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

1. Product Summary

1.1 Canadian Patents No. 2,458,929 and 2,445,276 pertaining to Abilify (aripiprazole) were issued to Otsuka Pharmaceutical Co. Ltd. (Japan) and Bristol-Myers Squibb Company (United States of America) on September 8, 2009 and October 13, 2009 with Laid-Open dates of July 9, 2004 and October 31, 2002 respectively. The last patent to expire is No. 2,458,929 on December 18, 2023. Bristol-Myers Squibb Canada Co. is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.2 On July 9, 2009, Health Canada granted a Notice of Compliance to Bristol-Myers Squibb Canada Co. for the marketing authorization of Abilify, though sales began on April 21, 2003 under the Special Access Programme.

1.3 The scientific review of Abilify was conducted based on its use when it first came under the Board's jurisdiction. At that time Abilify was used for the treatment of schizophrenia. Abilify is currently indicated for the treatment of schizophrenia and related psychotic disorders and for the acute treatment of manic or mixed episodes in Bipolar I Disorder.

1.4 Abilify is supplied in tablets containing 2 mg, 5 mg, 10 mg, 15 mg, 20 mg and 30 mg of aripiprazole. Only the 15 mg tablet is the subject of this Voluntary Compliance Undertaking.

2. Application of the Excessive Price Guidelines

2.1 Abilify 15 mg tablet was classified by the PMPRB's Human Drug Advisory Panel as a category 3 new medicine and its introductory price exceeded the Board's Guidelines. In particular, the price of $13.5000 was 100.0% above the maximum non-excessive (MNE) price of $6.75 as determined by the Therapeutic Class Comparison (TCC) test, resulting in excess revenues of $9,720.00.

2.2 A review of the subsequent reporting periods indicated that the price of Abilify 15 mg tablet continued to exceed the Guidelines with cumulative excess revenues of $1,043,311.33 at the end of December 2009.

3. Position of the Patentee

3.1. This Voluntary Compliance Undertaking constitutes no admission by Bristol-Myers Squibb Canada Co. that the price of Abilify 15 mg tablet is or was excessive for purposes of the *Patent Act*.

3.2. Bristol-Myers Squibb Canada Co. reduced the price of Abilify 15 mg tablet to $4.5000 per tablet at the end of 2009.

4. Terms of the Voluntary Compliance Undertaking (VCU)

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

4.1.1. To agree that the 2003 to 2009 MNE prices and the 2010 National Non-Excessive Average Price (N-NEAP) for Abilify 15 mg tablet are as follows:

a) $6.7500 for 2003
b) $6.8715 for 2004
c) $7.0268 for 2005
d) $7.1685 for 2006
e) $7.3181 for 2007
f) $7.4906 for 2008
g) $7.5198 for 2009
h) $7.6840 for 2010

4.1.2 To ensure that no customer pays a price exceeding $4.5000 per tablet of Abilify 15 mg tablet in 2010.

4.1.3 To offset cumulative excess revenues received from April 21, 2003 to December 31, 2009 in the amount of $1,043,311.33 through the price reduction implemented by Bristol-Myers Squibb Canada Co. The offset for 2010 shall be calculated in accordance with the Board's current Guidelines, with reference to the 2009 MNE price.

4.1.4 In the event that the full amount of cumulative excess revenues has not been offset by December 31, 2010, to make a 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, of such amount as will be calculated by Board Staff.

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

Signature: Teresa Bitetti Date: Jan 28, 2011

Name: Teresa Bitetti
Position: President and General Manager
Company: **Bristol-Myers Squibb Canada Co.**