCU.

4.1.4 To offset the cumulative excess revenues received from January 1, 2007 to the date of the price reduction per paragraph 4.1.2 above, by reducing the price of ALTACE HCT® (DINs 2283131, 2283158, 2283166, 2283174, 2283182). In the event that the full amount of excess revenues is not offset by December 31, 2008, sanofi-aventis undertakes to offset such amount by making a further payment to Her Majesty in Right of Canada within 30 days of the filing of the July to

December 2008 price and sales data in accordance with the Patented Medicines Regulations, 1994.

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reduction for LANTUS cartridge and that this price reduction is the result of an undertaking to the PMPRB, to provide a reference to the PMPRB Web site for the complete text of the VCU, and to further provide copies of such notifications to Board Staff forthwith.

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

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

Signature : Original signed by

Name : Jérôme Silvestre

Position : President and Chief Executive Officer

Company : Sanofi-aventis Canada Inc.

Date : March 4, 2008