VOLUNTARY COMPLIANCE UNDERTAKING
OF
EISAI LIMITED
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD

1.0 Product Summary

1.1. Dayvigo (lemborexant) is indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

1.2. Health Canada first issued a Notice of Compliance for Dayvigo on November 4, 2020. Dayvigo was first sold in Canada on November 6, 2020.

1.3. Dayvigo is available as a 5 mg/tablet (DIN 02507366) and as a 10 mg/tablet (DIN 02507374).

1.4. The first reported patent pertaining to Dayvigo was granted on December 8, 2015. The last reported patent pertaining to Dayvigo is set to expire on February 14, 2033. Eisai Limited ("Eisai") is the patentee 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 Dayvigo be classified as a Slight or No Improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted for Dayvigo 10 mg/tablet and a Reasonable Relationship (RR) test was conducted for Dayvigo 5 mg/tablet. The TCC and RR tests established the respective Maximum Average Potential Prices (MAPPs) for Dayvigo 10 mg/tablet and Dayvigo 5 mg/tablet.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Eisai that the prices of Dayvigo 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, Eisai will undertake:

4.1.1 To agree that the MAPPs of Dayvigo 10 mg/tablet and Dayvigo 5 mg/tablet are $1.4900 per tablet, which will establish the Introductory Benchmark Prices (IBPs);

4.1.2 To agree that the 2021 Non-Excessive Average Prices (NEAPs) of Dayvigo 10 mg/tablet and Dayvigo 5 mg/tablet are $1.5198 per tablet;

4.1.3 To ensure that the list prices of Dayvigo 10 mg/tablet and Dayvigo 5mg/tablet are no higher than the 2021 NEAPs, within 30 days of the acceptance of this VCU;

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

4.1.5 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, 2021, as calculated based on the semi-annual price and sales data filed by Eisai; and

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

Signature: _____

Name: Patrick Forsythe

Position: Country Manager

Patentee: Eisai Limited

Date: October 8, 2021