

VOLUNTARY COMPLIANCE UNDERTAKING
OF
SIGMA-TAU PHARMACEUTICALS INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

- 1.1 Carnitor IV is indicated for the prevention and treatment of carnitine deficiency in patients with end stage renal disease who are undergoing dialysis.
- 1.2 The first Canadian Patent No. 2,381, 187 pertaining to Carnitor IV was issued to Sigma-Tau Industrie Farmaceutiche Riunite, S.P.A (Italy) on June 2, 2009 and lapsed on January 15, 2015.
- 1.3 Health Canada granted a Notice of Compliance (NOC) for Carnitor IV 200 mg/ml on January 19, 1995 and sales in Canada for Carnitor IV 200 mg/ml commenced on that date.
- 1.4 The Patented Medicines Prices Review Board's (PMPRB's) jurisdiction commenced on the publication date of the patent on July 26, 2001.
- 1.5 Sigma-Tau Pharmaceuticals Inc. has been licensed the rights to Canadian Patent 2,381, 187 from Sigma-Tau Industrie Farmaceutiche Riunite, S.P.A (Italy) and is the patentee for the purposes of the PMPRB.

2.0 Background to Reporting of Pricing Information to the PMPRB

- 2.1 In January 2014, Sigma Tau Pharmaceuticals Inc. advised Board Staff that it became aware of the existence of Canadian Patent 2,381, 187 and subsequently filed the Form 1 Medicine Information Sheets and Form 2 price and sales data from July 2001 to January 2015.

3.1 Application of the Excessive Price Guidelines

- 3.2 Carnitor IV 200 mg/ml was reviewed as a Slight/No improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the July to December 2001 introductory price exceeded the Maximum Average Potential Price (MAPP) of \$1.5699 at a level that triggered the investigation criteria, resulting in excess revenues of \$225,909.13 as of December 31, 2001.
- 3.3 The price continued to exceed the Guidelines in the subsequent reporting periods and as of January 15, 2015, cumulative excess revenues were \$11,211,237.60.

4.0 Position of Patentee

4.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Sigma-Tau Pharmaceuticals Inc. that the price of Carnitor IV 200 mg/ml is or was excessive for purposes of the *Patent Act*.

5.0 Terms of the Voluntary Compliance Undertaking

5.1 In order to comply with the Guidelines, Sigma-Tau Pharmaceuticals Inc. agrees to undertake the following:

5.1.1 To offset part of the cumulative excess revenues received by Sigma-Tau Pharmaceuticals as of January 15, 2015, by making a payment to Her Majesty in right of Canada in the amount of \$5,688,632.64 within 30 days of the acceptance of the VCU;

5.1.2 To offset the remaining excess revenues (\$5,522,604.96) received by Sigma-Tau Pharmaceuticals Inc. as of January 15, 2015 by making payments to customers that purchased Carnitor IV 200 mg/ml over this period, based on Sigma-Tau Pharmaceuticals Inc.'s historic records, as provided to and agreed-upon with the PMPRB. It is the intention that each such repayment shall approximate the historic distribution of purchases of Carnitor IV 200 mg/ml across Canada up to January 15, 2015 by basing it on an extrapolation from the data available for the distribution between July 2013 and June 2014 so as to arrive at an approximate distribution allocation for the entirety of the period for which excess revenues accumulated. All payments shall be made within 30 days of acceptance of this VCU.

5.1.3 Within 30 days of acceptance of this VCU, to advise each of the aforementioned customers of the repayment specific to their hospital and to further advise that these actions are the result of an undertaking to the PMPRB, to provide a reference to the PMPRB website for the complete text of the VCU, and to further provide copies of such notifications to the PMPRB forthwith.

5.1.4 To notify the PMPRB in the event that other patents pertaining to Carnitor IV 200 mg/ml are issued in any future period.

Signature: _____

Name: Mike Minarich CEO

Position: CEO

Patentee: Sigma-Tau Pharmaceuticals

Inc. Date: August 27, 2015