VOLUNTARY COMPLIANCE UNDERTAKING OF SANOFI-AVENTIS CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 Eligard (leuprolide acetate) is indicated for the palliative treatment of advanced prostate cancer. It is supplied in vials of 7.5 mg, 22.5 mg, 30 mg and 45 mg for subcutaneous injection.

1.2 Health Canada issued Notices of Compliance (NOC) for Eligard 7.5 mg and 22.5 mg (DINs 02248239 and 02248240) on November 6, 2003, for Eligard 30 mg (DIN 02248999) on February 23, 2004 and for Eligard 45 mg (DIN 02268892) on July 20, 2005. Eligard 7.5 mg and 22.5 mg have been sold in Canada since December 1, 2003. Eligard 30 mg and 45 mg have been sold in Canada since April 29, 2004 and November 21, 2005 respectively.

1.3 Canadian Patents No. 2,079,831 and 2,436,275 pertaining to Eligard were granted to Atrix Laboratories Inc., USA on December 6, 2005 and January 2, 2007 respectively. The last patent will expire on September 21, 2021. Sanofi-aventis Canada Inc. (sanofi-aventis) is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 Eligard 7.5 mg, 22.5 mg, 30 mg and 45 mg were classified as category 1 new medicines under the PMPRB's *Excessive Price Guidelines* (Guidelines) as they represent new DINs of an existing or comparable dosage form of an existing medicine.

2.2 In accordance with the Guidelines, a Reasonable Relationship (RR) test and an International Price Comparison (IPC) test were conducted for each of the four strengths of Eligard. The results of these tests indicated that the introductory prices of $343.5800, $891.0000, $1285.2000 for Eligard 7.5 mg (Jan-June 2004), 22.5 mg (Jan-June 2004) and 30 mg (April-June 2004) respectively were within the Guidelines. The introductory price of $1,751.1267 for Eligard 45 mg (Nov-Dec 2005) exceeded the maximum non-excessive (MNE) price of $1,347.3596 by 30.0% as its price was higher than the prices of Eligard 45 mg in the

comparator countries in which it was sold. Excess revenues total $27,052.40 for this period.

2.3 A review of subsequent reporting periods indicated that the price of Eligard 45 mg continued to exceed its MNE price in all subsequent reporting periods and that the prices of Eligard 7.5 mg, 22.5 mg and 30 mg began to exceed the Guidelines in 2005, when the prices in the highest of the comparator countries in which Eligard was sold dropped below the Canadian prices. As a result, there were total cumulative excess revenues of $13,127,953.14 for all four strengths of Eligard as of December 31, 2008.

3.0 Position of the Patentee

3.1 This VCU constitutes no admission by sanofi-aventis that the prices in Canada of Eligard 7.5 mg, 22.5 mg, 30 mg and 45 mg are now, or were at any time since the date of the first sale, excessive for purposes of the *Patent Act*.

3.2 Eligard's prices are lower than those of the other brand of leuprolide acetate in Canada. Furthermore, the 22.5 mg, 30 mg and 45 mg offer the lowest cost Luteinizing Hormone-Releasing Hormone (LHRH) options in Canada. The 7.5 mg is the second lowest cost option in its class. Prices of the three strengths of Eligard sold in 2004 were in compliance with the Guidelines. Changes in a foreign market resulted in prices in Canada being considered excessive starting in 2005 – despite remaining below the MNE prices in 2004.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Sanofi-aventis agrees to undertake the following:

4.1.1 To agree that the prices for all strengths will be regulated at the level of each province/territory.

4.1.2 To agree that during the period 2005 to 2007, the introductory MNE price for each strength in each province/territory will be the highest IPC as set out in the table below.

	7.5 mg	22.5 mg	30 mg	45 mg
2005	$246.3360	$665.0470	$853.2754	$1347.3596
2006	$249.5041	$673.6011	$737.9748	$1212.4712
2007	$236.4789	$638.4361	$643.1517	$1210.0743

4.1.3 To agree that during the period 2005 to 2008, the MNE prices for each year after the introductory period will be as follows.

a) For provinces/territories where the introductory ATP or any subsequent ATP did not exceed the highest IPC, the MNE price will be set by the lower of the CPI-Adjustment Methodology and the highest IPC.

b) For provinces/territories where the ATP and the result of the CPI-Adjustment Methodology is greater than the highest IPC, the MNE price will be the lower of the highest IPC as set out in paragraph 4.1.2 above and below for 2008, or the introductory non-excessive price.

	7.5 mg	22.5 mg	30 mg	45 mg
2008	$242.0801	$726.2656	$968.3493	$1453.3465

c) For provinces/territories where the ATP exceeded the highest IPC but was previously less than the highest IPC, the MNE price will be set by the lower of the CPI-Adjustment Methodology and the highest IPC.

4.1.4 To offset the cumulative excess revenues received from January 1, 2005 to December 31, 2008 by making a payment to Her Majesty in right of Canada in the amount of $13,127,953.14 within 30 days of the acceptance of the VCU.

4.1.5 To agree that the 2009 MNE price for each strength of Eligard in each province/territory will be calculated as set out in sub-paragraphs a), b) and c) below.

a) Where the CPI-adjusted price established the MNE price for 2008, the CPI Adjustment Methodology will be used to establish the MNE price for 2009, as long as this price does not exceed the highest IPC.

b) Where the non-excessive introductory price established the MNE price in 2008, the CPI Adjustment Methodology will be applied for 2009 as though 2008 was the first year of sale, as long as this price does not exceed the highest IPC.

c) Where the highest IPC established the 2008 MNE price, the 2009 MNE price will be the lower of the 2009 highest IPC as at December 2009 or the non-excessive introductory price.

The 2009 MNE prices for each strength for each province/territory are included as an attachment to this VCU which Board Staff will hold confidential and will not publish.

4.1.6 To agree that from 2010 onward, the CPI Adjustment Methodology will be applied to the 2009 non-excessive prices determined in accordance with paragraph 4.1.5 a) and b) above. In provinces where paragraph 4.1.5 c) applied, the CPI Adjustment Methodology will be applied as though 2009 was the first year of sale.

4.1.7 To offset any excess revenues received from January 1, 2009 to December 31, 2009 as a result of charging prices in excess of the 2009 MNE prices calculated in accordance paragraph 4.1.3 by making payments to hospitals, cancer clinics and cancer boards that purchased Eligard, within 30 days of the filing of the July to December 2009 semi-annual price and sales data as required by the Regulations in the amount of the excess revenues, as calculated by Board Staff.

4.1.8 Within 15 days of acceptance of this VCU, to provide copies of the VCU to each province with the portion of the confidential Appendix specific to that province and to provide copies of such notifications to Board Staff; and

4.1.9 To ensure that the prices of Eligard 7.5 mg, 22.5 mg, 30 mg and 45 mg remain within the Guidelines in all future periods in which they are under the PMPRB's jurisdiction.

sanofi-aventis Canada Inc.

Signature: Original signed by

Company Officer: Axel Risse

Position: VP Finance, Admin. and SC

Date: 1. April 2009

sanofi-aventis Canada Inc.

Signature: Original signed by

Company Officer: Jerome Silvestre

Position: President & CEO

Date: April 3, 2009