

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
IROKO INTERNATIONAL LP
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Vancocin (vancomycin hydrochloride) is an antibiotic that is indicated for treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis cause by *Clostridium difficile*.
- 1.2 Health Canada issued a Notice of Compliance (NOC) for Vancocin 125 mg caplet and 250 mg caplet (DIN 00800430 and DIN 00788716) on October 16, 2007 to Iroko International LP (Iroko).
- 1.3 Canadian Patent No. 1,320,312 pertaining to Vancocin was granted to Eli Lilly & Co., USA on July 13, 1993 and will expire on July 13, 2010. Eli Lilly Canada began selling Vancocin in Canada on January 1, 1989 and was the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB) until it assigned its patent rights to Iroko on September 11, 2007. Iroko became the patentee for purposes of the PMPRB when it began selling Vancocin in Canada on September 11, 2007 and Iroko is the subject of this Voluntary Compliance Undertaking (VCU).

2.0 Application of the Excessive Price Guidelines

- 2.1 The introductory prices of Vancocin 125 mg caplet and 250 mg caplet were within the Guidelines when Iroko started to sell in 2007.
- 2.2 A review of subsequent periods indicated that the price of Vancocin 125 mg caplet exceeded the Guidelines for the January to December 2008 reporting period. The Average Transaction Price (ATP) of \$7.1270 exceeded the maximum non-excessive (MNE) price of \$7.0164 by 1.6% resulting in excess revenues of \$54,764.70. The price of Vancocin 250 mg caplet also exceeded the Guidelines during the January to December 2008 reporting period. The ATP of \$14.1700 exceeded the MNE price of \$14.0391 by 0.9% resulting in excess revenues of \$24,284.57. The prices of both strengths continued to exceed their MNE prices in 2009 such that total cumulative excess revenues for both strengths were \$173,003.30 as of December 31, 2009.

3.0 Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Iroko that the prices in Canada of Vancocin 125 mg and 250 mg caplets are or were excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

4.1 In order to comply with the Guidelines, Iroko agrees to undertake the following:

4.1.1 To agree that the 2008-2009 MNE prices and the 2010 National-Non Excessive Average Prices (N-NEAPs) for Vancocin 125 mg and 250 mg caplets are as set out in the table below:

	<u>125 mg/cap</u>	<u>250 mg/cap</u>
2008	\$7.0164	\$14.0391
2009	\$7.0146	\$14.0022
2010	\$7.1626	\$14.2308

4.1.2 To offset the cumulative excess revenues received from January 2008 to December 2009 by making a payment to Her Majesty in right of Canada in the amount of \$173,003.30 within 30 days of the acceptance of the VCU;

4.1.3 To offset any excess revenues received during the period January 1, 2010 through July 13, 2010 by making further payment to Her Majesty in right of Canada within 30 days of July 13, 2010, the patent expiry date, for such further amounts to be calculated by Board Staff;

4.1.4 To notify the PMPRB in the event that other patents pertaining to Vancocin are issued in any future period.

Signature: Original Signed by
Name: Fred Krieger
Position: VP Finance
Patentee: Iroko International LP
Date: July 21, 2010