September 3, 2009

PROTECTED
Without Prejudice

VOLUNTARY COMPLIANCE UNDERTAKING OF BAXTER CORPORATION TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

1.1 Brevibloc (esmolol hydrochloride) is indicated for the perioperative management of tachycardia and hypertension in patients in whom there is a concern for compromised myocardial oxygen balance and who, in the judgment of the physician, are clearly at risk of developing hemodynamically-induced myocardial ischemia, and for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in acute situations when the use of a short-acting agent is desirable.

1.2 Canadian Patent No. 1,242,395 that pertains to Brevibloc was granted on September 27, 1988 to E.I. Du Pont De Nemours and Company (United States) and later transferred to Baxter International Inc. (United States), and Canadian Patent No. 2,410,446 that also pertains to Brevibloc was granted to Baxter International Inc. (United States) on August 26, 2008. The last patent will expire on January 2, 2022.

1.3 On October 31, 1995, Health Canada issued a Notice of Compliance to Zeneca Pharma Inc. (now AstraZeneca Inc.) for Brevibloc. This drug product, DIN 02188880, is supplied in 10 mL per vial for injection. Astra Zeneca Inc. began selling this drug product in Canada on October 31, 1995. At introduction, the price of Brevibloc was within the Board's *Excessive Price Guidelines* (Guidelines).

1.4 On January 1, 2000, Baxter Corporation took over sales of Brevibloc.

2. Application of the Excessive Price Guidelines

2.1 Under the Guidelines, where an existing drug product is sold in Canada by persons other than the initial patentee, the Guidelines will apply to the DINs sold by these persons as if they were the DINs of the initial patentee.

2.2 During the January to June 2000 period, the price of Brevibloc was within the Guidelines and remained within the Guidelines until the end of 2006.

2.3 During the January to December 2007 period, the price of Brevibloc exceeded the Guidelines. In particular, the price in 2007 at $1.2108 per mL was 23.9% above the maximum non-excessive (MNE) price of $0.9773 per mL, as determined by the CPI-Adjustment Methodology, resulting in excess revenues of $56,357.56. By the end of June 2009, cumulative excess revenues were $212,440.76.

2.4 In June 2009, Baxter reduced the price of Brevibloc to $10.08 per vial (or $1.0080 per mL).

3. Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Baxter Corporation that the price of Brevibloc 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, Baxter Corporation undertakes as follows:

4.1.1. To agree that the MNE prices for Brevibloc are as follows:

a) $0.9773 for 2007
b) $1.0095 for 2008
c) $1.0086 for 2009

4.1.2 Within 30 days of the acceptance of this VCU, to offset cumulative excess revenues received from January 1, 2007 to June 30, 2009 by making payments totaling $212,440.76 to customers that previously purchased Brevibloc. The individual payments shall reflect the distribution of purchases of Brevibloc across Canada.

4.1.3 Within 30 days of acceptance of the VCU, to provide notification to customers receiving payments that the payment is the result of an undertaking to the PMPRB, to provide a reference to the PMPRB Website for the complete text of the VCU, and to further provide copies of such notifications to Board Staff.

4.1.4 To ensure that the price of Brevibloc remains within the Guidelines in all future periods in which Brevibloc remains under the PMPRB's jurisdiction.

Signature:	Original signed by
Name:	Ali Corbett
Position:	Vice President, Medication Delivery
Patentee:	Baxter Corporation
Date:	September 3, 2009