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

1 Product Summary

1.1 Paxil CR (paroxetine hydrochloride) is a patented medicine sold in Canada by GlaxoSmithKline Inc. (GlaxoSmithKline).

1.2 Paxil CR provides a controlled-release to the alternative range of presentations of Paxil, an anti-depressant. Paxil CR is classified in the WHO ATC index 2004 as N06AB05. It is supplied in the form of tablets in two strengths, 12.5 mg tablet (DIN 02248503) and 25 mg tablet (DIN 02248504)

1.3 Canadian Patent 2,227,298 pertaining to Paxil CR was granted to SmithKline Beecham PLC, UK on December 9, 2003 and will expire on July 19, 2016. GlaxoSmithKline is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 Health Canada issued a Notice of Compliance for Paxil CR on November 27, 2003. GlaxoSmithKline began selling Paxil CR on January 5, 2004. The price of Paxil CR has been approximately $1.6263 for the 12.5 mg tablet and $1.7373 for the 25 mg tablet since the date of first sale.

2 Application of the Excessive Price Guidelines

2.1 Board Staff has conducted a review of the price of Paxil CR in accordance with the PMPRB's Excessive Price Guidelines (Guidelines). Paxil CR was a new dosage form of an existing medicine. Paxil CR was classified by Board Staff as a category 1 new medicine for purposes of the Guidelines. A Reasonable Relationship (RR) test was conducted by Board Staff. The Unit Price Linear Relationship test compared Paxil CR 12.5 mg and 25 mg to Paxil 10 mg, 20 mg and 30 mg tablets.

2.2 By applying the Guidelines, Board Staff concluded that the introductory price of Paxil CR 12.5 mg of $1.6263 per tablet exceeded the maximum non-excessive (MNE) price of $1.5581 per tablet by 4.4%. The introductory price of Paxil CR 25 mg of $1.7373 exceeded the MNE price of $1.6718 by 3.9%. As a result, Board Staff has calculated that GlaxoSmithKline received excess revenues of $130,051.00 during the period January 5, 2004 to June 30, 2004.

3 Terms of the Voluntary Compliance Undertaking

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*.

3.2 In order to comply with the Guidelines and policies of the PMPRB, GlaxoSmithKline undertakes as follows:

3.2.1 To reduce the average transaction price by the end of the January 1 to June 30, 2005 regulatory filing period of such that the average transaction price for 2005 does not exceed the 2005 MNE price of $1.5861 for Paxil CR 12.5 mg and $1.7019 for Paxil CR 25 mg.

3.2.2 To offset excess revenues received by GlaxoSmithKline during the period of January 5, 2004 to December 31, 2004 by making a payment to Her Majesty the Queen in Right of Canada within 30 days of the acceptance of this undertaking in the amount of $310,403.64.

3.2.3 To ensure that the price of Paxil CR remains within the Guidelines in all future periods in which it remains under the PMPRB's jurisdiction.

GlaxoSmithKline Inc.

Signature: Original signed by

Name (printed): D.P. LOVAS

Title: G.M.C.

Date: 20/05