PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
PrSTRATTERA® (atomoxetine)

October 24, 2011

Subject: **Association of STRATTERA (atomoxetine) with Increased Blood Pressure and Increased Heart Rate**

Eli Lilly Canada Inc. together with Health Canada would like to inform patients and their caregivers of important information about the risk of increased blood pressure and increased heart rate with the use of STRATTERA (atomoxetine). STRATTERA (atomoxetine) is a medicine that is used for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children and adults.

Atomoxetine can increase heart rate and blood pressure. Patients and their caregivers should be aware of the following recommendations:

- Atomoxetine should not be used in patients with severe heart-related disorders.
- Atomoxetine should be used with caution in patients whose underlying medical conditions could be worsened by increases in blood pressure or heart rate, such as patients with high blood pressure, a faster than normal heart rate, or other problems relating to the heart or blood vessels to the brain.
- Patients or their caregivers should tell their doctor if they or their child with ADHD have any heart problems, heart defects, high blood pressure, or a family history of these problems.
- Patients or their caregivers should call their doctor right away if they or their child with ADHD have any signs of heart problems such as chest pain, irregular heart rate, palpitations, shortness of breath, dizziness, or fainting while taking atomoxetine.

Patients should not stop treatment with atomoxetine or modify the dosage, without discussing their condition with their healthcare professional. In addition to this advisory, a letter is being issued to health care professionals concerning this information. A copy of the letter can be accessed at Health Canada's website http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index-eng.php or at www.lilly.ca.

The Canadian prescribing information for STRATTERA has recently been revised to include this important safety information.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious increases in blood pressure or heart rate or other serious or unexpected adverse reactions in patients receiving STRATTERA should be reported to Eli Lilly Canada Inc. or Health Canada.

Eli Lilly Canada Inc.
Toronto, Ontario
1-888-545-5972

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, Ontario K1A 0K9

The Reporting Forms, postage paid labels, and Guidelines can be found on the MedEffect™ Canada website in the Adverse Reaction Reporting section.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php

For other health product inquiries related to this communication, please contact Health Canada at:

Lead Directorate: **Marketed Health Products Directorate**
E-mail: **MHPD_DPSC@hc-sc.gc.ca**
Telephone: **613-954-6522**
Fax: **613-952-7738**

Sincerely,

Loren D. Grossman, MD, FRCPC, FACP
Vice-President, Research and Development
Eli Lilly Canada Inc.