

Accepted by the Chairperson of the Board

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
PFIZER CANADA INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1. Product Summary

- 1.1 Diflucan (fluconazole) 2mg/mL – DIN 891835 is an antifungal antibiotic used to treat infections caused by fungus, which can invade any part of the body.
- 1.2 Canadian Patents No. 1,170,263, No. 2,030,911 and No. 1,340,275 pertaining to Diflucan were issued on July 3, 1984, November 27, 1995 and December 15, 1998 respectively, to Syngenta Ltd. of the UK. The last patent will expire on December 15, 2015. Pfizer Canada Inc. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 A Notice of Compliance was granted to Pfizer Canada Inc. for Diflucan 2 mg/mL (DIN 891835) on August 27, 1990. Diflucan was first sold in Canada on September 1, 1990.

2. Application of the Guidelines

- 2.1 At introduction, the Board's Human Drug Advisory Panel (HDAP) identified Diflucan as a category 2 new medicine. The national average transaction price (N-ATP) began to exceed the Guidelines in 2005. An investigation was commenced in 2009 when the N-ATP exceeded the maximum non-excessive price (MNE) by 5% or more and there were excess revenues in excess of \$25,000.00.
- 2.2 As of December 31, 2011, there were cumulative excess revenues of \$30,951.51.

3. Position of Patentee

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

4. Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Pfizer Canada Inc. undertakes as follows:

- 4.1.1 To agree that the 2011 and 2012 National Non-excessive Average Prices (N-NEAPs – previously referred to as MNE) of Diflucan 2 mg/mL are as follows:
- 2011 \$0.3691
2012 \$0.3756
- 4.1.2 To reduce the price of Diflucan 2 mg/mL within 30 days of the acceptance of this VCU, so that it does not exceed the 2012 N-NEAP price of \$0.3756;
- 4.1.3 To offset the cumulative excess revenues received from January 1, 2005 to December 31, 2011 by making a payment of \$30,951.51 to Her Majesty in right of Canada, within 30 days of the acceptance of this VCU;
- 4.1.4 To offset any excess revenues received during the period from January 1, 2012 to the date of reduction of the price of Diflucan as per 4.1.1 of this VCU by making a payment within 30 days of the filing of semi-annual price and sales data as required by the Patented Medicine Regulations in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Diflucan at a price in excess of the 2012 N-NEAP price set out in 4.1.1 above;
- 4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reductions for Diflucan and that this price reduction is the result of an undertaking to the PMPRB, to provide a reference to the PMPRB Web site for the complete text of the VCU, and to provide copies of such notifications to Board Staff;
- 4.1.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Diflucan has been reduced in a manner consistent with the terms of this VCU; and
- 4.1.7 To ensure that the price of Diflucan 2 mg/mL remains within the Guidelines in all future periods in which Diflucan is under the PMPRB's jurisdiction.

Signature: Original signed by
Name: Ghislain Boudreau
Position: Vice President, Public Affairs
Company: Pfizer Canada Inc.
Date: 27 April 2012