April 5, 2013

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

1.0 Product Summary

1.1 Mavik (trandolapril) is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive medication such as hydrochlorothiazide.

1.2 Canadian Patent No. 1,341,064 pertaining to Mavik was granted to Sanofi-Aventis Deutschland GMBH on August 1, 2000 and will expire on August 1, 2017. A second Canadian Patent No. 1,341,206 pertaining to Mavik was granted to Merck Sharp & Dohme Corp. (USA) on March 20, 2001 and will expire on March 20, 2018.

1.3 On June 11, 1997, Health Canada granted a Notice of Compliance (NOC) to Abbott Laboratories Limited for Mavik 0.5 mg capsule and sales began in Canada on August 13, 1998.

1.4 Abbott Laboratories Limited 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 Mavik 0.5 mg capsule was considered within the Guidelines from introduction until the end of 2010.

2.2 In 2011, the price of Mavik 0.5 mg capsule exceeded the Guidelines triggering the investigation criteria based on the highest international price comparison (HIPC). In particular, the 2011 price of Mavik 0.5 mg capsule was 33.4% above the National-Non Excessive Average Price (N-NEAP) resulting in excess revenues of $59,308.48 as of December 31, 2011. As of December 31, 2012, cumulative excess revenues were $118,168.48.

3.0 Position of Patentee

3.1 This Voluntary Compliance Undertaking (VCU) constitutes no admission by Abbott Laboratories Limited that the price of Mavik 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, Abbott Laboratories Limited agrees to undertake the following:

4.1 To agree that the 2011, 2012 and 2013 N-NEAPs for Mavik 0.5 mg capsule are as follows:

2011 $0.2733
2012 $0.2747
2013 $0.2829

4.2 To reduce the price of Mavik 0.5 mg capsule to the 2013 N-NEAP as stated in 4.1 within 30 days of the acceptance of this VCU, and as per the Guidelines, to adjust the N-ATP in 2014 if at the end of 2013 the Highest International Price is below the 2013 N-NEAP indicated in 4.1.

4.3 To offset the cumulative excess revenues received from January 1, 2011 to December 31, 2012 by making a payment to Her Majesty in right of Canada in the amount of $118,168.48 within 30 days of the acceptance of the VCU;

4.4 To offset any excess revenues received during the period January 1, 2013 to the date of reduction of the price of Mavik as per 4.2 of this VCU by making further payment to Her Majesty in right of Canada within 30 days of the filing of the January to June 2013 price and sales data in accordance with the *Patented Medicines Regulations* for such further amounts, to be calculated by Board Staff;

4.5 Within 15 days of acceptance of this VCU, to provide notification to customers of the price reductions and that this price reduction is the result of an undertaking to the PMPRB, to provide a reference to the PMPRB website for the complete text of the VCU, and to provide copies of such notifications to Board Staff;

4.6 To file evidence with Board Staff within 30 days of the acceptance of this VCU that the price of Mavik has been reduced in a manner consistent with the terms of this VCU; and

4.7 To ensure that the price of Mavik remains within the Guidelines in all future periods in which Mavik is under the PMPRB's jurisdiction.

Original signed by

Name: Benedetta Delia

Position: Finance Director

Patentee: Abbott Laboratories Limited

Date: April 6, 2013