

VOLUNTARY COMPLIANCE UNDERTAKING OF
FRESENIUS KABI CANADA
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD

1 Product Summary

- 1.1. Voluven (hydroxyethyl starch) is indicated for the treatment of hypovolemia when plasma volume is required.
- 1.2. Patent CA 2,299,405 that pertains to Voluven was granted on May 23, 2006 to Fresenius AG, Germany and lapsed on August 7, 2008.
- 1.3. On February 16, 2007, Health Canada issued a Notice of Compliance to Fresenius Kabi Canada (Fresenius) for Voluven and sales began on March 3, 2007.

2 Application of Excessive Price Guidelines

- 2.1 The PMPRB's Human Drug Advisory Panel recommended that Voluven be classified as a category 1 new medicine and identified Hextend and Pentaspan as the most appropriate comparable medicines.
- 2.2 In accordance with the Board's *Excessive Price Guidelines* (Guidelines), Board Staff concluded that the Reasonable Relationship (RR) test methodology was not considered adequate or appropriate because Voluven exhibits a different molecular structure from other hetastarch preparations and has different pharmacokinetic/pharmacodynamic properties.
- 2.3 As a result, Board Staff conducted a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test. The results of these tests indicated that the introductory price of Voluven exceeded the Guidelines. In particular, during the introductory period (March to June 2007), the price of Voluven was above the maximum non-excessive (MNE) price of \$0.0705, as determined by the highest international price, resulting in excess revenues of \$73,512.25.
- 2.4 A review of the subsequent reporting periods revealed that Voluven continued to exceed the Guidelines and by August 7, 2008, when the patent lapsed, excess revenues were \$1,448,002.25.

3 Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Fresenius that the price of Voluven is or was excessive for purposes of the *Patent Act*.

3.2 Voluven is the least expensive product in the therapeutic class.

4 Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Fresenius undertakes as follows:

4.1.1 To agree that the MNE prices for Voluven were as follows:

- a) \$0.0705 for March to June 2007
- b) \$0.0680 for July to December 2007
- c) \$0.0704 for January to August 2008

4.1.2 To offset cumulative excess revenues received from March 3, 2007 to August 7, 2008 in the amount of \$1,448,002.25 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU.

4.1.3 To notify the PMPRB in the event that other patents pertaining to Voluven are issued in any future period.

Signature: Original signed by

Name: Matthew Rotenberg

Position: Chief Executive Officer

Patentee: Fresenius Kabi Canada

Date: December 10, 2009