

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

**1.0 Product Summary**

- 1.1. Mitosol (mitomycin) is an antimetabolite indicated as an adjunct to ab externo glaucoma surgery.
- 1.2. Canadian Patent No. 2,659,314 pertaining to Mitosol was granted to Mobius Therapeutics, LLC (U.S.A.) on July 7, 2015, and will expire on July 11, 2027.
- 1.3. Mitosol was first sold on May 22, 2015 as an Investigational New Drug
- 1.4. Labtician Ophthalmics Inc. 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 (HDAP) recommended Mitosol be reviewed as a Moderate Improvement based on secondary factors and identified mitomycin as the most appropriate comparator.
- 2.2 In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted, and the Midpoint between the Median International Price Comparison (MIPC) and the TCC test was calculated. The results of these tests indicated that the introductory price of Mitosol exceeded the Guidelines by an amount which triggered the investigation criteria.
- 2.3 The National Average Transaction Price (N-ATP) and the Market Specific ATPs (MS-ATPs) of Mitosol were above the Maximum Average Potential Price (MAPP), resulting in excess revenues of \$190.58 as of June 30, 2015.

**3.0 Position of Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Labtician Ophthalmics Inc. that the price of Mitosol is now, or was at any time since the date of first sale, excessive for purposes of the *Patent Act*.

#### 4.0 Terms of the Voluntary Compliance Undertaking

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

4.1 To agree that the MAPP and N-NEAPs for Mitosol are as follows:

2015	\$189.4181
2016	\$193.2065

- 
- 4.2 To ensure the N-ATP of Mitosol in 2016 does not exceed the 2016 N-NEAP as stated in 4.1 above and ensure that the price in each market where Mitosol is sold is within the Guidelines;
- 4.3 To offset cumulative excess revenues received by Labtician Ophthalmics Inc. as of June 30, 2015, by making a payment to Her Majesty in right of Canada in the amount of \$190.58 within 30 days of the acceptance of this VCU;
- 4.4 To offset any additional excess revenues received from July 1, 2015, to the date of implementation of this VCU, as calculated by Board Staff, within 30 days of the filing of the July to December 2015 price and sales data;
- 4.5 To ensure that the price of Mitosol remains within the Guidelines in all future periods in which Mitosol is under the PMPRB's jurisdiction.

Signature: \_\_\_\_\_  
Original signed by

Name: Polydor Strouthos

Position: President

Patentee: Labtician Ophthalmics Inc.

Date: January 14, 2016