

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

1.0 Product Summary

- 1.1 Trelstar (triptorelin pamoate) Trelstar 11.25 mg/vial (Trelstar) is indicated for the palliative treatment of hormone dependent advanced carcinoma of the prostate gland.
- 1.2 Health Canada issued Notices of Compliance for Trelstar 11.25 mg/vial on May 24, 2001. Trelstar 11.25 mg/vial was first sold in Canada on August 15, 2006.
- 1.3 The first reported patent that pertains to Trelstar, Canadian Patent No. 1326438, was issued on January 25, 1994. The last reported patent pertaining to Trelstar, Canadian Patent No. 2688478, expires on June 6, 2028. Paladin Labs Inc. (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 The Human Drug Advisory Panel identified Trelstar as a Category 3 level of therapeutic improvement.
- 2.2 The National Average Transaction Price (N-ATP) of Trelstar 11.25 mg/vial first exceeded its N-NEAP during the January to December 2013 reporting period and continued to exceed its N-NEAP through the January to December 2014 reporting period. As of December 31, 2017, cumulative excess revenues for Trelstar were \$157,159.70.

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 Trelstar 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*.

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.

4.0 **Terms of the Voluntary Compliance Undertaking**

4.1 Pursuant to this VCU, Paladin undertakes to offset the cumulative excess revenues for Trelstar 11.25 mg/vial by making a payment of \$157,159.70 to Her Majesty in right of Canada within 30 days of acceptance of this VCU.

Signature: _____

Name: Livio Di Francesco

Position: GM Paladin Labs Inc.

Patentee: Paladin Labs Inc.

Date: January 11, 2019

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