

## **VOLUNTARY COMPLIANCE UNDERTAKING**

### **1.0 Product Summary:**

- 1.1 Anaprox (naproxen sodium) is an analgesic - anti-inflammatory drug product indicated for the relief of mild to moderately severe pain, accompanied by inflammation in conditions such as musculoskeletal trauma and postdental extraction. It is also indicated for the relief of pain associated with postpartum cramping and dysmenorrhea. Its ATC classification is M01AE02.
- 1.2 Anaprox 275 mg tablets (Anaprox - DIN 02162725) are being sold in Canada by Hoffmann-La Roche Limited (Roche).
- 1.3 Canadian Patent No. 1,259,627 pertains to Anaprox. This patent was granted to Syntex Pharma. Intl Ltd., U.K., on September 19, 1989 and expires on September 19, 2006.
- 1.4 Health Canada issued a Notice of Compliance for Anaprox on January 21, 1980. Anaprox is classified as an existing medicine for review purposes under the Board's Guidelines.

### **2.0 Application of the Guidelines:**

- 2.1 Following the procedures outlined in the Board's Guidelines for existing medicines, the price of Anaprox in 1987 was established as the benchmark price.
- 2.2 The price of this drug product was reviewed with reference to the Consumer Price Index (CPI) adjusted price.
- 2.3 Commencing in 1996, as shown in the table below, the price of this drug product exceeded the maximum non-excessive (MNE) price by a range of 0.02% to 1.39%. As a result, Roche received revenues in excess of the Guidelines totalling \$67,252.55.

**ANAPROX 275 mg tablets (DIN 02162725)**

Reporting Period	Price/Tablet		Excess	
	Actual	MNE*	Percent	Revenues
JAN - DEC 96	\$0.5628	<b>\$0.5568</b>	1.08%	<b>\$31,591.20</b>
JAN - DEC 97	\$0.5674	<b>\$0.5673</b>	0.02%	<b>\$465.35</b>
JAN - DEC 98	\$0.5838	<b>\$0.5758</b>	1.39%	<b>\$35,196.00</b>
Total				<b>\$67,252.55</b>

\* Maximum non-excessive

**3.0 Position of the Patentee:**

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Roche that the price of Anaprox is or was excessive.

**4.0 Terms of the VCU**

4.1 Having been advised by letter dated July 7, 1999 that the price of Anaprox may have been excessive under the Board's Guidelines as outlined above and excess revenues may have been derived from the sale of this medicine Roche undertakes to pay to Her Majesty in right of Canada the amount of \$67,252.55 within 30 days of acceptance of this VCU, and furthermore, will ensure that the average price of Anaprox is within the Board's Guidelines in future years, commencing with the 1999 MNE price of \$0.5841 per 275 mg tablet.

Signature: Peter J. Proctor

Company Officer: \_\_\_\_\_

Position: Vice President - Finance

Date: July 30, 1999

**VCU approved by Robert G. Elgie, Chairperson of the Patented Medicine Prices Review Board on August 11, 1999**