

June 1, 2007

WITHOUT PREJUDICE

PROTECTED: S. 87 PRIVILEGE

**VOLUNTARY COMPLIANCE UNDERTAKING
OF
ELI LILLY CANADA INC.
TO THE
PATENTED MEDICINE PRICES REVIEW BOARD**

1.0 Product Summary

- 1.1 Forteo is the brand name of a medicine known generically as teriparatide, recombinant human parathyroid hormone 1-34 (rhPTH1-34). Forteo is a patented medicine sold in Canada by Eli Lilly Canada Inc. ("Lilly Canada").
- 1.2 Forteo is the first in a new class of bone formation agents. It is supplied as an injectable solution in a 3 mL cartridge contained in a prefilled delivery device (pen) in a strength of 250 mcg/mL in packages of 1 unit. It is administered subcutaneously in a dosage of 20 mcg once per day, and each prefilled pen delivers the required daily dose of 20 mcg.
- 1.3 Health Canada issued a Notice of Compliance ("NOC") for the sale of Forteo on June 3, 2004 (DIN 02254689). Forteo is indicated for the treatment of postmenopausal women with severe osteoporosis who are at high risk of fracture or who have failed or are intolerant to previous osteoporosis therapy; and to increase bone mass in men with primary or hypogonadal severe osteoporosis who have failed or are intolerant to previous osteoporosis therapy. Forteo was first sold in Canada on July 15, 2004.
- 1.4 Canadian patent No. 2,325,371 pertaining to Forteo was granted to Eli Lilly and Company (United States) on August 17, 2004, and will expire on August 19, 2019. Lilly Canada is the patentee for purposes of the Patented Medicine Prices Review Board ("PMPRB").

2.0 Application of the Excessive Price Guidelines

- 2.1 The PMPRB's Human Drug Advisory Panel ("HDAP") recommended that Forteo should be classified as a category 3 new medicine and identified no comparator products
- 2.2 In accordance with PMPRB's *Excessive Price Guidelines* (Guidelines), an International Price Comparison (IPC) test was conducted during the introductory period (July 15 to December 31, 2004). The average transaction price (ATP) of Forteo in Canada, at \$215.5434 per mL, exceeded the Guidelines in that it was higher than the maximum non-excessive (MNE) price of \$192.1292 per mL determined by the median of the international prices in the seven countries listed in the *Patented Medicines Regulations* (Regulations) in which it was sold. Sales of

Forteo in Canada during this period of sale resulted in excess revenues in the amount of \$88,505.67.

- 2.3 A review of the subsequent reporting period (January to December 2005) indicated that the ATP of Forteo, at \$210.2488 per mL, continued to exceed the Guidelines with additional excess revenues in the amount of \$339,262.17, resulting in cumulative excess revenues in the amount of \$427,767.84. A review of the most recent reporting period (January to December 2006) indicated that the ATP of Forteo, at \$198.5165 per mL, was within Guidelines and that there were cumulative excess revenues remaining in the amount of \$333,629.25.

3.0 Position of the Patentee

- 3.1 This Voluntary Compliance Undertaking ("VCU") constitutes no admission by Lilly Canada that the price of Forteo in Canada is now or was excessive for purposes of the *Patent Act*.

4.0 Terms of the Voluntary Compliance Undertaking

- 4.1 In order to comply with the Guidelines, Lilly Canada agrees to undertake the following:
- 4.1.1 To agree that the MNE price of Forteo was \$192.1292 per mL for the period July to December 2004, \$196.3560 per mL for the period January to December 2005, \$200.3908 per mL for the period January to December 2006, and \$204.8097 for the period January to December 2007;
 - 4.1.2 To offset the remaining excess revenues of \$333,629.25 outstanding as at December 31, 2006 by maintaining the 2007 ATP of Forteo at levels below the 2007 MNE of \$204.8097 until December 31, 2007;
 - 4.1.3 To file price and sales data by January 30, 2008 as required by the *Patented Medicines Regulations, 1994* as evidence that the ATP has been reduced in a manner consistent with the terms of this undertaking;
 - 4.1.4 In the event any excess revenues have not been offset by December 31, 2007, Lilly Canada shall make a payment to Her Majesty the Queen in Right of Canada in the amount of the remainder of the excess revenues that have not been offset within 30 days of the filing of the July to December 2007 price and sales data;
 - 4.1.5 To ensure that the ATP (based on the calculation of revenues less reductions as appropriate under Subsection 4(4) of the Regulations divided by the quantity sold and distributed free of charge) of Forteo remains within the Guidelines in all future periods in which it remains under the Board's jurisdiction.

Eli Lilly Canada Inc

Signature: Original signed by
Company Officer: Terry M'Cool
Position: V.P. Corporate Affairs
Date: June 1, 2007