September 17, 2007

VOLUNTARY COMPLIANCE UNDERTAKING OF ABBOTT LABORATORIES LIMITED TO THE PATENTED MEDICINE PRICES REVIEW BOARD

1. Product Summary

1.1 Zemplar (parenteral paricalcitol) (Zemplar IV), a patented medicine sold in Canada by Abbott Laboratories Limited (Abbott), is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic renal failure.

1.2 Zemplar IV is classified in the 4th level of the World Health Organisation (WHO) Anatomical Therapeutic Chemical (ATC) classification index as A11CC, known as "Vitamin D and analogues."

1.3 Canadian Patent No. 1,333,616 pertaining to Zemplar IV was granted on December 20, 1994 to Wisconsin Alumni Res. Foundation, USA and will expire on December 20, 2011. Abbott is the patentee for purposes of the Patented Medicine Prices Review Board (PMPRB).

1.4 On January 1, 1999, Abbott began selling Zemplar IV 5 mcg/mL powder for solution in Canada under Health Canada's Special Access Program (SAP). Health Canada issued a Notice of Compliance (NOC) on March 31, 2005 for Zemplar IV 5 mcg/mL (DIN 02266202).

1.5 Although Zemplar IV was first sold as a patented medicine in 1999, Abbott first reported price and sales data for Zemplar IV to the PMPRB on June 5, 2005.

2. Application by Board Staff of the PMPRB's *Excessive Price Guidelines* (Guidelines)

2.1 The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Zemplar IV be classified as a category 3 new medicine based on the view of the HDAP that it provides moderate, little or no improvement over comparable medicines available in Canada at the time Zemplar IV was first introduced. The HDAP identified Calcijex (parenteral calcitriol) as the most appropriate comparator for Zemplar IV at the time it was first sold in Canada in 1999. The HDAP did not consider oral vitamin D analogues to

be appropriate comparators as they are not comparable dosage forms according to the Guidelines.

2.2 Based on the HDAP recommendation, a Therapeutic Class Comparison (TCC) test and an International Price Comparison (IPC) test were conducted by Board Staff. Board Staff takes the position that the price of Zemplar IV during the introductory period (January 1, 1999 to June 30, 1999) exceeded the Guidelines. In particular, Board Staff takes the position that the price of Zemplar IV of $27.6300 was 66.57% above the maximum non-excessive (MNE) price of $16.5873 as determined by its application of the TCC test. As a result, Board Staff has calculated that Abbott received excess revenues of $1,104.27 during the introductory period.

2.3 Based on the above position, a review of the subsequent reporting periods to the end of June 30, 2007 indicates that, at the end of June 30, 2007, cumulative excess revenues for Zemplar IV were $58,741.67.

3. Position of the Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Abbott that the price of Zemplar IV is or was excessive for purposes of the Guidelines or the *Patent Act*.

4. Terms of the Voluntary Compliance Undertaking (VCU)

4.1 Abbott undertakes as follows:

4.1.1. Board Staff alleges and Abbott, with no admission whatsoever, accepts that, for purposes of the Guidelines, the MNE prices of Zemplar IV 5 mcg/mL, are as follows:

	Zemplar IV 5 mcg/mL
1999	$16.5873
2000	$17.0352
2001	$17.4664
2002	$17.8645
2003	$18.3469
2004	$18.6890
2005	$19.1150
2006	$19.4844
2007	$19.9255

4.1.2. Subject to paragraphs 4.1.3 and 4.1.4, to ensure that the average transaction price of Zemplar IV for 2007 does not exceed the alleged 2007 MNE price of $19.9255;

4.1.3 To offset the cumulative alleged excess revenues received by Abbott during the period of January 1, 1999 to June 30, 2007 by making a payment to each hospital in Canada that paid the alleged excessive price, within 30 days of the acceptance of this VCU, in the total amount of $58,741.67;

4.1.4. To offset any alleged excess revenues received by Abbott during the period of July 1, 2007 to December 31, 2007 based on the alleged MNE for 2007 and the average transaction price of Zemplar IV as reported pursuant to the *Patented Medicines Regulations, 1994* for that period by making a payment to each hospital in Canada that paid the alleged excessive price, within 30 days of the filing of semi-annual price and sales data for the July to December 2007 reporting period, in the total amount of such alleged excess revenues;

4.1.5. To notify customers receiving payments that the payment is the result of an undertaking to the PMPRB, 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 Board Staff forthwith; and

4.1.6. To ensure that the price of Zemplar IV remains within the Guidelines in all future reporting periods in which Zemplar IV remains under the PMPRB's jurisdiction.

Name: Jeffrey J. Devlin

Position: General Manager

Company: Abbott Laboratories, Limited

Date: 9/12/07