

**IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4,
as amended**

**AND IN THE MATTER OF Janssen-Ortho Inc.
(the “Respondent”) and the medicine “Evra”**

A. Purpose of this Joint Submission

1. The purpose of this Joint Submission is to provide the Board with the rationale behind the attached proposed Voluntary Compliance Undertaking (VCU) and its terms and provisions.

B. Grounds for Approving the draft VCU

2. Board Staff and Janssen-Ortho recommend that it is appropriate for the Board to approve the VCU for the following reasons:
 - a. It provides for a reduction in the price of Evra to be within the Guidelines effective January 2005.
 - b. It protects Canadian consumers by ensuring that Janssen-Ortho will immediately lower the price of Evra by about 45%.
 - c. It respects the policies of the Board by ensuring that all of the excess revenues received by Janssen-Ortho to date will be offset. The offset will be achieved by a combination of a payment to Her Majesty the Queen in Right of Canada in the amount \$1,359,263.67 as well as a reduction in the price of one other patented drug product that is being sold in Canada by Janssen-Ortho.
 - d. The proposed maximum non-excessive (MNE) price in the VCU is based on the therapeutic class comparison and the proposed list price for Evra is based on the median of international prices.
 - e. In an effort to resolve the matter currently before the Board, it reflects a VCU based on meaningful and constructive consultation and discussion between Board Staff and Janssen-Ortho.

C. Background details of proposed VCU

3. The MNE price for Evra for 2005 will be \$4.4703 per patch. Janssen-Ortho will reduce its price in 2005 such that it does not exceed the 2005 MNE price.

This price is calculated using the Therapeutic Class Comparison (TCC) test established for the introductory period October to December 2002, and applying the CPI factors for 2003, 2004 and 2005.

October to December 2002	\$4.2133
2003	\$4.3313
2004	\$4.4113
2005	\$4.4703

The above result occurs in the course of the application of the Guidelines. A MNE price is determined in the introductory period. Following this period, a patentee's price would be presumed to be excessive if its price exceeded the MNE price adjusted for the Consumer Price Index.

4. Janssen-Ortho will lower its list price from \$8.33 to \$4.67 per patch effective on or before March 1, 2005.

The proposed \$4.67 list price is calculated based on the median international price noted in the Statement of Allegations of Board Staff for the year 2004 and adjusted for CPI in 2005. Since then it has been determined that the actual median international price is lower. Board Staff and Janssen-Ortho have agreed that for the purposes of this negotiated settlement it would not be necessary nor appropriate to review the median international price.

5. The inclusion in the VCU of references to the list price and the MNE price represents an approach that reflects the two possible price tests for category 3 new medicines under the Guidelines - the TCC and the median international price. While the Guidelines do not require this approach, it is consistent with the spirit of the Guidelines and the factors set out in the *Patent Act*. This approach reflects a negotiated compromise on behalf of both parties and incorporates elements that are fundamental to their positions.
6. Janssen-Ortho will offset excess revenues it may have received from the sale of Evra in the following manner. Janssen-Ortho will make a payment of \$1,359,263.67 to Her Majesty the Queen in Right of Canada. This amount represents the cumulative excess revenues accrued from the date of first sale to June 30, 2004. The balance of excess revenues remaining (estimated to be approximately \$2 million) for the reporting period of July 1 to December 31, 2004 will be offset by reducing the price of one of the company's patented medicines in 2005. Janssen-Ortho has identified the patented medicine. Once the amount to be repaid for the July to December 2004 period is calculated, this information and the details of the price reduction will be made public. This is to occur by the end of February 2005. Any balance of excess revenues not offset by the price reduction as at December 31, 2005 will be offset through a further payment to Her Majesty the Queen in Right of Canada by January 31, 2006.
7. Janssen-Ortho will ensure that the price of Evra remains within the Guidelines as

long as it is under the jurisdiction of the PMPRB.

8. The VCU is consistent with both the Guidelines and with the provisions of the Patent Act. The parties submit that it is in the public interest for the Board to approve this VCU.

Dated this 8th day of February, 2005.