

August 2007

PROTECTED

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
BRISTOL-MYERS SQUIBB MEDICAL IMAGING, A DIVISION OF
BRISTOL-MYERS SQUIBB CANADA CO.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1. Product Summary

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- 1.1 OctreoScan (indium 111 in pentetreotide) is a radiopharmaceutical agent used for the diagnosis of brain diseases and tumors.
- 1.2 OctreoScan is a member of the 4th level class V09IB, known as "Various, Diagnostic Radiopharmaceuticals, Tumour Detection, Indium 111 in compounds", in the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system.
- 1.3 Patent number CA 2004532 pertaining to OctreoScan was issued to Novartis AG, Switzerland on February 22, 2000 and will expire on December 4, 2009. Medical Imaging, a Division of Bristol-Myers Squibb Canada CO. (Bristol-Myers Squibb) has the exclusive right to sell Octreoscan in Canada and the the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.4 Sales of OctreoScan began in Canada in February 1996 under Health Canada's Special Access Program at a price of \$908.4211 per kit. Health Canada granted a Notice of Compliance on February 12, 1999.

2. Application of the Excessive Price Guidelines

- 2.1 At introduction in 1996, OctreoScan was classified as a category 2 new medicine and its price was within the PMPRB's *Excessive Price Guidelines* (Guidelines).
- 2.2 A review of the subsequent reporting periods indicated that, beginning in 1999, the price of OctreoScan exceeded the maximum non-excessive (MNE) price by an amount which did not trigger the investigation criteria. In 2001, the cumulative excess revenues triggered the criteria for commencing an investigation.
- 2.3 In 2006, Bristol-Myers Squibb began reducing the price of OctreoScan and during the January to June 2007 reporting period, the price of OctreoScan was below the MNE price. By June 30, 2007, cumulative excess revenues were \$387,181.87.

3. Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Bristol-Myers Squibb that the price of OctreoScan 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, Bristol-Myers Squibb undertakes as follows:

- 4.1.1. To agree that the MNE prices per kit for OctreoScan are as follows:

- a) \$890.9734 for 1999;
- b) \$902.4809 for 2000;
- c) \$930.9195 for 2001;
- d) \$959.5784 for 2002;
- e) \$971.9719 for 2003;
- f) \$996.0839 for 2004;
- g) \$1,026.7489 for 2005;
- h) \$1,032.2342 for 2006; and
- i) \$1,061.8254 for 2007.

- 4.1.2 To ensure that the price of OctreoScan from July to December 2007 does not exceed the 2007 MNE price of \$1,061.8254 per kit.

- 4.1.3 To offset cumulative excess revenues received from February 1996 to June 30, 2007 in the amount of \$387,181.87 by making a payment of \$7,439.82 to Her Majesty the Queen in Right of Canada within 30 days of the acceptance of this VCU, and for the balance of \$379,742.05 by making a payment to each of the customers that purchased OctreoScan from April 2000 to June 30, 2007. Each payment shall be calculated by taking the difference between the actual price paid and the MNE price at the time of purchase multiplied by the number of kits purchased over the period. All payments shall be made within 30 days of the acceptance of this VCU.

- 4.1.4. Within 30 days of making the payments outlined in 4.1.3 above, to provide copies to the PMPRB of the cheques made to each of the customers that purchased OctreoScan and the documentation to support the calculation of the said payments.

- 4.1.5 Within 15 days of acceptance of this VCU, to provide notice to customers of the price reduction for OctreoScan and that this price reduction is the result of an undertaking to the PMPRB, to provide a reference in the notice to customers to the PMPRB Web site for the complete text of the VCU, and to provide copies of such notifications to Board Staff forthwith.

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

Signature: Original signed by
Name: Cyrille Villeneuve
Position: General Manager
Company: Medical Imaging
Date: 2007-09-13