January 28, 2009 PROTECTED

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

1. Product Summary

1.1 Vepesid (etoposide) is a semi synthetic derivative of podophyllotoxin used as first line therapy in combination with other established antineoplastic agents in the treatment of neoplastic diseases.

1.2 It is a member of the 4th level class L01CB known as "Antineoplastic and Immunomodulating Agents; Antineoplastic Agents; Plant Alkaloids and Other Natural Products; podophyllotoxin derivatives", in the World Health Organization's Anatomical Therapeutic Chemical classification index.

1.3 Canadian Patent No. 2,133,594 pertaining to Vepesid was granted to Bristol-Myers Squibb Co. (United States) on February 23, 1999 and will expire on October 14, 2014. Bristol-Myers Squibb Canada Co. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 On May 15, 1981, Health Canada issued a Notice of Compliance to Bristol-Myers Squibb Canada Inc. for Vepesid and sales began in Canada in December 1981.

1.5 On January 24, 2008, Bristol-Myers Squibb Canada Co. notified Board Staff that Vepesid was discontinued. No sales were reported for the January to June 2008 reporting period.

2. Application of the Excessive Price Guidelines

2.1 Vepesid was already being sold in Canada when the PMPRB was created in 1987. As such, the introductory benchmark price was established by the price prevailing in 1987.

2.2 In 2005, the price of Vepesid began to exceed the Board's *Excessive Price Guidelines* (Guidelines). In particular, the price of $1.8160 per 20 mg/mL was 1.8% above the maximum non-excessive (MNE) price of $1.7843 per 20 mg/mL, as determined by the CPI-Adjustment methodology, resulting in excess revenues of $4,761.46. By June 30, 2008, cumulative excess revenues were $53,161.48.

3. Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Bristol-Myers Squibb Canada Co. that the price of Vepesid 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, Bristol-Myers Squibb Canada Co. undertakes as follows:

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

a) $1.7843 for 2005
b) $1.8378 for 2006
c) $1.8396 for 2007

4.1.2 Within 30 days of acceptance of this VCU, to offset excess revenues received from the sale of Vepesid by making payments totalling $53,161.48 to customers that previously purchased Vepesid at excessive prices. The individual payments shall reflect the distribution of purchases of Vepesid across Canada.

4.1.3 To notify customers receiving payments that the payment 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 further provide copies of such notifications to Board Staff forthwith.

4.1.4 To notify the PMPRB in the event Vepesid is sold by Bristol-Myers Squibb Canada Co. in any future period in which Vepesid remains under the PMPRB's jurisdiction.

Signature: Original signed by

Name: Wayne Quigley

Position: President and General Manager

Patentee: Bristol-Myers Squibb Canada Co.

Date: January 28, 2009