VOLUNTARY COMPLIANCE UNDERTAKING
OF
CHIESI USA, INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Cleviprex (clevidipine) is indicated for the management of acute elevation of blood pressure in perioperative settings.

1.2. Health Canada first issued a Notice of Compliance for Cleviprex on April 15, 2011. Cleviprex was first sold in Canada on December 10, 2019, pursuant to Special Access Program (SAP) authorization.

1.3. Cleviprex is available as 0.5 mg/mL (DIN 02366223) solution in 50mL and 100mL single use vials and continues to only be available pursuant to the SAP.

1.4. The first reported patent pertaining to Cleviprex was granted on May 17, 2005. The last reported patent pertaining to Cleviprex, being Canadian Patent No. 2889584, was granted on August 14, 2018, and is set to expire on October 26, 2033. Chiesi USA, Inc. (“Chiesi”) is the patentee for the purposes of the *Patent Act* (“Act”) and the corresponding Patented Medicines Regulations ("Regulations").

2.0 Application of the Guidelines

2.1 The Human Drug Advisory Panel (HDAP) recommended that Cleviprex be classified as a Slight or No Improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted for Cleviprex. The TCC test established the Maximum Average Potential Price (MAPP) for Cleviprex.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Chiesi that the price of Cleviprex is now, or was at any time since the date of first sale, excessive for the purposes of the Act, nor is this VCU binding upon any panel of the Board for the purposes of the Act. Chiesi reserves all rights to assert any position relating to the pricing of Cleviprex, or challenge the Board staff's position relating to the pricing of Cleviprex, at any time in the future.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 Pursuant to this VCU, Chiesi will undertake:

4.1.1 To agree that the MAPP of Cleviprex is $4.6120 per mL, which will establish the Introductory Benchmark Price (IBP);

4.1.2 To agree that the 2021 National Non-Excessive Average Price (N-NEAP) of Cleviprex is $4.7042 per mL;

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a patentee 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 patentee, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.

4.1.3 To agree that the 2022 N-NEAP of Cleviprex is $4.7365 per mL;

4.1.4 To offset the excess revenues accrued by Chiesi in respect of Cleviprex by further reducing the 2022 N-ATP for Cleviprex below its 2021 N-NEAP. The reduction in price will be applied to offset the cumulative excess totaling $128,391.00;

4.1.5 To offset any remaining cumulative excess revenues for Cleviprex at the end of the period from January 1 to December 31, 2022, by making a payment to Her Majesty in right of Canada, within 30 days of receiving PMPRB Staff's notification of remaining excess revenues calculated based on the semi-annual price and sales data filed by Chiesi, as required by the Regulations, and the N-NEAP set out in 4.1.3 or the acceptance of this VCU by the Chairperson of the PMPRB, whichever date is later;

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

Signature: _____

Name: Michael R. Gordon

Position: Sr. Vice President, Legal Affairs & General Counsel

Patentee: Chiesi USA, Inc.

Date: May 12, 2022