VOLUNTARY COMPLIANCE UNDERTAKING
OF
ABBVIE CORPORATION
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 HUMIRA (adalimumab) is a tumor necrosis factor (TNF) blocker that reduces the effects of substances in the body that cause inflammation. HUMIRA is used to reduce the signs and symptoms of moderately to severely active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, and a chronic skin condition called hidradenitis suppurativa. It is also used to reduce the signs and symptoms of moderately to severely active Crohn's disease or moderately to severely active ulcerative colitis, after other drugs have been tried without successful treatment of symptoms. HUMIRA is also used to treat non-infectious intermediate, posterior and panuveitis in adult patients.

1.2 Health Canada issued a Notice of Compliance (NOC) for HUMIRA 40 mg/0.8 mL Pre-filled syringe (DIN 2258595) on September 24, 2004 and it has been sold in Canada since that time, with additional dosing formats (Pen and Vial) under the same Drug Information Number (DIN). HUMIRA is currently marketed in Canada by AbbVie Corporation (AbbVie).

1.3 Health Canada issued a Notice of Compliance (NOC) for two new dosing formats of HUMIRA, HUMIRA 40 mg/0.4 mL Pre-filled syringe (DIN 2458349) and HUMIRA 40 mg/0.4 mL Pen (DIN 2458357), on October 13, 2016. These two new dosing formats have been marketed in Canada by AbbVie since November 16, 2016.

1.4 Canadian Patent No. 2,243,459 was the first patent that pertained to HUMIRA and was issued on September 17, 2002. The last-to-expire patent pertaining to HUMIRA (Canadian Patent No. 2,815,689) expires on November 11, 2031. AbbVie is the patentee in respect of Canadian Patent No. 2,815,689 for purposes of the *Patent Act* and the *Patented Medicine Regulations* (the Regulations).

2.0 Application of the Excessive Price Guidelines

2.1 For the introductory period of November 16, 2016 to December 31, 2016 (the Introductory Period), AbbVie filed Form 2, Block 4 filings as per the Regulations. The Maximum Average Potential Prices (MAPPs) were established in accordance with the Reasonable Relationship Test in Schedule 4 of the PMPRB's Compendium of Policies, Guidelines and Procedures (the Guidelines). The National Average Transaction Prices (N-ATPs) of HUMIRA 40 mg/0.4 mL Pre-filled syringe and Pen dosing formats exceeded by 6.8% their MAPPs, triggering the investigation criteria set out in the Guidelines.

2.2 During the Introductory Period, in markets in Canada where AbbVie sold HUMIRA 40mg/0.4mL Pre-filled syringe and Pen formats, AbbVie did so at a price consistent with the price of HUMIRA 40 mg/0.8 mL HUMIRA Pre-filled syringe and Pen formats in those markets.

3.0 Positions of the Patentee and Board Staff

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by AbbVie that the price of HUMIRA is now, or was at any time since the date of first sale, excessive for purposes of the *Patent Act*, nor is this VCU binding upon any panel of the Board for the purposes of the *Patent Act*.

3.2 It is the intention of this VCU to ensure that during the period from 2017 to 2019, the HUMIRA 40mg/0.4 mL dosing formats are not sold to any customer class in any province at a price greater than that of the respective Introductory Period Average Transaction Price (ATP) in each customer class in each province.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, AbbVie will undertake:

4.1.1 To ensure that the 2017, 2018 and 2019 ATP for each customer class in each province of each dosing format of HUMIRA 40mg/0.4mL does not exceed the respective Introductory Period ATP in each province and in each customer class in a province where HUMIRA 40mg/0.4mL is sold;

4.1.2 To repay any excess revenues, calculated on an annual basis, that are generated during the period from 2017 to 2019 in which the ATP of each dosing format of HUMIRA 40mg/0.4mL of a particular customer class in a particular province exceeds its respective Introductory Period ATP, by making a payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of annual excess revenues calculated for that particular customer class in that particular province based on the semi-annual price and sales data filed by AbbVie; and

4.1.3 To ensure that the price of HUMIRA 40mg/0.4mL dosing formats remain within the PMPRB's Guidelines in all future periods in which HUMIRA is under the PMPRB's jurisdiction.

Signature: _____

Name: Stephane Lassignardie

Position: General Manager

Patentee: AbbVie Corporation

Date: Nov. 16, 2017

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.