VOLUNTARY COMPLIANCE UNDERTAKING ("VCU")
OF
MEDEXUS INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Metoject Subcutaneous (methotrexate sodium) is indicated as a Disease Modifying Antirheumatic Drug ("DMARD") in the following diseases where standard therapeutic interventions fail:

- Severe disabling psoriasis/psoriatic arthritis
- Severe disabling rheumatoid arthritis ("RA")

1.2. As of the date of this VCU, Metoject Subcutaneous is marketed in Canada in four strengths: 17.5 mg/syringe (DIN 02454769), 20 mg/syringe DIN 02454866), 22.5 mg/syringe (DIN 02454777) and 25 mg/syringe (DIN 02454874).

1.3. The only Canadian Patent pertaining to Metoject Subcutaneous as filed by Medexus Inc. (No. 2,659,662) was issued to MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH (Germany) on January 20, 2017, and will expire on July 20, 2027.

1.4. Health Canada issued a Notice of Compliance ("NOC") for Metoject Subcutaneous on May 17, 2016. Medexus Inc. commenced sales in Canada on December 14, 2016 for the 25 mg strength and December 21, 2016 for the 17.5 mg, 20 mg and 22.5 mg strengths.

1.5. Medexus Inc. is the patentee for purposes of the *Patent Act* and the Patented Medicines Prices Review Board ("PMPRB").

2.0 Application of the Excessive Price Guidelines

2.1 Board Staff classified Metoject Subcutaneous as a Slight or No Improvement. Methotrexate was identified as the most appropriate comparator.

2.2 In accordance with PMPRB Guidelines, Board Staff conducted Reasonable Relationship ("RR") and Highest International Price Comparison ("HIPC") tests. The HIPC test established the Maximum Average Potential Prices ("MAPPs") for all four strengths of Metoject Subcutaneous.

2.3 The National Average Transaction Prices ("N-ATPs") of the 17.5mg, 20mg, 22.5mg and 25mg strengths were above their respective MAPPs during the introductory period by amounts with triggered the investigation criteria in the Guidelines. As of June 30, 2017, cumulative excess revenues totalled $380,154.75.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Medexus Inc. that any prices of Metoject Subcutaneous are 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

In order to comply with the Guidelines, Medexus Inc. undertakes:

4.1 To agree that the 2017 MAPPs for Metoject Subcutaneous are as follows:

17.5 mg/syringe	$31.9692
20 mg/syringe	$33.7692
22.5 mg/syringe	$33.3075
25 mg/syringe	$38.8287

4.2 To reduce the individual Canadian 2018 list prices of each strength of Metoject Subcutaneous within 30 days of acceptance of the VCU to no greater than:

17.5 mg/syringe	$32.0000
20 mg/syringe	$35.0000
22.5 mg/syringe	$35.0000
25 mg/syringe	$39.0000

4.3 To ensure the 2018 N-ATP and Market Specific ATP ("MS-ATP") of each strength of Metoject Subcutaneous does not exceed its respective National Non-Excessive Average Price ("N-NEAP") and Market Specific NEAP ("MS-NEAP") by June 30, 2018;

4.4 To offset cumulative excess revenues accrued as of December 31, 2017 by further reducing the 2018 N-ATP of one or more strengths of Metoject Subcutaneous below its respective 2017 MAPP;

4.5 To offset any remaining cumulative excess revenues at the end of the period from January 1, 2018 to December 31, 2018, by making a payment to Her Majesty in the right of Canada, within 30 days of receiving Board Staff's notification of remaining excess revenues calculated based on the semi-annual price and sales data filed by Medexus Inc. as required by the Patented Medicines Regulations; and

4.6 To ensure that the prices of Metoject Subcutaneous remain within the thresholds set out in the Guidelines in all future periods in which these products are under the PMPRB's jurisdiction.

Name: Ken d'Entremont

Position: President & CEO

Patentee: Medexus Inc.

Date: January 29, 2018