

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

1.0 Product Summary

- 1.1 Suprax 400 mg/tablet (cefixime) is an antibiotic used in the treatment of infections caused by susceptible strains of designated micro-organisms.
- 1.2 Health Canada issued a Notice of Compliance (NOC) for Suprax on November 29, 1995 (DIN 02195984). Suprax is classified in the 4th level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification index as J01DA, known as: Anti-infectives for Systemic Use; Antibacterials for Systemic Use; Other Beta-Lactam Antibacterials; Cephalosporins and related substances. Suprax 400 mg/tablet has been sold in Canada since 1995.
- 1.3 Canadian Patent No. 2,094,122 pertaining to Suprax was granted to Aventis Pharma SA, France on July 20, 2004 and will expire on November 8, 2011. 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 The introductory price of Suprax 400 mg/tablet was reviewed in accordance with the PMPRB's *Excessive Price Guidelines* (Guidelines) and was found by Board Staff to be within the Guidelines.
- 2.2 In 2006, the price of Suprax 400 mg/tablet exceeded the Guidelines, but did not trigger the criteria for commencing an investigation. In 2007 and 2008, the price triggered the investigation criteria. As a result, there were cumulative excess revenues of \$97,900.30 as of June 30, 2008.

3.0 Position of the Patentee

- 3.1 This VCU constitutes no admission by sanofi-aventis that the prices in Canada of Suprax 400 mg/tablet is now, or was at any time since the date of the first sale of the medicine, excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 Sanofi-aventis agrees to undertake the following:

- 4.1.1 To agree that the MNE price of Suprax 400 mg/tablet was \$3.2454 in 2006, \$3.2829 in 2007, \$3.3305 in 2008 and that it is calculated to be \$3.4304 in 2009;
- 4.1.2 To reduce the price of Suprax 400 mg/tablet within 30 days of the acceptance of this VCU so that it does not exceed the 2009 MNE price set out in sub-paragraph 4.1.1 above;
- 4.1.3 To offset the cumulative excess revenues received from July 1, 2007 to June 30, 2008 by making a payment to Her Majesty in right of Canada in the amount of \$97,900.30 within 30 days of the acceptance of the VCU;
- 4.1.4 To offset any excess revenues received during the period July 1, 2008 to December 31, 2008 by making a payment within 30 days of the filing of semi-annual price and sales data as required by the *Patented Medicines Regulations* in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Suprax 400 mg/tablet at prices in excess of the 2008 MNE price set out in sub-paragraph 4.1.1 above;
- 4.1.5 To offset any excess revenues received during the period January 1, 2009 to the date of the price reductions per sub-paragraph 4.1.2 above by making a payment within 30 days of the filing of semi-annual price and sales data as required by the *Patented Medicines Regulations* in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Suprax 400 mg/tablet at prices in excess of the 2009 MNE price set out in sub-paragraph 4.1.1 above;
- 4.1.6 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reductions for Suprax 400 mg/tablet 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 provide copies of such notifications to Board Staff;

- 4.1.7 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Suprax 400 mg/tablet has been reduced in a manner consistent with the terms of this VCU; and
- 4.1.8 To ensure that the price of Suprax 400 mg/tablet remains within the Guidelines in all future periods in which Suprax 400 mg/tablet is under the PMPRB's jurisdiction.

sanofi-aventis Canada Inc.

Signature: Original signed by
Company Officer: Jérôme Silvestre
Position: President and Chief Executive Officer
Date: 12 DEC. 2008

Signature: Original signed by
Company Officer: Pat Papillo
Position: Director, Financial Controlling
Date: 12/12/08