

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
HOSPIRA HEALTHCARE CORPORATION (CANADA)
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1. Product Summary

- 1.1 Precedex (dexmedetomidine hydrochloride for injection) is indicated for intensive care unit sedation and for conscious sedation.
- 1.2 Canadian Patent No. 1,337,659 and 2,326,339 pertaining to Precedex were issued to Abbott Laboratories (United States of America) on November 28, 1995 and December 23, 2008 respectively. The last patent expires on March 31, 2019. Hospira Healthcare Corporation (Canada) is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).
- 1.3 On December 9, 2009, Health Canada granted a Notice of Compliance to Hospira Healthcare Corporation (Canada) for the marketing authorization of Precedex, though sales began on July 10, 2008 under the Special Access Programme. It is supplied in a 2 mL glass vial containing 100 mcg/mL of dexmedetomidine hydrochloride.

2. Application of the Excessive Price Guidelines

- 2.1 Precedex was classified by the PMPRB's Human Drug Advisory Panel as a moderate improvement new medicine and its introductory price exceeded the Board's Guidelines. In particular, the price of \$33.0000 was 69.0% above the introductory maximum average potential price (MAPP) (formerly known as the maximum non-excessive (MNE) price) of \$19.5231 as determined by the higher of the highest non-excessive price identified in the Therapeutic Class Comparison (TCC) test and the midpoint between the TCC test and the median international price as determined by the Median International Price Comparison (MIPC) test, resulting in excess revenues of \$5,390.76 in the introductory period (July - December 2008).
- 2.2 A review of the subsequent reporting periods indicated that the price of Precedex continued to exceed the Guidelines with cumulative excess revenues estimated to be \$807,490 as of the end of February 2012.

3. Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking constitutes no admission by Hospira Healthcare Corporation (Canada) that the price of Precedex is or was excessive for purposes of the *Patent Act*.
- 3.2 Precedex offers a substantial improvement relative to other therapies indicated for intensive care unit sedation and for conscious sedation.

4. Terms of the Voluntary Compliance Undertaking (VCU)

4.1. In order to comply with the Guidelines, Hospira Healthcare Corporation (Canada) undertakes as follows:

4.1.1. To agree that the 2008 to 2009 MNE prices and the 2010, 2011 and 2012 National Non-Excessive Average Price (N-NEAP) for Precedex are as follows:

- a) \$19.5231 for 2008
- b) \$19.5817 for 2009
- c) \$19.9331 for 2010
- d) \$20.5188 for 2011
- e) \$20.8349 for 2012

4.1.2 For greater certainty, the N-NEAPs outlined in paragraph 4.1.1 are final and not subject to change as long as they do not exceed the highest international price as outlined in the Guidelines.

4.1.3 To file a Form-2 Block-4 for the period January to February 2012 for purposes of confirming the excess revenues that accrued over that period

4.1.4 To offset cumulative revenues in excess of the guidelines received from July 10, 2008 to February 2012 in the amount of \$807,490 (plus any additional amount identified by the review of the filings outlined in paragraph 4.1.3) by lowering the price of another patented medicine (Docetaxel) below its 2011 ATP/N-NEAP by not less than 10% effective January 1, 2012 and will remain at the discounted price until all Precedex excess revenues have been offset which should be by no later than December 31, 2012.

4.1.5 In the event that the full amount of the excess revenues has not been offset by December 31, 2012, to make a further payment to Her Majesty in right of Canada within 30 days of the filing of the July to December 2012 price and sales data in accordance with the Patented Medicines Regulations for the remainder of the excess revenues, to be calculated by Board Staff.

4.1.6 To ensure that the average transaction price of Precedex is within the Guidelines in all future reporting periods in which Precedex remains under the PMPRB's jurisdiction.

Signature: _____

Name: Gerry Stefanatos

Position: Vice President, Canada and Latin America

Company: Hospira Healthcare Corporation (Canada)

Date: 2/24/2012