

June 7, 2006

WITHOUT PREJUDICE

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**VOLUNTARY COMPLIANCE UNDERTAKING
OF
ORGANON CANADA LTD.
TO
THE PATENTED MEDICINE PRICES REVIEW BOARD**

1. Product Summary

- 1.1 NuvaRing™ (etonogestrel/ethinyl estradiol slow release, once a month vaginal ring) is a patented medicine sold in Canada by Organon Canada Ltd. (Organon).
- 1.2 NuvaRing (DIN 02253186) is a new form of contraception and is a combination of a new active substance (etonogestrel) and an already existing active substance (ethinyl estradiol). This combination has not yet been classified in the WHO ATC index 2005 on the temporary lists of new ATCs as per the WHO-ATC Web site.
- 1.3 Canadian Patent 2,233,753 pertaining to NuvaRing was granted to Akzo Nobel N.V., Netherlands on December 25, 2001 and will expire on March 31, 2018. Organon is the patentee for purposes of the Patented medicine Prices Review Board (PMPRB).
- 1.4 Health Canada issued a Notice of Compliance for NuvaRing on May 11, 2004. Organon began selling NuvaRing on January 17, 2005.

2. Application of the Excessive Price Guidelines

- 2.1 In accordance with the PMPRB's Excessive Price Guidelines (the Guidelines), Board Staff conducted the review of the price of NuvaRing. The PMPRB's Human Drug Advisory Panel (HDAP) classified NuvaRing as a category 3 new medicine and recommended all combined (estrogen/progestin) low-dose estrogen contraceptive products available in Canada as appropriate comparators for NuvaRing.
- 2.2 A Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted. The results of these tests indicated that the \$18.0007 average transaction price of NuvaRing appeared to exceed the maximum non-excessive (MNE) price of \$13.4109 by 34.2%, based on the TCC test. The NuvaRing MNE price is based on the MNE price for the comparator Evra per the Evra Voluntary Compliance Undertaking dated February 8, 2005. Excess revenues from the sale of NuvaRing as for the period from January 17, 2005 to December 31, 2005 totaled \$392,752.56.

3. Position of Patentee

- 3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Organon that the price of NuvaRing is or was excessive for purposes of the *Patent Act*
- 3.2 Effective February 6, 2006 Organon reduced the list price of NuvaRing to \$14.01, the list price of the Evra as per the Evra Voluntary Compliance Undertaking accepted by the PMPRB.



4. Terms of the Voluntary Compliance Undertaking

4.1 Under the terms of this VCU, Organon undertakes as follows:

- a) To agree that the MNE price of NuvaRing is \$13.4109 in 2005 and that it is calculated to be \$13.6791 in 2006.
- b) To reduce the average transaction price of NuvaRing to a level at or below the 2006 MNE price of \$13.6791 and to file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of NuvaRing has been reduced in a manner consistent with the terms of this VCU.
- c) To offset excess revenues, as calculated by Board Staff, during the period January 17 to June 30, 2005, by making a payment to Her Majesty in right of Canada within 30 days of the acceptance of this VCU, in the amount of \$115,584.93.
- d) The excess revenues remaining, as calculated by Board Staff, for the period July 1, 2005 to June 30, 2006 will be offset by the reduction of the price of Remeron RD 15mg (DIN 2248542), 30mg (DIN 2248543), and 45mg (DIN 2248544). In the event any excess revenues have not been offset, Organon shall make a payment to Her Majesty in right of Canada, by January 30, 2007 for such amount as determined by Board Staff.
- e) Within 15 days of acceptance of this VCU, to provide notice to customers of the price reduction for NuvaRing and that this price reduction is the result of an undertaking to the PMPRB and to provide a reference to the PMPRB Web site for the complete text of the VCU, and to further provide copies of such notifications to the PMPRB forthwith.
- f) To ensure that the price of NuvaRing remains within the Guidelines while NuvaRing is under the PMPRB's jurisdiction.

Organon Canada Ltd.

Signature: Original signed by
Company Officer: Norman H. Hudson
Position: Director, Business Development and Government Relations
Date: June 7, 2006