



**SOLVAY
PHARMA**

June 24, 2008

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

1.0 Product Summary

- 1.1 AndroGel 1% topical gel (testosterone) is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone. It is supplied in 2.5 g and 5.0 g gel unit-dose pouches and a 60 actuation metered dose dump delivering 1.25 g of gel per actuation. The 2.5 g/pouch is the subject of this Voluntary Compliance Undertaking (VCU).
- 1.2 Health Canada issued a Notice of Compliance (NOC) for AndroGel 2.5 g/pouch (AndroGel) on February 6, 2002 (DIN 02245345). The 2.5 g/pouch has been sold in Canada since May 2002.
- 1.3 Canadian Patent No. 2,420,895 pertaining to AndroGel was granted to Unimed Pharmaceuticals Inc., USA on March 13, 2007 and will expire on August 29, 2021. Solvay Pharma Inc. (Solvay Pharma) is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

- 2.1 AndroGel was classified as a category 1 new medicine under the PMPRB's *Excessive Price Guidelines* (Guidelines) as it represents a new DIN of an existing or comparable dosage form of an existing medicine. The existing medicine, Androderm 12.2 mg/patch, contains a different amount of testosterone, but delivers the same amount of testosterone per 24-hour period as AndroGel 2.5 g/pouch. As a result, a Reasonable Relationship (RR) test could not be conducted.
- 2.2 In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the May-June 2002 introductory price of \$3.7600 per pouch exceeded the maximum non-excessive (MNE) price of \$1.8800 by 100% with excess revenues of \$122,275.20 during this period.

- 2.3 A review of subsequent reporting periods indicated that the price of AndroGel 2.5 g/pouch continued to exceed the MNE price such that cumulative excess revenues as at December 31, 2007 were \$3,327,180.61.

3.0 Position of the Patentee

- 3.1 It is Solvay Pharma's position that the price in Canada of AndroGel 2.5 g/pouch is not now, and has never been, excessive for purposes of the *Patent Act*.

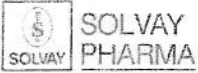
4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 In order to comply with the Guidelines, Solvay Pharma agrees to undertake the following:

- 4.1.1 To agree that the MNE prices of AndroGel 2.5 g/pouch are as follows:

| | |
|------|----------|
| 2002 | \$1.8800 |
| 2003 | \$1.9326 |
| 2004 | \$1.9665 |
| 2005 | \$2.0116 |
| 2006 | \$2.0524 |
| 2007 | \$2.0943 |
| 2008 | \$2.1263 |

- 4.1.2 To reduce the price of AndroGel 2.5 g/pouch within 30 days of the acceptance of this VCU to the 2008 MNE price of \$2.1263;
- 4.1.3 To offset the cumulative excess revenues received from May 2002 to December 31, 2007 by making a payment to Her Majesty in right of Canada in the amount of \$3,327,180.61 within 30 days of the acceptance of the VCU;
- 4.1.4 To offset the excess revenues for the period January 1, 2008 to the date of acceptance of this VCU, as calculated by Board Staff and verified by Solvay Pharma, by ensuring that the average transaction price of AndroGel 2.5 g/pouch for 2008 is at or below the 2008 MNE price of \$2.1263. In the event that any excess revenues remain as at December 31, 2008, Solvay Pharma shall make a payment to Her Majesty in right of Canada within 30 days of the filing of July-December 2008 price and sales data as required by the *Patented Medicines Regulations* in the amount of any remaining excess revenues, as calculated by Board Staff and verified by Solvay Pharma;
- 4.1.5 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reduction for AndroGel 2.5 g/pouch 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 AndroGel 2.5 g/pouch has been reduced in a manner consistent with the terms of this VCU; and
- 4.1.7 To ensure that the price of AndroGel 2.5 g/pouch remains within the Guidelines in all future periods in which AndroGel 2.5 g/pouch is under the PMPRB's jurisdiction.

Solvay Pharma Inc.

Signature: Original signed by

Company Officer: GARHAM S. JOHNSON

Position: PRESIDENT & CEO

Date: 24/6/08

