

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
SEPRACOR PHARMACEUTICALS, INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

1.1 Niaspan (extended-release niacin) is indicated as an adjunct to diet for reduction of elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B and triglyceride levels, and to increase high density lipoprotein cholesterol in patients with primary hypercholesterolaemia and mixed dyslipidaemia, when the response to an appropriate diet and other non-pharmacological measures have been inadequate.

2.0 Application of the Excessive Price Guidelines

2.1 Niaspan 500 mg tablets introductory price was within the Board's Guidelines.

2.2 In 2009, the price of Niaspan 500 mg began to exceed the Guidelines by an amount which did not trigger the investigation criteria. The price of Niaspan 500 mg exceeded the Guidelines in 2010 by an amount that resulted in excess revenue triggering the investigation criteria.

2.3 In particular, the National Average Transaction Price (N-ATP) in 2010 of \$1.1904 was 1.7% above the National Non-Excessive Average Price (N-NEAP) of \$1.1705, resulting in cumulative excess revenues of \$76,554.47 as of December 31, 2010.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Sepracor that the price in Canada of Niaspan 500 mg tablet is or was excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Sepracor undertakes as follows:

4.1.1 To agree that the 2009 maximum non-excessive (MNE) price, 2010 and 2011 N-NEAPs for Niaspan 500 mg tablet are as follows:

2009	\$1.1486
2010	\$1.1705
2011	\$1.1920

4.1.2 To reduce the price of Niaspan 500 mg tablet within 30 days of acceptance of this VCU so that it does not exceed the 2011 N-NEAP price of \$1.1920 for the remainder of 2011;

- 4.1.3 To offset the cumulative excess revenues received from January 2009 to December 2010 by making a payment to Her Majesty in right of Canada in the amount of \$76,554.47 within 30 days of the acceptance of this VCU;
- 4.1.4 To offset any excess revenues received by Sepracor from January 1, 2011 to the date of the implementation of the price reduction as per paragraph 4.1.2 by making a further payment to Her Majesty in right of Canada within 30 days of the filing of the 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 Niaspan 500 mg tablet at a price higher than the 2011 N-NEAP;
- 4.1.5 To ensure that the price of Niaspan 500 mg tablet remains within the Guidelines in all future periods in which Niaspan is under the PMPRB's jurisdiction.

Signature: Original signed by
Name: Douglas Reynolds
Position: President
Patentee: Sepracor Pharmaceuticals, Inc.
Date: May 9, 2011