VOLUNTARY COMPLIANCE UNDERTAKING
OF
TEVA CANADA INNOVATION
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Ajovy (fremanezumab) is a monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) and is indicated for the prevention of migraine in adults who have at least four migraine days per month.

1.2. Ajovy is available in two dosage formats: a 225 mg pre-filled syringe (DIN 02497859) ("Ajovy Syringe") and a 225 mg pre-filled autoinjector (DIN 02509474) ("Ajovy Autoinjector"), collectively "Ajovy".

1.3. Health Canada first issued a Notice of Compliance for Ajovy Syringe on April 9, 2020, and it was first sold in Canada on August 4, 2020. Health Canada issued a Notice of Compliance for Ajovy Autoinjector on December 15, 2020, and it was first sold in Canada on April 1, 2021.

1.4. The first reported patent pertaining to Ajovy was granted on December 4, 2012. The last reported patent pertaining to Ajovy is set to expire on November 2, 2026. Teva Canada Innovation ("Teva") is the rights holder for the purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Guidelines

2.1 The Human Drug Advisory Panel (HDAP) recommended that Ajovy be classified as a Slight or No Improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted for Ajovy Syringe and a Reasonable Relationship (RR) test was conducted for Ajovy Autoinjector. The TCC and RR tests established the respective Maximum Average Potential Prices (MAPPs) for Ajovy Syringe and Ajovy Autoinjector.

3.0 Position of the Rights Holder

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Teva that the prices of Ajovy 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*.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Teva will undertake:

4.1.1 To agree that the MAPPs and Non-Excessive Average Prices (NEAPs) for Ajovy are as follows:

Year	Ajovy Syringe	Ajovy Autoinjector
2020	$532.0000	--
2021	$542.6400	$532.0000
2022	$546.3640	$535.7240

4.1.2 To ensure that the list prices of Ajovy are reduced to $535.7240 by April 1, 2022;

4.1.3 To file evidence with PMPRB Staff within 30 days of the price reduction that customers have received notification that the price has been reduced;

4.1.4 To agree that excess revenues for 2020, 2021 and 2022, if any, will be calculated based on the reported National Average Transaction Prices (N-ATPs) and the ceiling prices described in 4.1.1;

4.1.5 To make a payment to Her Majesty in right of Canada within 30 days of receiving PMPRB Staff's notification of any excess revenues as of December 31, 2022, as calculated based on the semi-annual price and sales data filed by Teva and the ceiling prices described in 4.1.1 according to the method described in 4.1.4; and

4.1.6 To ensure that the prices of Ajovy remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: Chander Sehgal Director, Market Access Teva Canada Innovation Digitally signed by Chander Sehgal Date: 2022.02.25 11:38:03 -05'00'

Name: _____

Position: _____

Rights Holder: Teva Canada Innovation

Date: _____

Signature: Richard Gregoire Digitally signed by Richard Gregoire Date: 2022.02.25 12:05:12 -05'00'

Name: _____

Position: _____

Rights Holder: Teva Canada Innovation

Date: _____

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a rights holder to comply with the Board's Guidelines to close an investigation initiated by PMPRB Staff pursuant to those Guidelines. Consideration of a VCU is an administrative procedure and does not constitute an admission or determination by the PMPRB that the price submitted by the rights holder, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.