

October 28, 2009

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

**1. Product Summary**

- 1.1 Claritin Allergy & Sinus Extra Strength (10 mg loratadine / 240 mg pseudoephedrine sulphate) - (*Claritin Allergy & Sinus ES*) - is indicated for the relief of symptoms associated with allergic rhinitis, including nasal and sinus congestion, sneezing, postnasal discharge and tearing and redness of the eyes. It is supplied in oral solid dosage form in an extended release caplet of 250 mg containing 10 mg of loratadine and 240 mg of pseudoephedrine sulfate, and is sold over the counter (OTC).
- 1.2 Canadian Patents Nos. 1,272,480 and 2,147,606 pertaining to *Claritin Allergy & Sinus ES* were granted to Schering Corporation (United States) on August 7, 1990 and October 10, 2000 respectively. The last patent will expire on October 21, 2013. Schering-Plough Canada Inc. (Schering-Plough Canada) is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 On December 24, 2004, Health Canada issued a Notice of Compliance (NOC) to Schering-Plough Canada for *Claritin Allergy & Sinus ES*, and sales of the medicine began in Canada on March 3, 2005.

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

- 2.1 At introduction, *Claritin Allergy & Sinus ES* was classified as a category 1 new medicine under the Board's *Excessive Price Guidelines* (Guidelines). The introductory price of *Claritin Allergy & Sinus ES* in Canada at \$0.9738 per caplet was 4.5% above the maximum non-excessive (MNE) price of \$0.9318 per caplet, resulting in excess revenues of \$85,903.23.
- 2.2 During the subsequent reporting periods, the price of *Claritin Allergy & Sinus ES* continued to exceed the Guidelines until December 31, 2007 and by June 30, 2009 cumulative excess revenues remained in the amount of \$69,950.43.

**3. Position of Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Schering-Plough Canada that the price of *Claritin Allergy & Sinus ES* is or was excessive for purposes of the *Patent Act*.

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

4.1 In order to comply with the Guidelines, Schering-Plough Canada undertakes as follows:

4.1.1. To agree that the MNE prices for *Claritin Allergy & Sinus ES* are as follows:

- \$0.9318 for 2005;
- \$0.9504 for 2006;
- \$0.9709 for 2007;
- \$0.9933 for 2008;
- \$1.0122 for 2009.

4.1.2 To ensure that the price of *Claritin Allergy & Sinus ES* does not exceed the 2009 MNE price as per 4.1.1 of this VCU;

4.1.3 To offset the cumulative excess revenues received from January 1, 2005 to June 30, 2009 by making a payment to Her Majesty in right of Canada in the amount of \$69,950.43 within 30 days of the acceptance of this VCU;

4.1.4 To ensure that the price of *Claritin Allergy & Sinus ES* remains within the Guidelines in all future periods in which *Claritin Allergy & Sinus* is under the PMPRB's jurisdiction.

Signature: Original signed by

Name: Michael Tease

Position: General Manager, Consumer Health Care

Patentee: Schering-Plough Canada Inc.

Date: 26 October 28, 2009

c.c. Jacques Sénéchal, Director, Government and Health Affairs. Schering-Plough