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

1.0 Product summary

1.1 Trinipatch (nitroglycerin), a patented medicine sold in Canada from June 2, 2009 by Paladin Laboratories Inc. (Paladin), 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 Paladin for the sale of the three strengths of Trinipatch on January 13, 2009 (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. Paladin has been the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB) since June 2, 2009.

2.0 Application of the Excessive Price Guidelines

2.1 The prices of Trinipatch were within the Board's *Excessive Price Guidelines* (Guidelines) in 2009, when Paladin began selling Trinipatch in Canada. However, in 2010, the prices of Trinipatch 0.2, 0.4 and 0.6 exceeded their national non-excessive average price (N-NEAP) such that the cumulative excess revenues for all three strengths at the end of the January to December 2010 reporting period totalled $92,266.70.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission whatsoever by Paladin that the prices in Canada of Trinipatch 0.2, 0.4 and 0.6 are now, or were at any time since Paladin 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 comply with the Guidelines, Paladin agrees to undertake the following:

4.1.1 To agree that the N-NEAPS of Trinipatch are as follows:

Year	Trinipatch 0.2	Trinipatch 0.4	Trinipatch 0.6
2009	0.3511	0.4373	0.5063
2010	0.3574	0.4452	0.5154
2011	0.3648	0.4544	0.5260

4.1.2 To take such action as may be necessary to reduce the average selling price of the three strengths of Trinipatch within 30 days of the acceptance of this VCU so that it does not exceed the agreed upon 2011 N-NEAP;

4.1.3 To offset the cumulative excess revenues received from January 1, 2010 to December 31, 2010 by making a payment to Her Majesty in right of Canada in the amount of $92,266.70 within 30 days of the acceptance of this VCU;

4.1.4 To offset any excess revenues received by Paladin from January 1; 2011 to the date of the reduction of the price of Trinipatch as per 4.1.1 of this VCU by making a payment with 30 days of the filing of semi-annual price and sales data as required by the Patented Medicines Regulations in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Trinipatch at a price in excess of the 2011 N-NEAP set out in sub-paragraph 4.1.1 above;

4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers that the actions taken in sub-paragraph 4.1.2 reducing their price were the result of an undertaking to the PMPRB, and to provide those customers with a reference to the PMPRB Web site for the complete text of the VCU, and further, to provide Board Staff with copies of any such notifications;

4.1.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Trinipatch has been reduced in a manner consistent with the terms of this VCU; and

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

Paladin Laboratories Inc.

Signature: Original signed by

Company Officer: MICHAEL R. FREEMAN

Position: VICE-PRESIDENT GOVERNMENT AFFAIRS

Date: MAY 24, 2011