

To: Professor Kent Woods  
Chief Executive  
Medicines and Healthcare products Regulatory Agency – MHRA

Copy: All European Medical Agencies (concerned member states  
for Strattera)  
Copy: Media

May 15, 2008

## **Strattera: Eli Lilly gave false information about deaths from Strattera “treatment” – a request for full investigation**

In April I gave data to the MHRA about **reported** instances of deaths in connection with Strattera treatment. The agency has still not answered and no investigation has been announced about the fatal cases reported.

The following updated report – **a compilation of confirmed fatal cases in connection with Strattera treatment**, is sent to assist the agency in its investigation.

This report also contains proof that Eli Lilly in January gave false and misleading information to the MHRA about deaths from Strattera treatment.

**The children and teenagers getting Strattera “for ADHD” can be expected to be healthy normal children and in this group of “patients” there *should be* extremely low morbidity and mortality. This report tells another story.**

-----

In November 2007 I made an FOIA-request to the MHRA about the number of persons who have died while under Strattera treatment. The agency didn't know and asked the manufacturer, Eli Lilly.

Eli Lilly noted that the company up to November 30, 2007 **“has identified 41 fatal cases in our safety database”**. But as the company only accepts deaths reported by a “health care professional (HCP) or regulatory authority”, 17 of these cases were right away deducted. In Lilly's words: **“Of the 41, only 24 were Adverse Drug Reactions (ADR) with fatal outcomes.” [1]**

The MHRA did not get further data about these fatal cases from Lilly, only the numbers.

-----

A new investigation of cases, with death as outcome, reported to the FDA (2004-2007), and a review of Periodic Safety Update Reports (PSURs) for Strattera, have shown the following:

### **Children and teenagers:**

**31 children and teenagers have died while under Strattera treatment, with Strattera reported as the *Primary Suspect Drug (PS)*. 19 of these young persons committed suicide.**

**In addition** to the FDA reports, data in different PSURs in Europe show that an additional **6 children and teenagers have died** while under Strattera treatment.

### **Adults:**

**33 adults have died while under Strattera treatment, with Strattera reported as the *Primary Suspect Drug (PS)*. 17 of these adults committed suicide.**

**In addition** to the FDA reports, data in different PSURs in Europe show that an additional **4 adults have died** while under Strattera treatment (cardiac death).

In the reports to the FDA there are also **7 cases of stillbirth/abortion spontaneous** reported with Strattera noted to be the *Primary Suspect Drug*.

### **Summary of fatal cases from FDA 2004-2007 and PSURs:**

**37 children and adolescents + 37 adults + 7 stillbirth/abortion spontaneous = 81 deaths.**

**Of these 81 fatal cases at least 47 were reported by health care professionals (HCP).**

See specifics about all fatal cases reported to the FDA 2004-2007 in the table

***Strattera Deaths with Strattera as Primary Suspect Drug***

<http://www.psychdrugdangers.com/stratteradeath-new.html> [2],

and for **ALL** reported fatal cases in the attached (and linked) document

***StratteraDeath*** <http://jannel.se/StratteraDeath.pdf> [3].

-----

**In addition**, the following fatal cases in connection with Strattera treatment – with Strattera as Secondary Suspect Drug (SS) or with Concomitant drugs (C) – are reported to FDA 2004-2007: **4 children and teenagers and 10 adults [see also 3]**

**In total: From FDA 2004-2007 and PSURs including Strattera in all Role Codes (PS, SS, C):**

**22 (suicides) + 19 = 41 children and adolescents;**

**22 (suicides) + 25 = 47 adults**

**+ 7 stillbirth/abortion spontaneous**

**= 95 cases of death**

-----

Lilly gave the figure 41 deaths - but right away excluded 17 case reports, and said the figure to be used was 24. [1]

**I have now given specifics about confirmed cases of death in connection with Strattera treatment. *And the number is much higher than in the Lilly report.***

-----

I refer to the promise by the agency: to **“take any necessary action to protect the public promptly if there is a problem”** [4].

The above information does **definitely** tell there is a problem: As said, the children and teenagers getting Strattera “for ADHD” can be expected to be healthy normal children and in this group of “patients” there should be extremely low morbidity and mortality.

But the above data say that 41 children and teenagers have died in the last 5 years while under Strattera “treatment” – with 22 of them committing suicide.

Add to this the staggering number of adverse events reported internationally for Strattera (the majority for children) – Lilly has told the MHRA: “During this reporting period, **a total of 23,132 spontaneous adverse event reports of atomoxetine [Strattera], representing 58,048 adverse events, were collected** by the MAH [Market Authorization Holder; Eli Lilly].” [5] This covered the period from November 2002 to March 2006. The number of persons who have experienced **suicidality in connection with Strattera treatment has now reached 965** (PSUR 9, p. 106). Up to November 2007 (PSUR 9, Annex 16) there were also **513 case reports about mania, psychosis or hallucinations in connection with Strattera treatment.**

The MHRA has not taken any visible actions to protect children from all these harmful effects – not even answering on earlier reports about deaths from Strattera treatment.

I would like to get a swift answer to these two questions:

**1. Is the agency going to call in question the data given by Eli Lilly (41 deaths, 24 confirmed by HCPs) in light of the now presented evidence (81 deaths in FDA 2004-2007 with Strattera as *Primary Suspect Drug* and in PSURs, with at least 47 of these 81 confirmed by HCPs; and in total 95 cases of death)?**

**2. Will the agency, considering the harm caused to children, start an investigation of all the reported cases of death in connection with Strattera “treatment”?**

Yours sincerely,

Janne Larsson  
Reporter – investigating psychiatry  
Snöbollsgård 22  
129 45 Hägersten  
Sweden  
[janne.olv.larsson@telia.com](mailto:janne.olv.larsson@telia.com)

#### **References:**

[1] Eli Lilly, Letter to the MHRA, January 2, 2008, (see last 3 pages)

<http://jannel.se/FOI%2008-011.redacted.letters.Strattera.pdf>

[2] Psychdrugdangers, *Strattera Deaths with Strattera as Primary Suspect Drug*, (visited May 15, 2008, <http://www.psychdrugdangers.com/stratteradeath-new.html>)

[3] StratteraDeath, May 15, 2008, <http://jannel.se/StratteraDeath.pdf>

[4] MHRA, About us, (visited May 15, 2008, <http://www.mhra.gov.uk/Aboutus/index.htm>)

[5] Eli Lilly, *Main Report*, for Periodic Safety Update Report (PSUR) 6, page 105, period November 27, 2005 through May 28, 2006, [http://jannel.se/Mainreport\\_p105.pdf](http://jannel.se/Mainreport_p105.pdf)