September 30, 2009

VOLUNTARY COMPLIANCE UNDERTAKING
OF
SCHERING-PLOUGH CANADA INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

1.1 Andriol (testosterone undecanoate) is indicated for the replacement therapy in males in conditions associated with symptoms of deficiency or absence of endogenous testosterone: for the management of congenital or acquired primary hypogonadism and hypogonadotropic hypogonadism; to develop and maintain secondary sexual characteristics in males with testosterone deficiency; to stimulate puberty in carefully selected males with clearly delayed puberty not secondary to a pathological disorder. It is used as a replacement therapy in impotence or for male climacteric symptoms when the conditions are due to a measured or documented androgen deficiency. It is sold in 40 mg caps.

1.2 Health Canada issued a Notice of Compliance for the new formulation of Andriol on March 18, 2004 (DIN 00782328). Sales of the new formulation of Andriol in Canada commenced November 1, 2004.

1.3 Canadian Patent No. 2,366,856 pertaining to Andriol was granted to AKZO NOBEL N.V. on May 16, 2006 and will expire on March 27, 2020. Schering-Plough Canada Inc. (Schering-Plough) is the patentee for the purposes of the Patented Medicine Prices Review Board (PMPRB).

2. Application of the Excessive Price Guidelines

2.1 Andriol was classified as a category 1 new medicine under the Board's *Excessive Price Guidelines* (Guidelines) as it represents a new DIN of an existing or comparable dosage form of an existing medicine.

2.2 In accordance with the Guidelines, an International Price Comparison (IPC) test and a Therapeutic Class Comparison (TCC) test comparing Andriol to other testosterone drug products in the same 5th level ATC class were conducted. The results of these tests indicated that the November 1 to December 31, 2004 introductory price of $0.9400 exceeded the Guidelines as the Canadian price was the highest of the seven comparator countries in which it was sold. Specifically, the introductory price exceeded the maximum non-excessive (MNE) price of $0.8384 by 12.1%, with excess revenues of $348,605.86 during this period.

2.3 A review of subsequent reporting periods indicated that the prices of Andriol continued to exceed its MNE prices such that cumulative excess revenues as of June 30, 2009 were $3,392,652.63.

3. Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Schering-Plough that the price of Andriol 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, Schering-Plough agrees to undertake the following:

4.1.1 To agree that the 2004 to 2009 MNE prices of Andriol are as follows:

2004	$0.8384
2005	$0.8568
2006	$0.8745
2007	$0.8929
2008	$0.9133
2009	$0.9313

4.1.2 To offset excess revenues received from November 1, 2004 to December 31, 2004 by making a payment to Her Majesty in right of Canada in the amount of $348,605.86 within 30 days of the acceptance of this VCU;

4.1.3 To provide a discount of 21.25% against the 2009 MNE price to all customers within 30 days of the acceptance of this VCU and to maintain this discount until December 31, 2010;

4.1.4 In the event that the full amount of the excess revenues has not been offset by December 31, 2010, to make a further payment to Her Majesty in right of Canada within 30 days of the filing of the July to December 2010 price and sales data in accordance with the Patented Medicines Regulations for such further amount, to be calculated by Board Staff;

4.1.5 Effective January 1, 2011 the price of Andriol may return to the 2009 MNE price set out in paragraph 4.1.1 above. Non-excessive average prices for subsequent years will be calculated based on a 2010 non-excessive average price of $0.9313. The highest IPC test will also apply;

4.1.6 Within 15 days of acceptance of this VCU, to provide notification to customers of this discount, and that it 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 in this notification, and to provide copies of such notifications to Board Staff;

4.1.7 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the discount to all customers is in place in a manner consistent with the terms of this VCU; and

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

Signature: Original signed by

Name: Jacques Senechal

Position: Director, Government and Health Affairs

Patentee: Schering-Plough Canada Inc.

Date: September 30, 2009