VOLUNTARY COMPLIANCE UNDERTAKING
OF
SALIX PHARMACEUTICALS INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Zaxine is indicated for the reduction in risk of overt hepatic encephalopathy (HE) **recurrence in patients 18 years of age or older.**

1.2. Canadian Patent 2645724 pertaining to Zaxine was granted to Alfa Wassermann S.P.A. (Italy) on August 28, 2012, and will expire on July 31, 2027.

1.3. Health Canada issued a Notice of Compliance (NOC) for Zaxine on **August 13, 2013. Salix Phamaceuticals Inc. commenced sales in Canada on** November 7, 2013.

1.4. Salix Pharmaceuticals Inc. which is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB) was acquired by Valeant Pharmaceuticals International Inc. in 2015.

2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel recommended Zaxine be reviewed as a moderate improvement based on primary factors and identified no comparators.

2.2 In accordance with the Guidelines, a Median International Price Comparison test was conducted. The results this test indicated that the November to December 2013 introductory price exceeded the Guidelines at a level that triggered the investigation criteria.

2.3 The National Average Transaction Price (N-ATP) of Zaxine was 114.7% above the **Maximum Average Potential Price (MAPP) resulting in excess revenues of** $122,000.98. Cumulative excess revenues were calculated to be $915,738.19 as of February 3, 2015.

2.4 The Market Specific ATPs (MS-ATPs) were above the MAPP in the introductory period in 2013. In subsequent reporting periods, the MS-ATPs exceeded their **respective Non-Excessive Average Prices (NEAPs) in au markets where Zaxine was sold.**

2.5 The MIPC established the interim benchmark price at the national level for review in relation to the Guidelines in subsequent reporting periods as Zaxine was sold in fewer than five countries. At the end of three years or when the same patented drug product with the same strength and dosage form is sold in at least five countries, whichever occurs first, Board Staff will re-determine the Median International Price.

3.0 **Position of Patentee**

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Salix Pharmaceuticals Inc. that the price of Zaxine is or was excessive for purposes of the *Patent Act.*

3.2 The list price of Zaxine was reduced to $7.6775 on February 4, 2015.

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Salix Pharmaceuticals Inc. agrees to undertake the following:

4.1 To agree that the MAPP and 2014 and 2015 N-NEAPs for Zaxine are $7.3404, $7.4872 and $7.5239 respectively;

4.2 To reduce the N-ATP of Zaxine in 2015 to the 2015 N-NEAP as stated in 4.1 above and ensure that the price in each market where Zaxine is sold is within the Guidelines;

4.3 To offset cumulative excess revenues received by Salix Pharmaceuticals Inc. as of February 4, 2015, by making a payment to Her Majesty in right of Canada in the amount of $915,738.19 within 30 days of the acceptance of this VCU;

4.4 To ensure that the price of Zaxine remains within the Guidelines in all future periods in which Zaxine is under the PMPRB's jurisdiction.

Signature : [Original signed by]

Name : Deb Jorn

Title : Executive Vice-President

Patentee : Salix Pharmaceuticals Inc.

Date : 12/08/2015