

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

**1.0 Product Summary**

- 1.1 Crixivan in combination with antiretroviral agents is indicated for the treatment of HIV infection
- 1.2 The first Canadian Patent No. 2081970 pertaining to Crixivan was granted to Merck Sharp & Dohme Corp. on July 8, 1997 and the last Canadian Patent No. 2183976 expired on February 27, 2014.
- 1.3 On September 13, 1996 Health Canada granted a Notice of Compliance to Merck Canada Inc. for Crixivan 400 mg capsule and sales began in Canada on September 26, 1996.
- 1.4 Merck Canada Inc. was the patentee for purposes of the Patented Medicines Prices Review Board (PMPRB).

**2.0 Application of the Excessive Price Guidelines**

- 2.1 The price of Crixivan 400 mg capsule was within the Guidelines from introduction until 2010 when it began to exceed the Guidelines by an amount which did not trigger the investigation criteria.
- 2.2 In 2013, however, the price of Crixivan 400 mg capsule exceeded the Guidelines triggering the investigation criteria based on the Highest International Price Comparison. In particular, the 2013 price of Crixivan 400 mg capsule was above the National-Non Excessive Average Price (N-NEAP) resulting in excess revenues of \$56,617.91 as of December 31, 2013. As of February 27, 2014, cumulative excess revenues were \$58,917.68.

**3.0 Position of Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Merck Canada Inc. that the price of Crixivan 400 mg capsule is or was excessive for purposes of the *Patent Act*.
- 3.2 From 2001 to present, the list price of Crixivan 400 mg capsule, \$2.6933 per capsule, has not changed. In certain reporting periods, the price appeared higher than the list price but this was due to the inclusion of returns in the calculation.

#### 4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Merck Canada Inc. agrees to undertake the following:

- 4.1 To agree that the 2013 and 2014 N-NEAPs for Crixivan 400 mg capsule are \$2.4604 and \$2.5094 respectively.
- 4.2 To offset cumulative excess revenues received by Merck Canada Inc. as of February 27, 2014, by making a payment to Her Majesty in right of Canada in the amount of \$58,917.68 within 30 days of the acceptance of the VCU;
- 4.3 To notify the PMPRB in the event that other patents pertaining to Crixivan are issued in any future period.

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Patentee: Merck Canada Inc.

Date: \_\_\_\_\_