

**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
HOSPIRA HEALTHCARE CORPORATION  
TO  
THE PATENTED MEDICINES PRICES REVIEW BOARD**

**1.0 Product Summary**

- 1.1 Hextend (hetastarch) is a patented medicine sold in Canada by Hospira Healthcare Corporation (Hospira).
- 1.2 Hextend is indicated for the treatment of hypovolemia when plasma volume expansion is required. Hextend is classified in the WHO ATC index 2004 as B05AA07. It is supplied in the form of IV solution in one strength, 60 mg/100 mL (DIN 02246024).
- 1.3 Canadian Patents 2,066,374 and 2,164,321 pertaining to Hextend were granted to Biotime Inc., U.S.A on January 29, 2002 and August 20, 2002, respectively. The last patent will expire on June 3, 2014. Hospira is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.4 Health Canada issued a Notice of Compliance for Hextend on July 8, 2002. Hospira began selling Hextend on March 15, 2004 at a price of approximately \$0.1200 per mL.

**2.0 Application of the Excessive Price Guidelines**

- 2.1 The PMPRB's Human Drug Advisory Panel recommended that Hextend be classified as a category 3 new medicine and identified Pentaspan (pentastarch) as the appropriate comparator.
- 2.2 In accordance with the Guidelines a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted by Board Staff. The results of these tests indicated that the price of Hextend during the introductory period (March 15, 2004 to June 30, 2004) of \$0.1200 per mL exceeded the maximum non-excessive (MNE) price of \$0.0858 per mL by about 40% as determined by the IPC test. Hextend is only sold in the United States. As a result, Board Staff has calculated that Hospira received excess revenues of \$4,104.00 during the introductory period.
- 2.3 A review of the subsequent reporting periods indicated that the price of Hextend continued to exceed the Guidelines during the period July to December 2004, resulting in cumulative excess revenues totaling \$8,823.60 to end-December 2004. Hextend's price was within the guidelines for the period January to December 2005.

### 3.0 Position of the Patentee

- 3.1 At the time of its introduction, Hextend's price was established at a level that was 22.5% below its only competitor, Pentaspan. The lower US price for Hextend reflects the competitive market for plasma volume expanders in that country.
- 3.2 Decreasing the price of Hextend in Canada to reflect the US price of Cdn\$0.0858 per mL, as outlined in this VCU, represents a price that is 45% below Pentaspan's price in Canada.
- 3.3 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Hospira that the price of Hextend is or was excessive for purposes of the *Patent Act*.

### 4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 In order to comply with the Guidelines, Hospira undertakes as follows:
  - 4.1.1 To agree that the 2004 and 2005 MNE prices of Hextend are \$0.0858 per mL.
  - 4.1.2 To ensure that the average transaction price of Hextend in all future periods does not exceed the MNE price as set out below:
    - Where the price in the United States in local currency terms remains unchanged or increases, the MNE shall be the lower of the CPI-adjusted price and \$0.0858 per mL;
    - Where the price in the United States in local currency terms decreases, the MNE shall be calculated using the new U.S. price in conducting the IPC test as set out in the Guidelines;
  - 4.1.3 To ensure that the average transaction price for 2006 does not exceed the 2006 MNE price as calculated based on paragraph 4.1.2 above.
  - 4.1.4 To ensure that the price of Hextend remains within the Guidelines in all future periods in which Hextend remains under the PMPRB's jurisdiction.
  - 4.1.5 Within 30 days of acceptance of this VCU, to make a payment of \$8,823.60 to Her Majesty the Queen in Right of Canada for the excess revenues deemed to have accrued between March 15 and December 31, 2004.

Signature: Original signed by

Name (printed): TINA DEMATOS

Position: DIRECTOR OF FINANCE

Patentee: Hospira Healthcare Corporation

Date: March 27, 2006