

Draft attached to e-mail of May 6, 2010

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
SOLVAY PHARMA INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1. Product Summary

- 1.1 Dicetel (pinaverium bromide) is indicated for the treatment and relief of symptoms associated with irritable bowel syndrome (IBS), abdominal pain, bowel disturbances and intestinal discomfort; as well as the treatment of symptoms related to functional disorders of the biliary tract.
- 1.2 On October 23, 1993, Health Canada granted a Notice of Compliance to Solvay for Dicetel 50 mg/tablet (DIN 01950592). Sales in Canada of Dicetel 50 mg began in January 1994.
- 1.3 Canadian Patent No. 2,020,168 pertaining to Dicetel was issued to Solvay Pharmaceuticals GMBH (Federal Republic of Germany) on May 2, 2000 and will expire on June 29, 2010. Canadian Patent No. 2,254,395 pertaining to Dicetel was issued to Solvay Pharma (France) on October 23, 2007 and will expire May 6, 2017. Solvay Pharma Inc. (Solvay) is the patentee for purposes of the PMPRB.

2. Application of the Excessive Price Guidelines

- 2.1 Dicetel 50 mg was classified by the PMPRB's Human Drug Advisory Panel (HDAP) as a category 3 new medicine and the introductory price was within the Board's Guidelines.
- 2.2 In 2008, the price of Dicetel 50 mg exceeded the Guidelines. In particular, the price of \$0.3459 per tablet was 0.7% above the National Non-Excessive Average Price (N-NEAP) (previously known as the maximum non-excessive (MNE) price) of \$0.3434 per tablet, based on the CPI-Adjustment Methodology, resulting in excess revenues of \$72,703.25. By the end of December 2009, cumulative excess revenues were \$31,287.32.

3. Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Solvay that the price of Dicetel 50 mg is or was excessive for purposes of the *Patent Act*.

4. Terms of the Voluntary Compliance Undertaking

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

4.1.1. To agree that the N-NEAPs for Dicetel 50 mg are as follows:

\$0.3434 for 2008
\$0.3451 for 2009
\$0.3481 for 2010

4.1.2 Within 30 days of the acceptance of this VCU, to offset cumulative excess revenues received from January 1, 2008 to December 31, 2009 in the amount of \$31,287.32 by making a payment to Her Majesty in right of Canada.

4.1.3 To offset any excess revenues received from January 1, 2010 to the date of the acceptance 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 Medicines Regulations* in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Dicetel at a price higher than the 2010 N-NEAP.

4.1.4 To ensure that the price of Dicetel 50 mg remains within the Guidelines in all future reporting periods in which Dicetel remains under the PMPRB's jurisdiction.

Signature: _____

Name: _____

Position: _____

Company: Solvay Pharma Inc.

Date: _____