

VOLUNTARY COMPLIANCE UNDERTAKING
OF
ASTELLAS PHARMA CANADA, INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

- 1.1 Adenoscan (adenosine injection) is indicated as an adjunct to thallium-201 myocardial perfusion scintigraphy in patients unable to exercise adequately.
- 1.2 Canadian Patent No. 1,305,922 pertaining to Adenoscan was issued to Medco Research Inc., United States on August 4, 1992 and expired on August 4, 2009. Astellas Pharma Canada Inc. was the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 A Notice of Compliance was granted to Astellas Pharma Canada, Inc. (then Fujisawa Canada Inc.) for Adenoscan 3mg/ml (DIN 02139294) on October 19, 1992 and Adenoscan was first sold on July 1, 1995.

2. Application of the Excessive Price Guidelines

- 2.1 Adenoscan 3mg/ml was classified as a category 1 new medicine and the introductory price was within the Board's Guidelines.
- 2.2 In 1996, the price of Adenoscan began to exceed the Guidelines by an amount which did not trigger the investigation criteria. The price of Adenoscan exceeded the Guidelines in 2008 by an amount that resulted in excess revenue triggering the investigation criteria.
- 2.3 In particular, the price in 2008 of \$7.667 was 17.5% above the National Non-Excessive Price (N-NEAP) (previously known as the maximum non-excessive (MNE) price) of \$6.5244, resulting in excess revenues of \$28,655.14 in that year. From 1996 to August 4, 2009, the expiry date of the patent pertaining to Adenoscan, there were total cumulative excess revenues of \$34,545.32.

3. Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Astellas Pharma Canada, Inc. that the prices of Adenoscan 3mg/ml were excessive for purposes of the *Patent Act*.

4. Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Astellas Pharma Canada, Inc. undertakes as follows:

4.1.1 To offset the cumulative excess revenues received from 1996 to August 4, 2009 in the amount of \$34,545.32 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU.

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

Signature:

Name:

Position:

Company: Astellas Pharma Canada, Inc.

Date: