

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
EMD INC.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Pergoveris (follitropin alfa/lutropin alfa) (150IU/ 75fIU Kit) is a combination product consisting of the active ingredients Gonal-F (follitropin alfa) and Luveris (lutropin alfa). Pergoveris is indicated for the stimulation of follicular development in women with severe LH and FSH deficiency.
- 1.2 Canadian Patents 2,399,100 and 2,526,099 pertaining to Pergoveris were granted on November 8, 2011 and February 5, 2013 respectively and will expire on January 22, 2021 and June 16, 2024 respectively.
- 1.3 Health Canada issued a Notice of Compliance (NOC) for Pergoveris on August 25, 2015. Sales in Canada commenced October 2015.
- 1.4 EMD Inc., the Canadian subsidiary of Ares Trading S.A., is the patentee for purposes of the *Patent Act* and the Patented Medicine Prices Review Board (PMPRB).

2.0 Application of the Excessive Price Guidelines

- 2.1 Pergoveris was reviewed as a Slight/No improvement. The price at the national and market levels were above the Maximum Average Potential Price (MAPP) at introduction triggering the investigation criteria.
- 2.2 There have been no sales of Pergoveris in 2016. As of December 2016, cumulative excess revenues were \$63.10.

3.0 Position of Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by EMD Inc. that the price of Pergoveris was excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

In order to comply with the Guidelines, EMD Inc. agrees to undertake the following:

- 4.1 To reduce the list price of Pergoveris to \$141.7600 within 30 days of acceptance of this VCU.

VCUs represent a compromise between the PMPRB and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCUs are not intended to have precedential value.

- 4.2 To agree that the 2017 National Non-Excessive Average Price (N-NEAP) and Market-Specific Non-Excessive Average Price (MS-NEAPs) for Pergoveris is \$129.5350 and will serve as the benchmark price for sales of Pergoveris in future years.
- 4.3 To offset cumulative excess revenues received by EMD Inc. as of December 31, 2016, by making a payment to Her Majesty in right of Canada in the amount of \$63.10 within 30 days of the acceptance of this VCU.
- 4.4 To ensure that the prices of Pergoveris remain within the Guidelines in all future periods in which Pergoveris is under the PMPRB's jurisdiction.

Name: Norm Berberich
Position: Director, Patient Access & Government Affairs
Patentee: EMD Inc.
Date: December, 21, 2016

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