

VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
BAXALTA CANADA CORPORATION  
TO  
THE PATENTED MEDICINE PRICES REVIEW BOARD

**1.0 Product Summary**

- 1.1 Oncaspar (pegaspargase) is not approved in Canada. Oncaspar is made available by Baxalta Canada Corporation (“Baxalta”) to Canadian patients under the Health Canada Special Access Programme (“SAP”). In the United States, Oncaspar is approved as a component of multi-agent chemotherapeutic regimens to treat acute lymphoblastic leukemia (ALL).
- 1.2 Baxalta acquired the rights for Oncaspar in July 2015 from Sigma Tau Finanziaria S.p.A.
- 1.3 In the United States, Oncaspar is sold in single use vials containing 3,750 International Units per 5 mL solution.

**2.0 Application of the Excessive Price Guidelines (“Guidelines”)**

- 2.1 The PMPRB Staff conducted the Median International Price Comparison (“MIPC”) and Consumer Price Index (CPI) tests. The results of these tests indicate that the July to December 2015 and January to June 2016 average transaction prices at the national and market levels exceeded the Guidelines resulting in cumulative excess revenues of \$2,866,888.60.

**3.0 Position of Baxalta**

- 3.1 This Voluntary Compliance Undertaking (VCU) is a compromise between the PMPRB and Baxalta. This VCU constitutes no admission by Baxalta that the price of Oncaspar is now, or was at any time since the date of first sale of the medicine excessive for purposes of the *Patent Act*.

**4.0 Terms of the VCU**

Baxalta undertakes to:

- 4.1 Agree that the 2015 through 2018 National Non-Excessive Average Prices (“N-NEAPs”) for Oncaspar are:
  - July to December 2015: \$1,199.2106 / mL
  - January to December 2016: \$1,223.1948 / mL
  - January to December 2017: \$1,236.3861 / mL

- January to March 13, 2018: \$1,253.1751 / mL

- 4.2 The 2016 to 2018 N-NEAPS outlined in 4.1 are subject to change only if the N-NEAP in a given year exceeds the highest international price comparison (HIPC) test in that year.
- 4.3 Offset excess revenues of \$2,866,888.60 by making payments to customers that purchased Oncaspar between July 1, 2015 and June 30, 2016. The repayments to customers will be determined in amounts proportional to their purchases in the July 2015 to June 2016 period. The payments will be made within 30 days of the acceptance of this VCU.
- 4.4 Provide notice to customers of the price reduction for Oncaspar and that this price reduction and repayments are 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 further provide copies of such notifications and payments to Board Staff forthwith. The notice to customers will be provided within 30 days of acceptance of this VCU.
- 4.5 Ensure the price of Oncaspar remains within PMPRB Guidelines until March 13, 2018, and, in any future periods in which Oncaspar is under the PMPRB's jurisdiction.
- 4.6 To notify the PMPRB in the event that patents pertaining to Oncaspar are issued in any future period.

**Baxalta Canada Corporation:**

Company Officer: Eric Tse  
Position: General Manager  
Date: December 9, 2016