Eli Lilly Canada Inc.
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Canada

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September 28, 2005

Health Canada Endorsed Important Safety Information
STRATTERA™ (atomoxetine hydrochloride)

Subject: **WARNING for atomoxetine regarding the potential for behavioural and emotional changes, including risk of self-harm**

Dear Healthcare Professional:

Eli Lilly Canada Inc., following discussions with Health Canada, would like to inform you of important new safety information regarding the possibility that atomoxetine may be associated with behavioural and emotional changes, including risk of self harm.

The new warning to be incorporated in the product monograph of STRATTERA (atomoxetine hydrochloride) will reflect the information provided below.

POTENTIAL ASSOCIATION WITH THE OCCURRENCE OF BEHAVIOURAL AND EMOTIONAL CHANGES, INCLUDING SELF-HARM

Paediatrics: Placebo-Controlled Clinical Trial Data

Recent analyses of placebo-controlled clinical trial data showed that suicidal ideation was more frequently observed in clinical trials among children and adolescents treated with STRATTERA (5/1357 [0.37%]) compared to those treated with placebo (0/851). There was one suicide attempt in the atomoxetine treated group. No completed suicides occurred during these trials.

As described in the Product Monograph, there have been very rare post-marketing reports of suicidal ideation, suicide attempts, suicidal depression and completed suicides, in children, adolescents and adults.

Rigorous clinical monitoring for suicidal ideation or other indicators of potential for suicidal behaviour is advised in patients of all ages. This includes monitoring for agitation-type emotional and behavioural changes.

Background
Strattera is a selective norepinephrine reuptake inhibitor, indicated for the treatment of Attention Deficit/ Hyperactivity Disorder (ADHD) in children 6 years of age or older, adolescents and adults. Strattera is not indicated for the treatment of major depressive episodes and/or anxiety.

The findings described here resulted from a meta analysis of data from placebo-controlled clinical trials of atomoxetine. All events of suicidal thoughts occurred in children between 7 and 12 years old. There were no events in older adolescents, who comprised about 25 percent of the study population. Analysis of adult data in clinical trials did not indicate an increased risk of suicide related events among patients treated with atomoxetine.

The **CONSUMER INFORMATION** section of the Strattera Product Monograph will also be updated to reflect this new warning, and to advise patients to inform their doctor immediately if these symptoms develop or worsen during Strattera treatment:

Patients may have an increased risk of side-effects such as suicidal thoughts, hostility, and mood swings. You/your caregiver should inform your doctor right away if any of these symptoms develop or worsen after beginning treatment with STRATTERA.

Eli Lilly Canada Inc. continues to work closely with Health Canada to monitor adverse event reporting and to ensure that up-to-date information regarding the use of Strattera is available.

Reporting rates determined on the basis of spontaneously reported post-marketing adverse events are generally presumed to **underestimate the risks** associated with drug treatments. The identification, characterization and management of marketed health product-related adverse reactions are dependent on the active participation of healthcare professionals in adverse reaction reporting programs. Any occurrences of any serious and/or unexpected adverse reactions in patients receiving Strattera should be reported to either or both Eli Lilly Canada Inc. and/or Health Canada at the following addresses:

Customer Response Centre
Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario M1N 2E8
Toll Free Number: 1-888-545-5972 or Fax: 1-888-898-2961

Any suspected adverse reaction can also be reported to:
Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
Ottawa, Ontario K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335

To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 1-866-234-2345 or Fax: 1-866-678-6789
cadrmp@hc-sc.gc.ca

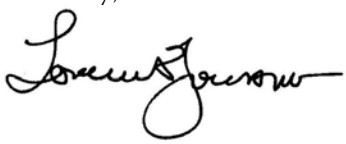
For other inquiries, please refer to contact information.

The AR Reporting Form and the AR Guidelines can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties.*

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adverse_e.html
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/adr_guideline_e.html

Any questions from healthcare professionals should be directed to Eli Lilly Canada Customer Response Centre at 1-888-545-5972 between 8:00 a.m. and 6:00 p.m. ET.

Sincerely,



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