

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
BIOGEN IDEC CANADA INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1. Product Summary

- 1.1. Avonex PS (interferon beta-1a) is indicated for the treatment of people with relapsing forms of multiple sclerosis, to slow the progression of the disease, to decrease the frequency of relapses, and to reduce the number and volume of active brain lesions seen on magnetic resonance imaging.
- 1.2. Canadian Patents CA 1341604 and CA 2275890 pertaining to Avonex PS were granted to Biogen Idec MA Inc. (United States of America) on May 4, 2010 and on November 1, 2011, respectively. The PMPRB jurisdiction began on July 2, 1998, and the last patent will expire on May 4, 2027. Biogen Idec Canada Inc. (Biogen) is the patentee for purposes of the PMPRB.
- 1.3. On July 18, 2005 Health Canada granted a Notice of Compliance to Biogen for the marketing authorization of Avonex PS (DIN 02269201) and sales began in Canada on December 2, 2005.

2. Application of the Excessive Price Guidelines

- 2.1. The introductory price of Avonex PS exceeded but did not trigger the investigation criteria. Subsequently, the price was within the Board's Guidelines until the end of 2009. In 2010, the price of Avonex PS exceeded the Guidelines again with excess revenues of \$76,347.23, but the price in 2011 was within the Guidelines.

3. Position of Patentee

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

4. Terms of the Voluntary Compliance Undertaking (VCU)

- 4.1. In order to comply with the Guidelines, Biogen undertakes as follows:
 - 4.1.1. To agree that the 2010, 2011 and 2012 National Non-Excessive Average Prices (N-NEAPs) for Avonex PS are as follows:

2010	\$ 352.9634
2011	\$ 360.0318
2012	\$ 366.3075

- 4.1.2 To offset cumulative excess revenues received from January 1, 2010 to December 31, 2010 in the amount of \$76,347.23 by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU; and
- 4.1.3 To ensure that the price of Avonex PS continues to remain within the Guidelines in all future reporting periods in which this drug product remains under the PMPRB's jurisdiction.

Signature: _____

Name: _____

Position: _____

Company: Biogen Idec Canada Inc.

Date: _____