Accepted by the Chairperson of the Board

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

1.0 Product Summary

1.1 Trileptal® (oxcarbazepine) is a patented medicine sold in Canada by Novartis Pharmaceuticals Canada Inc. (Novartis). Trileptal® is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults and in children and adolescents aged 6 to 16 years.

1.2 Trileptal® is supplied in tablet form in strengths of 150 mg, 300 mg and 600 mg and in a 60 mg/mL oral suspension. This document relates to the tablet formulations. Health Canada issued a Notice of Compliance (NOC) for the sale of the three strengths of Trileptal® tablets on April 13, 2000 (DINs 02242067, 02242068 and 02242069). All three strengths have been sold in Canada since April 2002.

1.3 Trileptal® is a patented product and Novartis is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 Board Staff has concluded that the pricing of the oral suspension is compliant therefore the present VCU applies exclusively to the tablet formulations.

2.0 Application of the Excessive Price Guidelines – Position of Board Staff

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Trileptal® tablets be classified as category 3 new medicines as they provide moderate, little or no improvement over comparable medicines available in Canada at the time of first sale. The HDAP identified Tegretol®, Lamictal® and Topamax® as the most appropriate comparators for Trileptal 300 mg and 600 mg. The HDAP recommended that Trileptal® 150 mg be compared on a mg to mg basis to the 300 mg and 600 mg strengths, as the 150 mg strength is generally a titration or a pediatric dose.

2.2 In accordance with the Board's then *Excessive Price Guidelines* (Guidelines), a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted for Trileptal® 300 mg and 600 mg. A Reasonable Relationship (RR) test and an IPC test were conducted for Trileptal® 150 mg. Board Staff's position is that the results of these tests indicated that the introductory price of Trileptal® 150 mg was within the Guidelines, but that the introductory prices of Trileptal® 300 mg and 600 mg exceeded the Guidelines based on their respective TCC tests, and therefore, the introductory prices of Trileptal® 300 mg and 600 mg exceeded their maximum non-excessive (MNE) prices of $0.9950 and $1.9900.

2.3 Furthermore, the prices of Trileptal® 300 mg and 600 mg tablets continued to exceed the Guidelines in all subsequent reporting periods. For purposes of this VCU, alleged cumulative excess revenues for Trileptal® 300 mg and 600 mg tablets are calculated to be $3,471,084.02 as of December 31, 2011.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) is the result of discussions with Board Staff and constitutes no admission by Novartis that the prices of Trileptal® tablets in Canada are now, or were at any time since date of first sale, excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 Novartis agrees to undertake the following:

4.1.1 To agree that the 2002 to 2009 MNE prices and the 2010 to 2012 National Non-Excessive Average Prices (N-NEAPs) of Trileptal® 150 mg, 300 mg and 600 mg are as follows:

	150 mg	300 mg	600 mg
2002	$0.7497	$0.9950	$1.9900
2003	$0.7707	$1.0229	$2.0457
2004	$0.7703	$1.0408	$2.0815
2005	$0.7749	$1.0647	$2.1293
2006	$0.7965	$1.0863	$2.1725
2007	$0.7989	$1.1085	$2.2168
2008	$0.8260	$1.1350	$2.2698
2009	$0.8039	$1.1395	$2.2790
2010	$0.8191	$1.1584	$2.3166
2011	$0.8333	$1.1929	$2.3856
2012	$0.8236	$1.2124	$2.4249

4.1.2 In order to align the pricing relationship between Trileptal® 150 mg, 300 mg and 600 mg, to maintain the price of Trileptal® 150 mg at its 2012 N-NEAP of $0.8236 until such time as the N-NEAPs of Trileptal® 300 mg and 600 mg reach $1.6472 and $3.2944 respectively;

4.1.3 To reduce the prices of Trileptal® 300 mg and 600 mg tablets within 30 days of the acceptance of this VCU so that they do not exceed the 2012 N-NEAPs set out in paragraph 4.1.1;

4.1.4 To offset alleged cumulative excess revenues received by Novartis from April 2002 to December 31, 2011 by making a payment to Her Majesty in right of Canada in the amount of $1,000,000 within 30 days of the acceptance of this VCU**;**

4.1.5 To offset alleged remaining excess revenues of $2,471,084.02 by reducing the prices of Trileptal® 300 mg and 600 mg tablets by an additional twenty-seven percent (27%) below their respective 2012 N-NEAPs until December 31, 2015 after which time Novartis can increase the price of Trileptal® 300 mg and 600 mg tablets until such time that the ATPs reach the 2015 N-NEAPs.

4.1.6 Any of the $2,471,084.02 excess revenues and any additional excess revenues received by Novartis from January 1, 2012 to the date of the implementation of the price reduction in paragraph 4.1.3 that have not been offset by December 31, 2015 are to be offset by further payments to Her Majesty in right of Canada within 30 days of the filing of the December 31, 2015 price and sales data as required by the *Patented Medicines Regulations.*

4.1.7 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reductions for Trileptal® tablets and that these price reductions are the result of discussions with PMPRB Staff that includes an undertaking to the PMPRB to provide a reference to the PMPRB website for the complete text of the VCU, and to provide copies of such notifications to Board Staff;

4.1.8 To file evidence with Board Staff, within 30 days of the acceptance of this VCU, that the prices of Trileptal® 300 mg and 600 mg tablets have been reduced in a manner consistent with the terms of this VCU; and

4.1.9 To ensure that the prices of Trileptal® remain within the Guidelines in all future periods during which Trileptal is under the PMPRB's jurisdiction.

Novartis Pharmaceuticals Canada Inc.

Signature:	Original signed by
Company Officer:	Karen Netherton
Position:	Vice President – Reimbursement and Public Affairs
Date:	May 2, 2012