Accepted by the Chairman – November 18, 2009
September 25, 2009

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

1.0 Product summary

1.1 Trinipatch® (nitroglycerin), a patented medicine sold in Canada from March 16, 2006 to January 13, 2009 by Novartis Pharmaceuticals Canada Inc. (Novartis) is indicated for the prevention of anginal attacks in patients with stable angina pectoris associated with coronary artery disease.

1.2 Trinipatch® is supplied in transdermal patches delivering 0.2 mg, 0.4 mg and 0.6 mg of nitroglycerin per hour (Trinipatch® 0.2, 0.4 and 0.6). Health Canada issued a Notice of Compliance (NOC) to Novartis for the sale of the three strengths of Trinipatch® on January 26, 2006 (DINs 02230732, 02230733 and 02230734). All three strengths have been sold by other manufacturers in Canada since April 1999.

1.3 Canadian Patent No. 2,098,196 pertaining to Trinipatch® was granted to Theratec Inc., USA on January 21, 1997 and will expire on December 6, 2011. Novartis has been the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB) since March 2006 until January 13, 2009 at which time the company ceased selling Trinipatch® in Canada.

2.0 Application of the Excessive Price Guidelines

2.1 The prices of Trinipatch® were within the Board's *Excessive Price Guidelines* (Guidelines) in 2006, when Novartis began selling Trinipatch® in Canada and continued to be within the Guidelines in 2007. However, in 2008, the prices of Trinipatch® 0.2, 0.4 and 0.6 exceeded their CPI-adjusted maximum non-excessive (MNE) prices such that excess revenues for all three strengths at the end of the January to June 2009 reporting period totalled $47,099.61.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission whatsoever by Novartis that the prices in Canada of Trinipatch® 0.2, 0.4 and 0.6 are now, or were at any time since Novartis began selling Trinipatch® in Canada, excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 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 MNE prices of Trinipatch® 0.2, 0.4 and 0.6 were $0.2521, $0.3294 and $0.3397 respectively in 2008 and that they are calculated to be $0.2597, $0.3393 and $0.3499 for 2009;

4.1.2 To offset the cumulative excess revenues received by Novartis from January 1, 2008 to January 13, 2009 by making a payment to Her Majesty in right of Canada in the amount of $47,099.61 within 30 days of the acceptance of this VCU;

4.1.3 In the event that Novartis resumes selling Trinipatch® in Canada, to ensure that the prices of Trinipatch® are within the Guidelines in all future periods during which Trinipatch® is under the PMPRB's jurisdiction.

Novartis Pharmaceuticals Canada Inc.

Signature: Original signed by

Company Officer: Alain Boisvert

Position: Vice-President, Policy & Reimbursement

Date: September 25, 2009