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Draft VCU attached to letter of August 4, 2011

VOLUNTARY COMPLIANCE UNDERTAKING OF MERCK CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

1.1. Nasonex {mometasone furoate 0.05 mg / dose} (DIN 02238465) is indicated:

- For use in adults, adolescents, and children between the ages of 3 and 11 years to treat the symptoms of seasonal or perennial allergic rhinitis.
- For use in adults and children 12 years of age and older as adjunctive treatment to antibiotics in acute episodes of rhinosinusitis, where signs or symptoms of bacterial infection are present.
- For use in adults and children 12 years of age and older in the treatment of symptoms associated with mild to moderate uncomplicated acute rhinosinusitis where signs or symptoms of bacterial infection are not present.
- The treatment of nasal polyps in adult patients 18 years of age or older.

1.2. On July 22, 1998, Health Canada granted a Notice of Compliance to Schering Canada Inc. for the marketing authorization of Nasonex. Canadian sales began on September 9, 1998.

1.3. Canadian Patent No. 2,091,360 pertaining to Nasonex was issued to Schering Corp. (USA) on April 8, 1997. This patent will expire on September 6, 2011. Schering Canada Inc. became Schering Plough Canada Inc., which then merged with Merck Frosst Canada Inc. to form Merck Canada Inc., which is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2. Application of the Excessive Price Guidelines

2.1. At introduction, Nasonex was classified as a category 3 new drug and was within the Guidelines.

2.2. The 2010 ATP of Nasonex exceeded the Guidelines by an amount that resulted in excess revenue triggering the investigation criteria.

2.1 Cumulative excess revenues were $165,098.43 as of December 31, 2010.

3 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Merck Canada Inc. that the prices of Nasonex were excessive for purposes of the *Patent Act*.

4 Terms of the Voluntary Compliance Undertaking

4.1 Merck Canada Inc. agrees to undertake the following:

4.1.1 To agree that the 2010 and 2011 National Non-Excessive Average Prices (N-NEAPs) are as follows:

2010	$0.1938
2011	$0.1986

4.1.2 To reduce the price of Nasonex within 30 days of the acceptance of this VCU so that it does not exceed the 2011 N-NEAP of $0.1986;

4.1.3 To offset the cumulative excess revenues received from January 1, 2010 to December 31, 2010 by making a payment to Her Majesty in right of Canada in the amount of $165,098.43 within 30 days of the acceptance of the VCU;

4.1.4 To offset any excess revenues received during the period January 1, 2011 to the date of reduction of the price of Nasonex as per sub-paragraph 4.1.2 of this VCU 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 Nasonex at a price in excess of the 2011 N-NEAP set out in sub-paragraph 4.1.1 above;

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reductions for Nasonex and to communicate 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;

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

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

Signature: Original signed by

Name: C SCHIEVER

Position: PRESIDENT

Company: Merck Canada Inc.

Date: 11/09/19