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: