

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
BRISTOL-MYERS SQUIBB PHARMACEUTICAL GROUP
AND
SANOFI-SYNTHELABO CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1 Product Summary

- 1.1 Plavix (clopidogrel bisulfate) is a patented medicine sold in Canada by Bristol-Myers Squibb Pharmaceutical Group (BMS). It is indicated for the secondary prevention of vascular ischemic events (myocardial infarction, stroke, vascular death) in patients with a history of symptomatic atherosclerotic disease.
- 1.2 Sanofi-Synthélabo Inc. of France holds two Canadian Patents, Nos. 1,194,875 and 1,336,777, that pertain to Plavix. These patents were granted on October 8, 1985 and August 22, 1995, respectively and will expire on October 8, 2002 and August 22, 2012, respectively.
- 1.3 Health Canada issued a Notice of Compliance to Sanofi-Synthélabo Canada Inc. (Sanofi) for Plavix 75mg/tablet (DIN 2238682) on October 7, 1998. Pursuant to agreements between Sanofi and BMS, BMS has been selling Plavix at a price agreed to by both companies, since October 7, 1998.

2 Application of the Excessive Price Guidelines

- 2.1 BMS has been selling Plavix at a price of approximately \$2.4700 per tablet since October 1998.
- 2.2 On March 2, 2000, the staff of the Patented Medicine Prices Review Board advised BMS and Sanofi that they considered the introductory price of Plavix to exceed the Excessive Price Guidelines because, in their view, it exceeded the prices of other drugs in the therapeutic class.

3 Terms of VCU

- 3.1 For purposes of resolving this matter and without any admission that the price of Plavix is or was excessive under section 83 of the Patent Act, BMS and Sanofi make the following undertakings:
- 3.1.1 To agree that, for purposes of the Guidelines, the maximum non-excessive price (MNE) of Plavix, at the time of its introduction in Canada in 1998, be considered to be \$2.3316 per tablet and that the price of \$2.4015 per tablet is the maximum non-excessive price in 2000.
- 3.1.2 To reduce the current price of Plavix to the MNE price for the year 2000 of \$2.4015 per tablet, effective April 10, 2000.
- 3.1.3 To report to the Board no later than 15 days following the acceptance of this undertaking, the prices and quantities of Plavix sold during the periods January 1 to February 29, 2000 and March 1, 2000 to April 9, 2000.
- 3.1.4 To offset, within 30 days of acceptance of this VCU, all of the excess revenues received from the sale of Plavix at prices higher than the MNE from October 1998 to April 9, 2000 as calculated by the Board in the following manner:
- (a) With respect to sales prior to March 1, 2000, by making a payment to Her Majesty the Queen in the right of Canada to offset excess revenues as calculated by the Board; and
- (b) With respect to sales between March 1, 2000 and April 9, 2000, by issuing credit notes to pharmacies, wholesalers, hospitals and other customers for the difference between actual prices paid and the MNE of \$2.4015, with copies of the credit notes being provided to the Board at the same time.

Signature: *Original signed by*
J. Hatfield

Signature: *Original signed by*
Y. Bastien

Company: Bristol-Myers Squibb
Pharmaceutical Group

Company: Sanofi-Synthélabo
Canada Inc.

Date: 19-04-00

Date: April 14, 2000
