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

April 13, 2008

The ADHD drug Strattera: 55 young persons have died – a request for full investigation

Reports indicate that **55 children and adolescents have died under Strattera treatment in 5 years – 31 of them committed suicide.**

In total there are **reports of 102 instances of death – 57 of them from suicide**.

This is a request for an official investigation into ALL instances of death in connection with the ADHD drug Strattera.

In November I made an FOI-request to the MHRA about the number of persons who have died while under Strattera treatment.

The agency didn't know and had to ask the manufacturer, Eli Lilly.

In its answer Lilly wanted to educate the agency how to handle such sensitive FOI-requests. The company "had concerns" and asked:

> "Given the degree of work required by the MHRA in answering this request, has the MHRA not considered the effort required to do so?" **[1]**

In other words Lilly wanted to convince the agency *not* to release the data about instances of death in connection with Strattera treatment. The company further wrote:

> "If we were to provide you with a figure, we would go beyond that which was envisaged by FOI..."

Nevertheless, the company saw no other solution than to answer the question from the agency – hoping the MHRA would not release the figure in its turn. And in case the agency should release the number Lilly asked for the following:

> "Finally we should be grateful if you would please let me know what you decide to provide to the FOI requestor and any further actions as Lilly needs to be prepared for follow-up requests from the media."

Well, I hope the MHRA has notified Lilly that the agency actually released the data – so that the company has prepared itself for answering the questions raised below.

Lilly says in its answer, that it 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 are right away deducted. In Lilly's words: **"Of the 41, only 24 were Adverse Drug Reactions (ADR) with fatal outcomes."**

The information above seems to be the ***only*** "compilation" the MHRA has as regards instances of death from Strattera. This is a bit meagre, considering that Strattera is to be a drug under intensive surveillance (Black Triangle List).

With the information below I strongly want to question the data given by Lilly and to **request a full investigation by the agency into ALL reported cases of death in connection with Strattera treatment.**

I attach (and link to) a compilation of ***reports of deaths*** **[2]** made up from:

1. reports submitted to the FDA for 2004-2006, where Strattera is reported to be the Primary Suspect Drug (in some cases there are more than one report; in presenting the figures this is taken into account);
2. data presented in different Periodic Safety Reports (PSURs) sent out by the MHRA and Lilly;
3. reports about deaths collected in a database over international reports (reported 2006-2007).

The data in the FDA reports (1) **show the deaths of 19 children and adolescents, including 15 suicides** – where Strattera is reported as the Primary Suspect Drug (PS). **[3]** The reports **show the deaths of 19 adults** (or of persons where age is not noted), **including 13 suicides.**

The data in the different Periodic Safety Update Reports (and Risk-Benefit Assessments) (2) **show the deaths of an *additional* 8 children and adolescents, including 1 suicide. [2]** The reports also **show the deaths of an *additional* 12 adults, including 8 suicides.**

The data collected in the database for 2006-2007 (3) **show the deaths of an *additional* 28 children and adolescents, including 15 suicides**. **[4]** The reports also **show the deaths of an *additional* 16 adults, including 5 suicides.**

In total this gives 102 deaths.

It is to be noted that ***at least* 60 of the reports from these three sources are from health care professionals**; Lilly claimed in its answer to the MHRA that it only had 24 reports about fatal outcome from health care professionals.

For the decision to launch a full investigation into the deadly effects of Strattera the following updated information should also help:

An ***adverse event*** is defined as an undesirable experience associated with the use of a medical product in a patient. The event is ***serious*** when the patient outcome is: a) *death*; b) *life-threatening*; c) *hospitalization* (initial or prolonged); d) *disability*; e) *congenital anomaly* (as birth defects); f) *requiring intervention to prevent permanent impairment or damage*. **[5]**

When reading the figures below it should be borne in mind that it is generally accepted that only 1-10 percent of all serious adverse events are reported as part of the spontaneous reporting system.

For Strattera a staggering number of adverse events are reported: "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]." **[6]** This covered the period from November 2002 to March 2006. Over **70 percent** of the adverse events reported to the FDA are for children and adolescents. **[7]**

As for ***serious*** adverse events: **1,650 serious events are reported for the three years 2004-2007** (according to data in PSUR 4-PSUR 9).

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 did not (in November 2007) have any data about the number of persons who had died while under Strattera treatment. The agency had to ask Lilly.

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

And still the MHRA had only the *figure* from Lilly; no compilation was available.

I have now given data about 102 deaths – and it must be very clear that a full investigation has to be launched.

The data given above should be of real help for the agency. It must be an excellent starting point in the full and complete investigation into ALL instances of death in connection with Strattera.

I look forward to an answer saying that such an investigation with the potential outcome of removing this harmful drug from the market will start.

Yours sincerely,

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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] Compilation of reports of deaths Strattera, April 13, 2008,
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[3] Psychdrugdangers, *Strattera Deaths with Strattera as Primary Suspect Drug,* (visited April 13, 2008, http://www.psychdrugdangers.com/stratteradeath-ps.html
[4] Patientsville, search Strattera, counted reported deaths, visited April 13, 2008, http://patientsville.com/medication/strattera_side_effects.htm
[5] FDA, *What Is A Serious Adverse Event?,* January 23, 2004, http://www.fda.gov/medwatch/report/DESK/advevnt.htm
[6] 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
[7] Psychdrugdangers, *Reports for Strattera 2004-2006* (visited April 13, 2008, http://www.psychdrugdangers.com/ (search: Strattera).