

Approved by the Chairman of the PMPRB – March 31, 2010

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

**1. Product Summary**

- 1.1 FSME-IMMUN (tick-borne encephalitis vaccine - inactivated) is indicated for immunization against the TBE virus in individuals 16 years and older who are at risk of contact with ticks that carry TBE virus.
- 1.2 Canadian Patents No. 2,073,168 and 2,159,204 pertaining to FSME-IMMUN were issued to Immuno Aktiengesellschaft (Austria) on April 27, 1999 and January 9, 2001, respectively. The last patent will expire on March 29, 2014. Baxter Corporation is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 Sales in Canada through Health Canada's Special Access Programme (SAP) began on April 27, 1999. On February 3, 2005, Health Canada granted a Notice of Compliance to Baxter Corporation for FSME-IMMUN (DIN 02264625).

**2. Application of the Excessive Price Guidelines**

- 2.1 FSME-IMMUN was classified as a category 2 new medicine and the introductory price was within the Board's *Excessive Price Guidelines* (Guidelines).
- 2.2 In 2002, the price of FSME-IMMUN exceeded the Guidelines. In particular, the price of \$31.9953 per vial was 5.5% above the National Non-Excessive Average Price (N-NEAP) (previously known as the maximum non-excessive (MNE) price) of \$30.3397 per vial, based on the Highest International Price test, resulting in excess revenues of \$708.61. By the end of December 2009, cumulative excess revenues were \$53,578.62.

**3. Position of the Patentee**

- 3.1 On October 1, 2009, Baxter reduced the price of FSME-IMMUN to \$35.6108 per vial.
- 3.2 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Baxter Corporation that the price of FSME-IMMUN 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 N-NEAPs for FSME-IMMUN are as follows:

- a) \$30.3397 for 2002
- b) \$31.6140 for 2003
- c) \$32.1000 for 2004
- d) \$32.4635 for 2005
- e) \$33.4374 for 2006
- f) \$34.0800 for 2007
- g) \$34.6061 for 2008
- h) \$34.7791 for 2009
- i) \$35.7840 for 2010

4.1.2 Within 30 days of the acceptance of this VCU, to offset cumulative excess revenues received from January 1, 2002 to December 31, 2009 in the amount of \$53,578.62 by making a payment to Her Majesty in right of Canada.

4.1.3 To ensure that the price of FSME-IMMUN remains within the Guidelines in all future reporting periods in which FSME-IMMUN remains under the PMPRB's jurisdiction.

Signature: Original signed by  
Name: Serge Messerlian  
Position: Business Unit Director  
Company: Baxter Corporation  
Date: March 17, 2010