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

1.0 Product Summary

1.1 Tridural (tramadol hydrochloride) 100, 200 and 300 mg/tab (Tridural) is indicated for the management of moderate to moderately severe pain in adults who require treatment for several days of more.

1.2 Health Canada issued a Notice of Compliance (NOC) for Tridural on June 15, 2007. Tridural was first sold in Canada on August 14, 2007 and is currently marketed in Canada by Paladin Labs Inc. (Paladin)

1.3 Canadian Patent No. 2,123,160 is the first patent that pertains to Tridural and was issued on April 29, 2003. The last patent pertaining to Tridural (Canadian Patent No. 2,489,855) expires on October 7, 2024. Paladin is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 As of December 31, 2016, Tridural exceeded its 2016 National Non-Excessive Average Price (N-NEAP), based on the HIPC, by 39.75%, 116.52% and 126.35% for the 100 mg/tab, 200 mg/tab and 300 mg/tab respectively.

2.2 As of December 31, 2016 cumulative excess revenues for the three dosage strengths of Tridural were $1,101,679.19, $1,995,170.43 and $2,074,789.44 respectively.

3.0 Positions of the Patentee and Board Staff

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Paladin that the price of Tridural is now, or was at any time since the date of first sale, excessive for purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

4.0 **Terms of the Voluntary Compliance Undertaking**

In order to comply with the Guidelines, Paladin will undertake:

4.1. To agree that the National-Non-Excessive Average Prices (N-NEAPs) of Tridural, for the purposes of compliance verification by Board Staff, are as follows:

Tridural		
Dosage	2017(2) N-NEAP	2018(1) N-NEAP
100 mg/tab	$1.0070	$0.8725
200 mg/tab	$1.4944	$1.0271
300 mg/tab	$2.2610	$1.4282

4.2 To ensure that the 2018 N-ATPs of each dosage strength of Tridural outlined in 4.1 above does not exceed its 2018(1) N-NEAP and to ensure that the price in each market where Tridural is sold is within the Guidelines;

4.3 To repay the excess revenues dating back to the first period in which the price of any of the three dosage strengths of Tridural exceeded the HIPC test if the N-ATPs of any of the three strengths exceed their respective N-NEAPs outlined in 4.1 above; and

4.4 To ensure that the price of Tridural remains within the PMPRB's Guidelines in all future periods in which Tridural is under the PMPRB's jurisdiction.

Signature: _____

Name: Livio Di Francesco

Position: General Manager

Patentee: Paladin Labs Inc.

Date: July 24, 2017.

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.