

Accepted by the Chairperson of the Board

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

1.0 Product Summary

- 1.1 Pariet (rabeprazole sodium) is indicated for the treatment of conditions where a reduction of gastric secretion is required.
- 1.2 Canadian Patent No. 1,265,138 pertaining to Pariet was granted to Eisai Co. Ltd., Japan on January 30, 1990. A second Canadian Patent No. 2,104,531 pertaining to Pariet was granted to Eisai Co. Ltd., Japan on January 5, 1999 and will expire on August 20, 2013.
- 1.3 Health Canada issued a Notice of Compliance (NOC) for Pariet 20 mg tablet on May 7, 2001 to Janssen Ortho Inc. which sold Pariet in Canada from July 3, 2002.
- 1.4 Janssen Inc. is the Canadian patentee for all purposes relating to the *Patent Act* (Act) and the *Patented Medicines Regulations* (Regulations) in respect of the jurisdiction of the PMPRB.

2.0 Application of the Excessive Price Guidelines

- 2.1 The price of Pariet 20 mg tablet was within the Guidelines at introduction and remained so until 2011.
- 2.2 In 2011, the price of Pariet 20 mg tablet exceeded the Guidelines triggering the investigation criteria. In particular, the 2011 price of Pariet 20 mg tablet was 3.1% above the National Non-Excessive Average Price (N-NEAP) resulting in excess revenues of \$217,413.07 as of December 31, 2011.

3.0 Position of Patentee

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

4.0 Terms of the Voluntary Compliance Undertaking

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

- 4.1 To agree that the 2011 and 2012 N-NEAPs for Pariet 20 mg tablet are \$1.2707 and \$1.2914 respectively;
- 4.2 To reduce the national average transaction price of Pariet 20mg tablet to the 2012 N-NEAP as stated in 4.1 before December 31, 2012;
- 4.3 To offset the cumulative excess revenues received from January 1, 2011 to December 31, 2011 by making a payment to Her Majesty in right of Canada in the amount of \$217,413.07 within 30 days of the acceptance of the VCU;

- 4.4 In the event that the national average transaction price of Pariet 20 mg is not within the Guidelines as per 4.2, to offset any excess revenues received during the period January 1, 2012 to December 31, 2012 by making 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 such further amounts, to be calculated by Board Staff;
- 4.5 To ensure that the price of Pariet remains within the Guidelines in all future periods in which Pariet is under the PMPRB's jurisdiction.

Signature:	Original signed by
Name:	Chris Halyk
Position:	President
Patentee:	Janssen Inc.
Date:	May 14, 2012