

VOLUNTARY COMPLIANCE UNDERTAKING OF  
VALEANT CANADA LP TO  
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

- 1.1 Loprox 10 mg/milliliter (ciclopirox olamine) is indicated for the topical treatment of dermal infections.
- 1.2 Canadian Patent 2,267,309 pertaining to Loprox was granted to Sanofi-Aventis Deutschland GmbH (Germany) on February 21, 2006, and will expire on September 16, 2017.
- 1.3 Health Canada issued a Notice of Compliance (NOC) for Loprox 10 mg/milliliter on April 23, 1990. Sales in Canada commenced on April 1, 1998.
- 1.4 Valeant Canada LP is the patentee for purposes of the *Patent Act* and the Patented Medicines Prices Review Board (PMPRB).

2.0 Application of the *Excessive Price Guidelines*

- 2.1 Loprox 10 mg/milliliter was classified as a category 1 new medicine under the **PMPRB's Excessive Price Guidelines as it represented a new DIN of an existing or comparable dosage form of an existing medicine.**
- 2.2 The price of Loprox 10 mg/milliliter was within the Guidelines as of December 31, 2012. In 2013, it began to exceed the Guidelines by an amount which did not trigger the investigation criteria. In particular, the National Average Transaction Price (N-ATP) exceeded the National Non-Excessive Average Price (N-NEAP) by 31.0%.
- 2.3 In 2014, the price of Loprox 10 mg/milliliter continued to exceed the Guidelines. The N-ATP exceeded the N-NEAP as established by the Highest International Price Comparison test by 5.6%. As of December 31, 2014, cumulative excess revenues were \$23,947.35.

3.0 Position of Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Valeant Canada LP that the price of Loprox 10 mg/milliliter is or was excessive for purposes of the *Patent Act*.

#### 4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Valeant Canada LP agrees to undertake the following:

- 4.1 To agree that the 2013 and 2014 N-NEAPs for Loprox 10 mg/milliliter are \$0.3107 and \$0.3023, respectively;
- 4.2 To reduce the 2015 N-ATP to be lower than the 2014 N-NEAP as set out in paragraph 4.1 above within 30 days of the acceptance of this VCU;
- 4.3 To offset cumulative excess revenues received by Valeant Canada LP as of December 31, 2014, by making a payment to Her Majesty in right of Canada in the amount of \$23,947.35 within 30 days of the acceptance of this VCU;
- 4.4 To ensure that the price of Loprox 10 mg/milliliter remains within the Guidelines in all future periods in which Loprox is under the PMPRB's jurisdiction.

Name: Richard Lajoie

Position: Vice President

Patentee: Valeant Canada LP

Date: 21/10/2015