

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

## 1.0 Product Summary

- 1.1. Aimovig (erenumab) is indicated for prevention of migraine in adults who have at least four migraine days per month.
- 1.2. Health Canada granted a Notice of Compliance to Novartis Pharmaceuticals Canada Inc. (“Novartis”) for Aimovig 70 mg/milliliter (“Aimovig 70 mg”) on August 1, 2018, and for Aimovig 140 mg/milliliter (“Aimovig 140 mg”) on April 11, 2019.
- 1.3. Each strength of Aimovig is available in two formulations: a prefilled syringe and a prefilled autoinjector pen. The prefilled syringes have not been sold in Canada. The prefilled pens were first sold in Canada on December 4, 2018 and May 22, 2019 for Aimovig 70 mg (DIN 02479613) and Aimovig 140 mg (DIN 02487306), respectively.
- 1.4. The first reported patent pertaining to Aimovig was granted on October 3, 2017. The last reported patent pertaining to Aimovig is set to expire on August 10, 2035. Novartis is the patentee for the purposes of the *Patent Act* and the Patented Medicines Prices Review Board.

## 2.0 Position of the Patentee

- 2.1 This Voluntary Compliance Undertaking (“VCU”) constitutes no admission by Novartis that the prices of Aimovig are now, or were at any time since the date of first sale, excessive for the purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

## 3.0 Terms of the Voluntary Compliance Undertaking

- 3.1 Pursuant to this VCU, Novartis will undertake:

- 3.1.1 To accept the Lowest International Price Comparison (“LIPC”) as the price test in the determination of the Maximum Average Potential Price (“MAPP”) for Aimovig 70 mg and Aimovig 140 mg;
- 3.1.2 To agree that the MAPP and 2020 Non-Excessive Average Prices (“NEAPs”) for Aimovig 70 mg and Aimovig 140 mg are as follows:

Year	70 mg (DIN 02479613)	140 mg (DIN 02487306)
2019	\$560.0994	\$656.8106
2020	\$544.2360	\$544.2360

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties geared towards a satisfactory resolution of an investigation initiated by Board Staff as per the Guidelines. VCUs take into account the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

- 3.1.3 To ensure that the list prices of Aimovig are below the 2020 N-NEAPs within 30 days of the acceptance of this VCU;
- 3.1.4 To ensure that the 2020 National Average Transaction Prices (“N-ATPs”) are below the 2020 N-NEAPs; and
- 3.1.5 To ensure that the prices of Aimovig remain within the PMPRB’s Guidelines in all future periods in which it is under the PMPRB’s jurisdiction.

Name: Colleen Proctor

Position: Vice-President, Finance and Country CFO

Patentee: Novartis Pharmaceuticals Canada Inc.

Date: October 22, 2020

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