

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
BRISTOL-MYERS SQUIBB CANADA CO.  
TO THE  
PATENTED MEDICINE PRICES REVIEW BOARD**

**1. Product Summary**

- 1.1. Sinemet CR 200/50 (200 mg levodopa and 50 mg carbidopa controlled release tablets) (DIN 00870935) is indicated for the treatment of Parkinson's disease.
- 1.2. On May 28, 1991, Health Canada granted a Notice of Compliance to MERCK SHARP & DOHME for the marketing authorization of Sinemet CR 200/50. Canadian sales began on July 1, 1991.
- 1.3. Canadian Patent No. 919,691 pertaining to Sinemet CR 200/50 was issued to Merck & Co. Inc. (USA) on January 23, 1973. The last pertaining patent No. 1,318,602 expired on June 1, 2010. Bristol-Myers Squibb Canada Co. had a distribution agreement with Merck Canada Inc. for the product Sinemet CR 200/50. This agreement expired June 30, 2010. Bristol-Myers Squibb Canada Co. is the former patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

**2. Application of the Excessive Price Guidelines**

- 2.1 Sinemet CR 200/50 was classified as a category 1 new medicine and the introductory price was within the Board's Guidelines.
- 2.2 In 2009, the average transaction price (ATP) of Sinemet CR 200/50 began to exceed the Guidelines by an amount which did not trigger the investigation criteria. The ATP of Sinemet CR 200/50 exceeded the Guidelines in 2010 by an amount that resulted in excess revenue triggering the investigation criteria.
- 2.3 Cumulative excess revenues were \$64,442.01 as of June 1, 2010.

**3 Position of the Patentee**

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Bristol-Myers Squibb Canada Co. that the prices of Sinemet CR 200/50 were excessive for purposes of the *Patent Act*.

**4 Terms of the Voluntary Compliance Undertaking**

- 4.1 In order to comply with the Guidelines, Bristol-Myers Squibb Canada Co. undertakes as follows:

- 4.1.1 To offset the cumulative excess revenues received from 2009 to June 1, 2010 in the amount of \$64,442.01 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU.

Signature: Original signed by  
Name: ALAIN BOISVERT  
Position: VICE-PRESIDENT, MARKET ACCESS  
Company: Bristol-Myers Squibb Canada Co.  
Date: June 27, 2011