

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

1.0 Product Summary

- 1.1. Nocdurna (desmopressin acetate) is an antidiuretic indicated for treatment of nocturia in adults with four or less nocturnal voids.
- 1.2. Health Canada granted a Notice of Compliance to Ferring Inc. (**Ferring**) for Nocdurna 25 mcg/tablet (DIN 02397927) (**Nocdurna 25 mcg**) on December 6, 2012. Nocdurna 25 mcg was first sold in Canada on July 31, 2013. Health Canada granted a second Notice of Compliance to Ferring for Nocdurna 50 mcg/tablet (DIN 02431076) (**Nocdurna 50 mcg**) on September 4, 2014. Nocdurna 50 mcg was first sold in Canada on November 17, 2014.
- 1.3. The last reported patent pertaining to Nocdurna 25 mcg and Nocdurna 50 mcg is Canadian Patent No. 2484724, which will expire on May 7, 2023. Ferring is the patentee for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board.

2.0 Application of the Excessive Price Guidelines

- 2.1 The National Average Transaction Prices (**N-ATPs**) of Nocdurna 25 mcg and Nocdurna 50 mcg sold by Ferring began to exceed the thresholds set out in the Guidelines in 2016. As of December 31, 2017, cumulative excess revenues were determined to be \$94,977.75.

3.0 Position of the Patentee

- 3.1 This VCU constitutes no admission by Ferring that the price of Nocdurna 25 mcg or Nocdurna 50 mcg is now, or was at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 Pursuant to this VCU, Ferring undertakes:
 - 4.1.1 To agree that the 2019 Non-Excessive Average Prices (**NEAPs**) for Nocdurna 25 mcg and Nocdurna 50 mcg are \$1.3200 per tablet;
 - 4.1.2 To abstain from taking any list price increase above the current list price of \$1.3200 per tablet for the remainder of the PMPRB's jurisdiction over Nocdurna 25 mcg or Nocdurna 50 mcg;
 - 4.1.3 To offset the excess revenues accrued by Ferring in respect of Nocdurna 25 mcg and Nocdurna 50 mcg by making a payment of \$94,977.75 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU; and

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

- 4.1.4 To ensure that the prices of Nocdurna 25 mcg and Nocdurna 50 mcg remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Sumintra Singh_____

Position: Senior Director Finance__

Patentee: Ferring Inc.

Date: July 2, 2019_____

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