**DRAFT ONLY – WITHOUT PREJUDICE**

# VOLUNTARY COMPLIANCE UNDERTAKING OF BARRIER THERAPEUTICS CANADA INC. TO THE PATENTED MEDICINE PRICES REVIEW BOARD

## 1. Product Summary

1.1 Denavir (penciclovir), a new active substance, is indicated for the treatment of recurrent herpes labialis (cold sores) in adults.

1.2 It is a member of the 4th level class D06BB, known as "Dermatologicals; Antibiotics and Chemotherapeutics for Dermatological Use; Chemotherapeutics for Topical Use; Antivirals" in the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system.

1.3 Patent No. CA 2,113,080 pertaining to Denavir was issued to Novartis Consumer Health Canada Inc. on February 25, 2003 and will expire on July 3, 2012. Barrier Therapeutics Canada Inc. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 On February 2, 1999, Health Canada issued a Notice of Compliance (NOC) for Denavir to SmithKline Beecham Pharma, Division of SmithKline Beecham Inc. Two additional NOCs were issued on January 26, 2001 and May 4, 2006, respectively to Novartis Consumer Health Canada Inc. On August 15, 2006, Barrier Therapeutics Canada Inc. began selling Denavir. It is supplied in a 1.5 gram tube containing 10 mg of penciclovir per gram.

## 2. Application of the Excessive Price Guidelines

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Denavir be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing drug products) and identified Abreva (docosanol) cream and Zovirax (acyclovir) cream and ointment as comparable medicines.

2.2 Pursuant to the Board's *Excessive Price Guidelines* (Guidelines), a Therapeutic Class Comparison test and an International Price Comparison test were conducted on the introductory price of Denavir. The results of the tests indicated that the price of $14.3200 per gram exceeded by 67.5% the maximum non-excessive (MNE) price of $8.5505 per gram resulting in excess revenues of $29,528.30. By December 31, 2007, cumulative excess revenues were $61,021.80.

2.3 On January 30, 2008 Barrier Therapeutics Canada Inc. notified Board Staff that, as of December 2007, Denavir is no longer being sold in Canada.

## 3. Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Barrier Therapeutics Canada Inc. that the price of Denavir is or was excessive for purposes of the *Patent Act*.

## 4. Terms of the Voluntary Compliance Undertaking (VCU)

4.1 In order to comply with the Guidelines, Barrier Therapeutics Canada Inc. undertakes as follows:

4.1.1 To agree that the MNE prices for Denavir are as follows:

a) $8.5505 per gram for 2006
b) $8.7301 per gram for 2007

4.1.2 To offset cumulative excess revenues received from August 15, 2006 to December 31, 2007 in the amount of $61,021.80 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU.

4.1.3 To notify the PMPRB in the event Denavir is sold by Barrier Therapeutics Canada Inc. in any future period in which Denavir remains under the PMPRB's jurisdiction.

Signature: Original signed by

Name: Joan Chypyha

Position: General Manager

Patentee: Barrier Therapeutics Canada Inc.

Date: May 5/08