

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
HOFFMANN-LA ROCHE LIMITED
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Tamiflu (oseltamivir) is a direct acting antiviral neuraminidase inhibitor introduced to the Canadian market on December 23, 1999. It is a new active substance classified under the WHO ATC index as J05H02.
- 1.2 Tamiflu 75 mg capsule (Tamiflu - DIN 02241472) is being sold in Canada by Hoffmann-La Roche Limited (Roche).
- 1.3 Canadian Patent No. 2,271,396 pertains to Tamiflu. This patent was granted to F. Hoffmann-La Roche AG, Switzerland on October 8, 2002 and will expire on May 7, 2019. Hoffmann-La Roche Limited is the Canadian patentee.
- 1.4 Health Canada issued a Notice of Compliance for Tamiflu 75 mg capsules on December 23, 1999 for the treatment of uncomplicated acute illness due to influenza infection in adults who have been symptomatic for no more than two days. Health Canada issued a second Notice of Compliance for Tamiflu on December 24, 2003 for the prevention of influenza illness in adults and adolescents 13 years and older following close contact with an infected individual.
- 1.5 Roche began selling Tamiflu 75 mg capsules at a list price of \$4.20 per capsule. On July 1, 2004, Roche lowered the list price of Tamiflu to \$3.90 per capsule.

2.0 Application of the Excessive Price Guidelines

- 2.1 In accordance with the PMPRB's Excessive Price guidelines (the "Guidelines"), Board Staff conducted the review of the price of Tamiflu. Board Staff advised Roche that Tamiflu was classified by the Human Drug Advisory Panel (HDAP) as a category 3 new drug product.
- 2.2 A Therapeutic Class Comparison (TCC) test was conducted using Relenza (zanamivir) as the sole comparable medicine. The results of the TCC for 2003 based on the first patented sale indicated that the average selling price of Tamiflu, \$4.1982 per 75 mg capsule, appeared to exceed the maximum non-excessive (MNE) price of \$3.7695 per 75 mg capsule by 11.37%. As a result, Roche received revenues in excess of the Guidelines of \$276,867.96 during that period.
- 2.3 The price review results for the period January 1, 2004 to December 31, 2004 showed that the average transaction price (ATP) of Tamiflu, \$4.0878 per capsule, continued to exceed the MNE price of \$3.8386 per capsule by 6.49%. As a result, Roche received revenues in excess of the Guidelines of \$166,105.51 during that period.

- 2.4 An International Price comparison (IPC) test was also conducted in 2003 and showed that the Canadian price of Tamiflu 75 mg capsule did not exceed the PMPRB's Guidelines with respect to the highest international price based on six countries, France, Germany, Sweden, Switzerland, the United Kingdom, and the United States.
- 2.5 By letter dated October 17, 2003, Board Staff informed Roche that it had commenced an investigation in the price of Tamiflu in Canada pursuant to the PMPRB's *Compliance and Enforcement Policy*.

3.0 Terms of the VCU

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Roche that the price of Tamiflu 75 mg capsule is or was excessive for purposes of the *Patent Act*.
- 3.2 In order to comply with the Guidelines, Roche undertakes as follows:
- a) To agree that the MNE price of Tamiflu 75 mg capsule was \$3.7695 for the period January to December 2003, \$3.8386 for the period January to December 2004, and is \$3.8917 for the period January to December 2005.
 - b) To ensure that the ATP of Tamiflu 75 mg capsule does not exceed the MNE price of \$3.8917 per capsule for 2005.
 - c) To ensure that the price of Tamiflu 75 mg capsule will be within the Guidelines in all subsequent periods during which it remains under the jurisdiction of the Patented Medicine Prices Review Board.
 - d) To offset excess revenues received for the reporting periods January 1, 2003 to December 31, 2004 by making payment to Her Majesty the Queen in Right of Canada, within 30 days of acceptance of this VCU, in the amount \$442,973.47.

Hoffmann-La Roche Limited

Signature: _____

Company Officer: _____

Position: _____

Date: _____