

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

1. Product Summary

- 1.1 Xarelto (rivaroxaban) is indicated for the prevention of venous thromboembolic events in patients who have undergone elective hip or total knee replacement surgery.
- 1.2 Canadian Patent No. 2,396,561 pertaining to Xarelto was issued to Bayer Healthcare AG (Germany) on October 14, 2008, and will expire on December 11, 2020. Bayer Inc. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 On September 15, 2008, Health Canada granted a Notice of Compliance to Bayer Inc. for the marketing authorization of Xarelto and sales began in Canada on September 18, 2008. It is supplied in a tablet containing 10 mg of rivaroxaban.

2. Application of the Excessive Price Guidelines

- 2.1 The PMPRB's Human Drug Advisory Panel classified Xarelto as a category 3 new medicine as it provides moderate, little or no therapeutic advantage over other available therapies.
- 2.2 The introductory price of Xarelto exceeded the Board's *Excessive Price Guidelines* (Guidelines). In particular, the price of \$9.6608 was 7.7% above the maximum non-excessive (MNE) price of \$8.9702, as determined by the International Price Comparison (IPC) test, resulting in excess revenues of \$16,781.58. At introduction, Xarelto was sold in Germany, Sweden, Switzerland and the United Kingdom.
- 2.3 A review of the subsequent reporting period indicated that the price of Xarelto continued to exceed the Guidelines with cumulative excess revenues of \$49,978.33 at the end of June 2009.

3. Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking constitutes no admission by Bayer Inc. that the price of Xarelto is or was excessive for purposes of the *Patent Act*.

4. Terms of the Voluntary Compliance Undertaking (VCU)

4.1 In order to comply with the Guidelines, Bayer Inc. undertakes as follows:

4.1.1. To agree that the MNE prices for Xarelto are as follows:

- a) \$8.9702 for 2008
- b) \$8.6102 for 2009
- c) \$8.8599 for 2010

4.1.2 To offset cumulative excess revenues received from September 18, 2008 to June 30, 2009 in the amount of \$49,978.33 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU.

4.1.3 To offset any excess revenues received from July 1, 2009 to the date of the implementation of the price reduction as per paragraph 4.1.1 by making a further payment to Her Majesty in right of Canada within 30 days of the filing of the 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 Xarelto at a price higher than the MNE price as per paragraph 4.1.1 above.

4.1.4 To provide notification to customers of the price reduction for Xarelto and that this price is the result of an undertaking to the PMPRB, to provide a reference in the notification to customers to the PMPRB Web site for the complete text of the VCU, and to provide copies of such notifications to Board Staff within 30 days of acceptance of this VCU.

4.1.5 To ensure that the price of Xarelto is within the Guidelines in all future reporting periods in which Xarelto remains under the PMPRB's jurisdiction.

Signature: (Original signed by)

Name: Doug Grant

Position: Sr. V.P. and Head, Corporate Affairs

Company: Bayer Inc.

Date: December 15, 2009