VOLUNTARY COMPLIANCE UNDERTAKING
OF
SUNOVION PHARMACEUTICALS CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Angiomax (bivalirudin) is indicated for use as an anticoagulant in patients undergoing percutaneous coronary intervention and in the treatments of patients with moderate to high risk acute coronary syndromes due to unstable angina or non-ST-segment elevation in whom early percutaneous coronary intervention is planned.

1.2. The first Canadian Patent No. 2,065,150 pertaining to Angiomax was issued to Biogen, Inc. (USA) on December 14, 1999, and the last issued Canadian Patent No. 2,623,449 will expire on March 27, 2028.

1.3. Health Canada issued a Notice of Compliance (NOC) for Angiomax on October 9, 2002. Sunovion Pharmaceuticals Canada Inc. commenced sales in Canada on May 8, 2003.

1.4. Sunovion is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

2.1 The price of Angiomax was within the Guidelines from introduction until 2013, when the price exceeded the Guidelines by an amount which did not trigger the investigation criteria.

2.2 In 2015, the National Average Transaction Price (N-ATP) exceeded the National Non-Excessive Average Price (N-NEAP) triggering the investigation criteria based on the CPI methodology. In particular, the 2015 price of Angiomax was above the N-NEAP resulting in cumulative excess revenues of $88,412.60.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Sunovion Pharmaceuticals Canada Inc. that the price of Angiomax is now, or was at any time since the date of first sale, excessive for purposes of the *Patent Act.*

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, Sunovion Pharmaceuticals Canada Inc. agrees to undertake the following:

4.1 To agree that the N-NEAPs for Angiomax 250 mg/vial are as follows:

2013	$439.3328
2014	$437.6975
2015	$441.7098
2016	$451.3899

4.2 To ensure the 2016 N-ATP for Angiomax 250 mg/vial does not exceed the 2016 N-NEAP as stated in sub-paragraph 4.1;

4.3 To offset cumulative excess revenues received by Sunovion Pharmaceuticals Canada Inc. as of December 31, 2015, by making a payment to Her Majesty in right of Canada in the amount of $88,412.60 within 30 days of the acceptance of this VCU;

4.4 To offset any excess revenues received during the period January 1, 2016 to June 30, 2016 by making a payment, within 30 days of the filing of semi-annual price and sales data as required by the Patented Medicines Regulations, in the amount of the excess revenues, as calculated by Board Staff, received as a result of selling Angiomax at a price in excess of the 2016 N-NEAP set out in sub-paragraph 4.1 above;

4.5 To ensure that the price of Angiomax remains within the Guidelines in all future periods in which Angiomax is under the PMPRB's jurisdiction.

Signature: _____

Name: Douglas Reynolds

Position: President

Patentee: Sunovion Pharmaceuticals Canada Inc.

Date: March 30, 2016