

Approved by the Chairman of the PMPRB – March 31, 2010

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
GLAXOSMITHKLINE INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1 Product Summary

- 1.1 Paxil CR (paroxetine hydrochloride) is indicated as a selective serotonin reuptake inhibitor in a new dosage form: controlled release tablets for the symptomatic treatment of depression and panic disorder.
- 1.2 Canadian Patent Nos. 1,287,060 and 2,227,298 pertaining to Paxil CR were issued to SmithKline Beecham PLC (United Kingdom) on July 30, 1991 and December 9, 2003 respectively. The last patent will expire on July 19, 2016. GlaxoSmithKline Inc. (GlaxoSmithKline) is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 On November 27, 2003, Health Canada granted a Notice of Compliance to GlaxoSmithKline for the marketing authorization of Paxil CR and sales began in Canada on January 5, 2004. It is supplied in a tablet containing 12.5 mg of paroxetine hydrochloride.

2 Application of the Excessive Price Guidelines

- 2.1 A Voluntary Compliance Undertaking (VCU) was approved by the PMPRB Chairperson in March 2005.
- 2.2 A coding problem related to the processing of returns was discovered by GSK in 2009. As such GlaxoSmithKline filed revised price and sales data since product introduction in 2004. This impacted on the excess revenues previously calculated which GlaxoSmithKline had to offset through the VCU signed in March 2005.

3. Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by GlaxoSmithKline that the price of Paxil CR 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, GlaxoSmithKline undertakes to offset the

additional excess revenues received in the January to December 2004 and January to December 2005 reporting periods in the amount of \$53,177.88 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU by the PMPRB Chairman.

- 4.2 GlaxoSmithKline also undertakes to ensure that the price of Paxil CR remains within the Guidelines in all future reporting periods in which it remains under the PMPRB's jurisdiction.

Signature: Original signed by

Name: Paul Lucas

Position: CEO

Company: GlaxoSmithKline Inc.

Date: March 24, 2010