

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
BAUSCH HEALTH, CANADA INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1. Duobrii (halobetasol proprionate/tazarotene) is indicated for improving the signs and symptoms of plaque psoriasis in adult patients with moderate to severe plaque psoriasis.
- 1.2. Health Canada first issued a Notice of Compliance for Duobrii on June 10, 2020. Duobrii was first sold in Canada on August 4, 2020.
- 1.3. Duobrii is available as 0.55 mg/gram (DIN 02499967) lotion supplied in a tube containing 100 grams.
- 1.4. The first reported patent pertaining to Duobrii was granted on May 4, 2010. The last reported patent pertaining to Duobrii is set to expire on November 9, 2031. Bausch Health, Canada Inc. (“Bausch”) is the Rights Holder 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 Duobrii be classified as a Slight or No Improvement. In accordance with the Guidelines, a Therapeutic Class Comparison (TCC) test was conducted for Duobrii. The TCC test established the Maximum Average Potential Price (MAPP) for Duobrii.

3.0 Position of the Rights Holder

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Bausch that the price of Duobrii is now, or was 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, Bausch will undertake:
 - 4.1.1 To agree that the MAPP of Duobrii is \$1.8958 per gram, which will establish the Introductory Benchmark Price (IBP);
 - 4.1.2 To agree that the 2021 National Non-Excessive Average Price (N-NEAP) of Duobrii is \$1.9337 per gram;
 - 4.1.3 To agree that the 2022 N-NEAP of Duobrii is \$1.9550 per gram;

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a rights holder to comply with the terms of the VCU to close an investigation initiated by PMPRB Staff. 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 rights holder, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.

VCU (May 2022)

- 4.1.4 To make a payment to Her Majesty in right of Canada within 30 days of acceptance of this VCU for excess revenues of \$97,247.04 as of December 31, 2021, as calculated based on the semi-annual price and sales data filed by Bausch. ; and
- 4.1.5 To offset alleged excess revenue accrued by Duobrii by December 31, 2022, and that the 2022 N-ATP does not exceed the 2022 N-NEAP.
- 4.1.6 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, 2022, as calculated based on the semi-annual price and sales data filed by Bausch; and
- 4.1.7 To ensure that the prices of Duobrii remain within the PMPRB's Guidelines in all future periods in which it is under the PMPRB's jurisdiction.

Signature: _____

Name: Cees Heiman

Position: Senior Vice President, Europe and Canada

Rights Holder: Bausch Health, Canada Inc.

Date: May 11, 2022

A Voluntary Compliance Undertaking (VCU) is a voluntary and unilateral written promise by a rights holder to comply with the terms of the VCU to close an investigation initiated by PMPRB Staff. 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 rights holder, or used to calculate a revenue offset, is not excessive. VCUs do not have precedential value.