WITHOUT PREJUDICE
PREPARED FOR PURPOSES OF SETTLEMENT
PROTECTED - s.87 PRIVILEGE

IN THE MATTER OF the *Patent Act*,
R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Eli Lilly
Canada Inc. and the medicine "Strattera"

VOLUNTARY COMPLIANCE UNDERTAKING

1.0 Product Summary

1.1 Strattera is a medicine indicated for the treatment of Attention Deficit/Hyperactivity Disorder ("ADHD") in children 6 years of age and over, adolescents and adults. It is a selective norepinephrine reuptake inhibitor in the form of atomoxetine hydrochloride capsules. Atomoxetine is a new active substance.

1.2 Health Canada issued a Notice of Compliance for Strattera (10 mg, 18 mg, 25 mg, 40 mg and 60 mg) to Eli Lilly Canada Inc. ("Eli Lilly") on December 24, 2004.

1.3 Eli Lilly began selling Strattera (10 mg and 18 mg) in Canada on February 24, 2005, followed by the introduction of Strattera (25 mg, 40 mg and 60 mg) on March 3, 2005.

2.0 Patents and Reporting Compliance

2.1 Canadian Patent Nos. 2,061,665, 2,209,735 and 2,304,657 pertain to Strattera. These patents were granted to Eli Lilly and Company on April 16, 2002, October 1, 2002, and October 25, 2005 and will expire on February 21, 2012, January 4, 2016 and September 1, 2018, respectively.

2.2 Eli Lilly is the licensee of the patents referred to above and as such is, for the purposes of the Patented Medicine Prices Review Board (the "Board"), considered as the Canadian patentee.

2.3 In accordance with the *Patented Medicines Regulations* or predecessor versions, as applicable ("Regulations"), Eli Lilly began filing its price and sales information for all five strengths of Strattera on April 26, 2005 and has since continued to file its price and sales information for all five strengths as per the Regulations.

3.0 Terms of the Undertaking

3.1 This Voluntary Compliance Undertaking ("VCU") is being made for purposes of resolving the issues relating to the pricing and sale of Strattera and compliance with the

Patent Act in respect thereof to date and as a result of settlement discussions with Board Staff following the issuance of a Notice of Hearing by the Board. This VCU constitutes no admission by Eli Lilly that the price of Strattera in Canada is now, or was at any time since the date of the first sale of the medicine, excessive for purposes of the Guidelines or the *Patent Act*.

3.2 Subject to section 3.3 below and for purposes of settlement, Eli Lilly agrees to abide by the approach of the Board taken in the April 10 and July 16, 2008 decisions of the Board in the Adderall XR matter (Board decisions PMPRB-06-D3-ADDERALL XR and PMPRB-06-D4-ADDERALL XR) in calculating the MNE prices for each strength of Strattera, namely the greater of:

(i) the MNE price for Strattera that would be generated by the Domestic Therapeutic Class Comparison where the therapeutic class consists of Ritalin, Ritalin SR and Dexedrine tablets and spansules; and

(ii) the mid-point between the MNE price for Strattera that would be generated by the Domestic Therapeutic Class Comparison described in (i) and the median international price ("MIP") for Strattera.

3.3 For the purposes of settlement, Eli Lilly agrees to the application of the Reasonable Relationship Test in respect of the 25 mg strength of Strattera.

3.4 Consequently, Eli Lilly agrees that the MNE prices for Strattera are as follows:

	10 mg	18 mg	25 mg	40 mg	60 mg
2005	$2.3463	$2.6930	$2.9701	$3.3859	$4.1096
2006	$2.3932	$2.7469	$3.0295	$3.4536	$4.0191
2007	$2.4435	$2.8045	$3.0931	$3.5261	$4.0439
2008	$2.5021	$2.8719	$3.1674	$3.6108	$4.0580
2009	$2.5488	$2.9254	$3.2264	$3.6781	$4.0832

3.5 Eli Lilly shall cause the maximum prices at which it sells Strattera in Canada to be reduced to the 2009 MNE prices, where applicable, within thirty (30) days from the date of the acceptance of this VCU by the Board.

3.6 Eli Lilly undertakes to make a payment to Her Majesty in right of Canada in the amount of $15,326,066.49 to offset all alleged excess revenues for Strattera from date of introduction to December 31, 2008, such payment to be made no later than thirty (30) days after acceptance of this VCU by the Board.

3.7 To offset any alleged excess revenues received by Eli Lilly during the period commencing January 1, 2009 to the date on which the price reductions referred to in section 3.5 come into effect, Eli Lilly shall ensure that the average transaction price for each strength of Strattera for the period January 1, 2009 to June 30, 2009 is at or below

the 2009 MNE prices. In the event that any excess revenues remain as at June 30, 2009, Eli Lilly shall make a payment to Her Majesty in right of Canada within thirty (30) days of the filing of the January to June 2009 price and sales data as required by the Regulations in the amount of any remaining excess revenues, as calculated by Board Staff and verified by Eli Lilly.

3.8 To provide notice to customers within 15 days of acceptance of this VCU of the price reductions, where applicable, for Strattera and that these price reductions are the result of an undertaking pursuant to an agreement with 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.

3.9 For years following 2009, Eli Lilly undertakes to ensure the prices of Strattera remain within the Guidelines in all future periods in which Strattera remains under the Board's jurisdiction.

ELI LILLY CANADA INC.

Original signature redacted

Name: Terry McCool
Title: Vice President, Corporate Affairs
Date: February 4, 2009