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

1.0 Product Summary

1.1 Fibristal 5 mg/tablet (ulipristal acetate) is indicated for the treatment of moderate to severe signs and symptoms of uterine fibroids in adult women of reproductive age, who are eligible for surgery.

1.2 Health Canada issued a Notice of Compliance (NOC) for Fibristal 5 mg/tablet on June 24, 2013. Sales in Canada commenced on July 4, 2013.

1.3 Canadian Patents 2,713,254 and 2,745,084 pertain to Fibristal 5 mg/tablet and were granted to Laboratoire HRA Pharma (France). The first patent pertaining was granted on October 7, 2014.The last patent pertaining will expire on December *8,* 2029.

1.4 Actavis Specialty Pharmaceuticals Co.is the patentee for purposes of the *Patent Act* and the Patented Medicines Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 The Human Drug Advisory Panel recommended Fibristal 5 mg/tablet be reviewed as a Moderate Improvement based on primary factors and identified Lupron Depot, Zoladex/Zoladex LA, Trelstar and Suprefact Depot as the most appropriate comparators.

2.2 In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test, Midpoint test and a Highest International Price Comparison (HIPC) test were conducted. The results of these tests indicated that the July to December 2013 introductory price passed the TCC test but exceeded the Guidelines based on the HIPC test at the national level and in each of the markets. In particular the introductory list price of $11.46 and the National Average Transaction Price (N-ATP) of $11.0959 were above the Maximum Average Potential Price (MAPP) of $9.0651 resulting in excess revenues of $401,001.77. The MAPP was established by the HIPC test.

2.3 In the subsequent reporting periods, the N-ATP and the Market Specific Average Transaction Prices (MS-ATP) were above their respective Non-Excessive Average Prices (NEAP).

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Allergan Inc. that the price of Fibristal 5 mg/tablet is or was excessive for purposes of the *Patent Act.*

4.0 Terms of the Voluntary Compliance Undertaking

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

4.1 To offset cumulative excess revenues received by Allergan Inc.in 2013 and 2014 by making a payment to Her Majesty in right of Canada in the amount of $809,568.89 within 30 days of the acceptance of this VCU.

4.2 To ensure the 2016 N-ATP of Fibristal 5 mg/tablet is at or below the 2015 HIPC. If Allergan Inc. complies with this N-ATP then Board Staff will not pursue the excess revenue generated in 2015 by Fibristal 5 mg/tab.

4.3 To ensure that the N-ATP of Fibristal remains within the HIPC (because the N-NEAP will be set by the HIPC) of the previous year until such time as the HIPC exceeds $11.46. At which time the N-ATP of Fibristal 5 mg/tablet would be considered within the Guidelines at or below $11.46/tablet and usual CPI Methodology and Guidelines would apply.

4.4 To ensure that the price of Fibristal 5 mg/tablet remains within the Guidelines in all future periods in which Fibristal 5 mg/tablet is under the PMPRB's jurisdiction.

Name: Arima Ventin

Position: Executive Director

Patentee: Allergan Inc.

Date: June 24, 2016