

June 29, 2006

WITHOUT PREJUDICE  
Protected s.87 Privilege

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

**1. Product Summary**

- 1.1 Eloxatin (oxaliplatin) is a patented medicine sold in Canada by sanofi-aventis Canada Inc. ("Sanofi-Aventis").
- 1.2 Eloxatin is used to treat patients with metastatic carcinoma of the colon or rectum whose disease has recurred or progressed during or within six months of completion of first-line therapy with the combination of bolus 5-FU/LV and irinotecan. Eloxatin is classified in the WHO ATC index 2004 as a member of the 4<sup>th</sup> level ATC class L01XA: antineoplastic and immunomodulating agents; antineoplastic agents, other antineoplastic agents; platinum compounds. It is the third entry in this 4<sup>th</sup> level ATC class to be introduced in Canada.
- 1.3 A Notice of Compliance has not been issued; however, Eloxatin has been sold in 50 mg and 100 mg vials since May 1, 2000 under Health Canada's Special Access Program at \$500 and \$1000 per vial respectively.

**2. Application of the Excessive Price Guidelines**

- 2.1 The Patented Medicine Prices Review Board (PMPRB)'s Human Drug Advisory Panel (HDAP) recommended that Eloxatin be classified as a category 3 new medicine and further recommended Camptosar as the most appropriate comparator.
- 2.2 In accordance with the PMPRB's *Excessive Price Guidelines* (Guidelines), Therapeutic Class Comparison (TCC) tests and International Price Comparison (IPC) tests were conducted. The results of the IPC tests indicated that the introductory prices of Eloxatin 50 mg and Eloxatin 100 mg vials of \$500.0000 and \$1,000.0000 per vial appeared to exceed the maximum non-excessive (MNE) prices of \$430.9208 and \$922.6750 by 16.0% and 8.4%, respectively, based on the highest international price, namely Switzerland. At the time of introduction in Canada, Eloxatin was sold in six of the seven comparator countries; it was not sold in the US. Eloxatin is presently sold in all seven comparator countries.
- 2.3 The price review results showed that the average transaction price (ATP) of Eloxatin 50 mg and 100 mg vials continued to exceed the Guidelines in subsequent years, such that cumulative excess revenues as of March 31, 2006 totalled \$1,767,078.84 for the two vial sizes.

**3. Position of the Patentee**

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Sanofi-Aventis that the prices of Eloxatin 50 mg and 100 mg are or were excessive for purposes of the *Patent Act*.

**4. Terms of the Voluntary Compliance Undertaking**

4.1 Under the terms of this VCU, Sanofi-Aventis undertakes as follows:

- a) To agree that the MNE prices for Eloxatin 50 mg and 100 mg were \$430.9208 and \$922.6750 at introduction and that they are \$490.5901 and \$1,030.0175 in 2006.
- b) In lieu of a price reduction for the 50 mg vial and in order to avoid a distortion in the pricing relationship between the 50 mg and 100 mg vials, to maintain the price of Eloxatin 100 mg vial at \$1,000.00 until such time as the MNE price for the 50 mg vial reaches \$500.00.
- c) Within 30 days of acceptance of this VCU, to offset excess revenues received from the sale of Eloxatin by making payments totalling \$1,767,078.84 to hospitals, cancer clinics and cancer boards that previously purchased Eloxatin at excessive prices. The individual payments shall reflect the distribution of purchases of Eloxatin across Canada up to the end of March 31, 2006.
- d) To notify customers receiving payments that the payment 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.
- e) To ensure that the prices remain within the Guidelines while Eloxatin is under the PMPRB's jurisdiction, at least until the end of the January to June 2019 reporting period.

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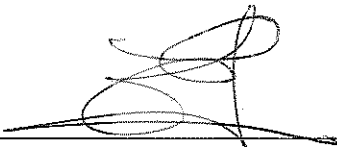
**sanofi-aventis Canada Inc.**

Signature: Original signed by

Company Officer (1): JÉRÔME SILVESTRE

Position: President

Date: 29.6.06

Signature: 

Company Officer (2): E. BRODAURST

Position: Vice President Finance & Administration

Date: 29/06/06