

----- Original Message -----

From: MHRA Information Centre

To: jan.olv.larsson@telia.com

Sent: Tuesday, August 12, 2008 4:49 PM

Subject: RE: FOIA-request about deaths from Strattera treatment

Dear Mr Larsson,

There is only one question in your email of 16 May 2008 that meets the criteria of a request for information under the UK Freedom of Information Act. That is the request for *"The updated list over ALL fatal cases reported for Strattera, as compiled by the MHRA."*

You also asked *"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)?"*

The MHRA holds no data other than that previously released to you under the references 07/355 and 08/011, which was the data provided by the company. If you have any questions about FDA data or the data provided by the company, you should contact those organisations

It is important to be aware that all medicines, including Strattera, have both potential benefits and also possible risks of harm. Before any medicine, including Strattera, is licensed the available data on its safety and how well it works are carefully evaluated to ensure that the balance of risk and benefits is positive. Once a medicine is marketed its safety in routine clinical practice is continually monitored using emerging safety data that is collected and analysed by the national competent medicines authorities in each of the European Member States.

Each national competent medicines authority acts within European and national medicines legislation to ensure that licensed medicines are used as safely and effectively as possible and all new data is carefully evaluated. A variety of sources of data are used to monitor the safety of medicines including i) data from spontaneous reports of suspected adverse drug reactions (ADRs) reported to Member States through their national ADR reporting schemes, ii) data from clinical trials, iii) data from the published literature and data submitted by the Marketing Authorisation holder (MAH) including information submitted in the routine Periodic Safety Updates that the MAH is legally obliged to submit.

All these data sources are carefully evaluated for emerging drug safety signals and particular attention is paid to serious and fatal. For any emerging safety signal, all available data is analysed and careful consideration given to the strength of the evidence for a direct causal association with the medicine. The opinion of European Member States is that the balance of benefits and risk for Strattera remains positive. If in the future, new and reliable evidence emerges that alters this decision, regulatory action will be taken to assess the impact on the benefit/risk balance and to implement any necessary additional risk minimisation measures or other actions.

The views of patients and the public regarding the suitability of medical treatments for ADHD are respected and valued. The EMEA and national competent medicines authorities must make regulatory decisions on the balance of benefits and risks of a medicine based on a robust scientific evaluation of the all available scientific information. This allows patients, their carers and health professionals to make informed decisions about the appropriate use of medicines, supported by reliable information on the benefits and risks.

Kind Regards,
Central Enquiry Point
Information Centre
Medicines and Healthcare products Regulatory Agency
Tel: 020 7084 2000

From: Jan Larsson]
Sent: 02 July 2008 08:02
To:
Cc: MHRA Information Centre
Subject: FOIA-request about deaths from Strattera treatment
Importance: High

Regarding my FOIA-request below

My request was sent May 16. Hope to get an answer to this now.

Yours sincerely

Janne Larsson
Reporter

----- Original Message -----

From: Jan Larsson
To:
Cc: info@mhra.gsi.gov.uk
Sent: Monday, June 16, 2008 9:10 PM
Subject: FOIA-request about deaths from Strattera treatment

Regarding the request below

I hope to get an answer to this now.

Yours sincerely

Janne Larsson
Reporter

----- Original Message -----

From: Jan Larsson

To: info@mhra.gsi.gov.uk

Cc:

Sent: Friday, May 16, 2008 12:22 AM

Subject: FOIA-request about deaths from Strattera treatment

To: Medicines and Healthcare products Regulatory Agency, FOIA-Department

May 15, 2008

FOIA-request about deaths from Strattera treatment

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 at that time 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 (HCPs).

See specifics about all fatal cases reported to the FDA 2004-2007 in the table **Strattera Deaths with Strattera as Primary Suspect Drug [2]**, and for ALL reported fatal cases in the attached (and linked) document **StratteraDeath [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.*

It is my assumption that the MHRA as a result of my earlier letters has taken action and gathered data over ALL confirmed fatal cases reported for Strattera, and that the agency now is able to present that compilation.

I therefore request the following information:

The updated list over ALL fatal cases reported for Strattera, as compiled by the MHRA.

In case no such compilation is available I would be happy to get an answer to the following question:

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)?

Yours sincerely,

Janne Larsson
Reporter – investigating psychiatry

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>