September 29, 2010

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

1.0 Product Summary

1.1 Miochol-E® (acetylcholine chloride), a patented medicine sold in Canada since July 29, 1996 by Novartis Pharmaceuticals Canada Inc. (Novartis), is indicated to obtain miosis of the iris in seconds after delivery of the lens in cataract surgery, in penetrating keratoplasty, iridectomy and other anterior segment surgery where rapid miosis may be required.

1.2 Canadian Patent No. 2,327,398 pertaining to Miochol-E® was granted to Novartis on December 30, 2008 and will expire on April 27, 2019. Novartis is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 Miochol-E® was classified by the PMPRB as a category 1 new drug product. Its introductory price was reviewed in accordance with the PMPRB's *Excessive Price Guidelines* (Guidelines) and was found by Board Staff to be within the Guidelines.

2.2 A review of subsequent periods indicated that Miochol-E® began to exceed the guidelines in the July-Dec 2000 reporting period, and continued to do so in 2001, 2004, 2005 and from 2007 into the first half of 2010. Excess revenues accrued through to June 30, 2010 totaled $323,870.70.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission whatsoever by Novartis that the price of Miochol-E® in Canada is now or was at any time excessive for purposes of the Patent Act.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 Notwithstanding paragraph 3.1 above, in order to settle the file, Novartis agrees, on a without prejudice basis and without admission of any liability whatsoever, to the following:

4.1.1 That the PMPRB has concluded that the 2000 to 2009 MNE prices and the 2010 National Non-Excessive Average Price (N-NEAP) for Miochol-E® are as follows:

2000: $15.5318
2001: $15.9201
2002: $16.2773
2003: $16.0355
2004: $15.7534
2005: $16.2733
2006: $16.2902
2007: $15.7639
2008: $16.3314
2009: $16.0236
2010: $16.4883

4.1.2 To reduce the price of Miochol-E® effective September 27, 2010 such that it does not exceed the 2010 N-NEAP price of $16.4883 for the remainder of 2010;

4.1.3 To offset the cumulative excess revenues received by Novartis from July 1, 2000 to June 30, 2010 by making a payment to Her Majesty in right of Canada in the amount of $323,870.70 within 30 days of the acceptance of this VCU;

4.1.4 To offset any excess revenues received by Novartis from July 1, 2010 through September 26, 2010 by making a further payment to Her Majesty in right of Canada within 30 days of the acceptance of the VCU in the amount of the excess revenues, as calculated by Board Staff based on the company's filing of price and sales data from July through September 26, 2010, received as a result of selling Miochol-E® at a price higher than the 2010 N-NEAP;

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers that the September 27, 2010 price reduction of Miochol-E® was for purposes of ensuring adherence to the Guidelines, include a reference to the PMPRB Web Site for the complete text of this VCU, and provide copies of such notifications to Board Staff;

4.1.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Miochol-E® has been reduced in a manner consistent with the terms of this VCU.

4.1.7 To ensure that the price of Miochol-E® remains within the Guidelines in all future reporting periods during which Novartis continues to sell the product as a patented medicine.

Novartis Pharmaceuticals Canada Inc.

Signature:	Original signed by
Company Officer:	Tom Rossi
Position:	President
Date:	September 29, 2010