

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

- 1.0 Product Summary
  - 1.1 Dificid (fidaxomicin) is indicated for the treatment of *Clostridium difficile* infection (CDI) in adults 18 years of age and older.
  - 1.2 Health Canada Issued a Notice of Compliance (NOC) to Cubist Pharmaceuticals Canada Inc. (Cubist) for the sale of Dificid on June 7, 2012. Sales in Canada commenced on June 21, 2012.
  - 1.3 Canadian Patent No. 2,676,003 pertaining to Dificid was issued on April 10, 2012 and will expire January 17, 2028.
  - 1.4 Merck acquired Cubist in January 2015.
  - 1.5 Merck Canada Inc. is the patentee for purposes of the *Patent Act* and Patented Medicine Prices Review Board (PMPRB).
- 2.0 Application of the Excessive Price Guidelines
  - 2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended Dificid be reviewed as a moderate level of therapeutic improvement based on primary **factors and identified vancomycin and metronidazole as comparators.**
  - 2.2 In accordance with the Guidelines, a TCC test was conducted, and the Midpoint between the Median International Price Comparison (MIPC) test and the TCC test was calculated. The results of these tests indicated that the introductory price of Dificid exceeded the Guidelines at a level that triggered the investigation **criteria.**
  - 2.3 The National Average Transaction Price (N-ATP) of Dificid was above the Maximum Average Potential Price (MAPP) resulting in excess revenues of \$137,518.36. Cumulative excess revenues were calculated to be \$400,000.00
- 3.0 Position of the Patentee
  - 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Merck Canada Inc. that the price of Dificid in Canada is now, or was at any time since date of first sale, excessive for purposes of the Patent Act.
  - 3.2 The list price of Dificid will be reduced to \$94.6000 on January 1, 2016.

3.3 The list prices as of June 2015 of the seven PMPRB international comparator countries are;

Country	Class of Customer	Local Price	36-month Exchange Rate*	Price (\$CDN)*
Italy	Wholesaler	75 (EURO)	1.3859	\$104
Italy	Retail	79 (EURO)	1.3859	\$109
Sweden	Retail	719 (SEK)	0.1558	\$112
Switzerland	Wholesaler	97 (CHF)	1.1660	\$113
United Kingdom	Retail	68 (GBP)	1.7210	\$116
Germany	Wholesaler	87 (EURO)	1.3859	\$121
Germany	Retail	89 (EURO)	1.3859	\$123
USA	FSS	85 (USD)	1.0830	\$92
USA	Wholesaler	165 (USD)	1.0830	\$179
*Based on 36-month average exchange rate ending June 2015				

#### 4.0 Terms of the Voluntary Compliance Undertaking (VCU)

4.1 In order to comply with the Guidelines, Merck Canada Inc. agrees to undertake the following:

4.1.1 To agree that 2016 National Non-Excessive Average Price (N-NEAP) of Difigid is \$94.6000

4.1.2 To reduce the price of Difigid 200 mg tablet on January 1, 2016;

4.1.3 To offset cumulative excess revenues received by Merck Canada Inc. by making a payment to Her Majesty In right of Canada in the amount of \$400,000.00 within 30 days of the acceptance of this VCU;

4.1.4 Within 15 days of the price reduction, to provide notification to customers that the price reduction of Difigid was for purposes of ensuring adherence to the Guidelines, include a reference to the PMPRB website for the complete text of this VCU, and provide copies of such notifications to Board Staff.

4.1.5 To file evidence with Board Staff within 30 days of the price reduction to ensure that the prices of Difigid have been reduced in a manner consistent with the terms of this VCU; and

4.1.6 To ensure that the price of Difigid remains within the Guidelines in all future periods during which Difigid is under the PMPRB's jurisdiction.

Signature : [Original signed by]  
Name : Chirfi Guindo  
Title : President & Managing Director  
Patentee : Merck Canada Inc.  
Date : November 20, 2015