VOLUNTARY COMPLIANCE UNDERTAKING
OF
ELI LILLY CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1 Taltz (ixekizumab) is indicated for:

1.1.1 the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy; and

1.1.2 the treatment of adult patients with active psoriatic arthritis who have responded inadequately to, or are intolerant to one or more disease-modifying antirheumatic drugs (DMARD).

1.2 Taltz is available at a strength of 80 mg/milliliter and marketed in two formulations:

Taltz	80 mg/milliliter	Single Dose Prefilled Syringe	DIN: 02455110
Taltz	80 mg/milliliter	Single Dose Prefilled Autoinjector	DIN: 02455102

1.3 Health Canada issued a Notice of Compliance ("NOC") for Taltz on May 25, 2016. Eli Lilly Canada Inc. ("Lilly") began selling both formulations on August 11, 2016.

1.4 Canadian Patent Nos. 2,631,938 and 2,866,128 are the current Canadian Patents that pertain to Taltz. The last reported patent pertaining to Taltz expires on March 1, 2033. Lilly is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board ("PMPRB").

2.0 Application of Excessive Price Guidelines

2.1 The Human Drug Advisory Panel ("HDAP") recommended that Taltz be classified as a Slight or No Improvement.

2.2 The National Average Transaction Prices ("N-ATPs") of both formulations of Taltz were within the thresholds set out in the Guidelines at introduction.

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.

2.3 As a result of a price increase, in 2017, the N-ATPs of Taltz began to exceed the thresholds set out in the Guidelines.

2.4 The N-ATP of the Single Dose Prefilled Autoinjector (DIN: 02455102) continued to exceed the thresholds set out in the Guidelines in 2018, resulting in the commencement of an investigation based on the application of the CPI-Adjustment Methodology. As of December 31, 2018, cumulative excess revenues were determined to be $75,844.49.

2.5 The excess revenues generated by the Single Dose Prefilled Syringe (DIN: 02455110) did not trigger the investigation criteria.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Lilly that the prices of Taltz are or were at any time since the date of first sale of the medicine 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 In order to comply with the Guidelines, Lilly agrees to undertake the following:

4.1.1 To ensure that the 2019 N-ATPs do not exceed the 2019 National Non-Excessive Average Prices ("N-NEAPs") of $1,579.1840 and $1,579.3445 per milliliter for the Single Dose Prefilled Autoinjector (DIN: 02455102) and Single Dose Prefilled Syringe (DIN: 02455110), respectively;

4.1.2 To offset the cumulative excess revenues received by Lilly in connection with the Single Dose Prefilled Autoinjector (DIN: 02455102) by making a payment of $75,844.49 to Her Majesty in right of Canada, within 30 days of the acceptance of this VCU;

4.1.3 To make a further payment to Her Majesty in right of Canada within 30 days of receiving Board Staff's notification of any remaining excess revenues for the Single Dose Prefilled Autoinjector (DIN: 02455102) as of December 31, 2019, as calculated based on the total 2019 price and sales data filed by Lilly; and

4.1.4 To ensure that prices of both formulations of Taltz remain within the PMPRB's Guidelines in all future periods in which Taltz remains under the PMPRB's jurisdiction.

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Signature:

Name: Lauren Fischer

Position: **Vice President, Corporate Affairs**

Patentee: **Eli Lilly Canada Inc.**

Date: **1/10/2020**

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