

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
OTSUKA AMERICA PHARMACEUTICAL, INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1 Background

- 1.1 This Voluntary Compliance Undertaking (VCU) is submitted pursuant to Schedule 13, paragraph 1.3.1 of the Patented Medicine Prices Review Board (PMPRB) Guidelines.
- 1.2 Busulfex is a patented medicine being sold in Canada by Otsuka America Pharmaceutical, Inc. (Otsuka). It is indicated for use in combination with other chemotherapeutic agents and/or radiotherapy as a conditioning regimen prior to hematopoietic progenitor cell transplantation. Otsuka began selling Busulfex following acquisition of the product on March 7, 2008.
- 1.3 Canadian Patent No. 2,171,738 pertaining to Busulfex was issued July 16, 2002 and will expire August 30, 2014. Otsuka is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.4 In 2008, the price of Busulfex exceeded the Guidelines by an amount which did not trigger the investigation criteria. In 2009, the average transaction price of Busulfex was below its maximum non-excessive price, but there were cumulative excess revenues of \$22,092.48 remaining as of December 31, 2009.

2 Terms of the Voluntary Compliance Undertaking:

- 2.1 This VCU constitutes no admission by Otsuka that the price of Busulfex is or was excessive for purposes of the Patent Act.
- 2.2 In order to comply with the Guidelines, Otsuka undertakes as follows:
 - 2.2.1 To offset excess revenues received during the period March 8, 2008 to December 31, 2009 by making a payment to Her Majesty the Queen in Right of Canada, within 30 days of acceptance of this VCU, in the amount of \$22,092.48.
 - 2.2.2 To ensure that the price of Busulfex remains within the Guidelines in all future periods in which Busulfex is under the PMPRB's jurisdiction.

Signature: Original signed by

Company Officer: _____

Position: President and CEO

Date: June 11, 2010