

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

**1.0 Product Summary**

- 1.1. Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is an antiretroviral agent indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults and adolescents (aged 12 years and older with a body weight at least 40 kilograms) and with no known mutations associated with resistance to the individual components of Symtuza.
- 1.2. Health Canada granted a Notice of Compliance to Janssen Inc. (Janssen) for Symtuza 1160 mg per tablet (DIN 02473720) on March 8, 2018. Symtuza was first sold in Canada on April 26, 2018.
- 1.3. The last reported patent pertaining to Symtuza will expire on May 1, 2029. Janssen 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 Board Scientific Staff classified Symtuza as a Slight or No Level of Therapeutic Improvement. Board Staff conducted Therapeutic Class Comparison (TCC) and Highest International Price Comparison (HIPC) tests. The TCC test established the Maximum Average Potential Price (MAPP).
- 2.2 The introductory National Average Transaction Price (N-ATP) of Symtuza exceeded the MAPP by 7.6%, triggering the investigation criteria in the Guidelines. As of December 31, 2018, cumulative excess revenues totaled \$4,590.73.

**3.0 Position of the Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Janssen that the price of Symtuza 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, Janssen will undertake:
  - 4.1.1 To agree that the 2018 MAPP for Symtuza is \$47.7260 per tablet, and that the 2019 NEAP for Symtuza is \$48.4896 per tablet;
  - 4.1.2 To reduce the list price of Symtuza to the 2019 NEAP of \$48.4896 per tablet within 30 days of the acceptance of this VCU;

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.

- 4.1.3 To file evidence with Board Staff within 30 days of the price reduction that customers have received notification that the price has been reduced;
- 4.1.4 To offset the excess revenues accrued by Janssen in respect of Symtuza in 2018 by making a payment of \$4,590.73 to Her Majesty in right of Canada within 30 days of the acceptance of this VCU;
- 4.1.5 To ensure that the 2019 N-ATP does not exceed the 2019 NEAP of \$48.4896 per tablet;
- 4.1.6 To offset any accrued cumulative excess revenues at the end of the period from January 1, 2019 to December 31, 2019 by making a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining cumulative excess revenues, as calculated based on the semi-annual price and sales data filed by Janssen; and
- 4.1.7 To ensure that the price of Symtuza remains within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Name: Alaine Grand

Position: Vice President, Government Affairs & Market Access

Patentee: Janssen Inc.

Date: April 4, 2019

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