



GE Healthcare

Amersham Health Inc.

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**VOLUNTARY COMPLIANCE UNDERTAKING  
OF  
AMERSHAM HEALTH INC., GE HEALTHCARE  
TO THE  
PATENTED MEDICINE PRICES REVIEW BOARD**

**1. Product Summary**

- 1.1. Ceretec (technetium TC-99M exametazine), a radiopharmaceutical agent used for the diagnosis of brain diseases and tumors, is a patented medicine sold in Canada by Amersham Health Inc., GE Healthcare (“Amersham”).
- 1.2. It is a member of the 4<sup>th</sup> level ATC class V09AA known as “Technetium 99mtc compounds” and there is one other agent (technetium 99mtc bicisate) listed under that same 4<sup>th</sup> level ATC class.
- 1.3. Canadian Patent No.1,252,481 pertaining to Ceretec was granted to Amersham on April 11, 1989 and will expire on April 11, 2006.
- 1.4. On October 21, 1986, Health Canada issued a Notice of Compliance to Amersham and the sales of Ceretec began in Canada on January 1, 1988.
- 1.5. In 2004, Ceretec was sold at \$174.3484 per kit of five multi dose units for the preparation of a technetium TC-99M exametazine injection. Further, Ceretec was sold in the seven countries listed in the *Patented Medicines Regulations* (“*Regulations*”) and Canada had the lowest price.

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

- 2.1 At introduction, Ceretec was classified as a category 2 new medicine and its price was within the PMPRB’s Guidelines (the “Guidelines”).
- 2.2 At the end of 2002, Board Staff commenced an investigation as the average transaction price (ATP) of \$181.9188 was 8.6% above the

maximum non-excessive (MNE) price of \$167.5283 with cumulative excess revenues in the amount of \$67,606.57.

- 2.3 A review of the subsequent reporting periods indicated that the price of Ceretec continued to appear to be excessive under the Guidelines and as of December 31, 2004, the cumulative excess revenues were in the amount of \$278,112.65.

### **3. Position of Patentee**

- 3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Amersham that the price of Ceretec is or was excessive pursuant to the application of the patented medicines provisions of the *Patent Act*.

### **4. Terms of the Voluntary Compliance Undertaking**

- 4.1 In order to comply with the Guidelines, Amersham undertakes the followings:
- 4.1.1 To agree that the MNE price of Ceretec for 2004 was \$173.1935 and is \$177.7475 for 2005;
  - 4.1.2 To ensure that the ATP price of Ceretec does not exceed the MNE price of \$177.7475 for 2005;
  - 4.1.3 To offset excess revenues of \$278,112.65 received by Amersham from January 1, 2002 to December 31, 2004 by maintaining the price of Ceretec below the 2005 MNE price of \$177.7475 until the end of December 31, 2005;
  - 4.1.4. In the event any excess revenues have not been offset by the end of December 31, 2005, Amersham shall make a payment to each of the customers (hospitals and institutions) that purchased Ceretec from January 1, 2002 to December 31, 2004. Each payment shall be calculated by taking the difference between the actual price paid and the MNE price at the time of purchase times the number of kits purchased over the period. All payments shall be made by January 31, 2006;
  - 4.1.5 To provide, within 30 days of making the payments provided for in paragraph 4.1.4 above, copies to the PMPRB of the cheques made to each of the customers that purchased Ceretec and the documentation to support the calculation of the said payments; and

4.1.6. To ensure that the price of Ceretec complies with the Guidelines in all future reporting periods in which it remains under the PMPRB's jurisdiction.

Signature: Original signed by

Name: GEORGE BANWISTER

Position: SECRETARY

Patentee: Amersham Health Inc., GE Healthcare

Date: 11/7/05