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

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MHRA and Strattera deaths – a follow-up

This is where we stand today as regards deaths in connection with the ADHD drug Strattera:

87 cases of death with Strattera as *Primary Suspect Drug* reported to the FDA, 2004 - September 2008.
See http://www.psychdrugdangers.com/StratteraDeathsPS.html

115 cases of death with Strattera *involved* reported to the FDA 2004 – September 2008 and in Periodic Safety Update Reports from Lilly/MHRA.
See http://www.psychdrugdangers.com/StratteraDeathsAll.html
For FDA reports.

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 48 children and teenagers have died, 25 of them committed suicide.
See summary http://jannel.se/StratteraDeath3.pdf

MHRA is responsible for the "safety work" for Strattera in Europe. But so far the agency has done *nothing* to investigate the cases of deaths described. And now the agency has decided to not release any more documents or information about its actions around Strattera.

This story starts in November 2007 when I made a FOIA request to the MHRA about the number of persons who had died while under Strattera treatment. The answer was – ***the Agency didn't know*** – and had to ask the manufacturer, Eli Lilly.

In its answer, January 2008, Lilly said the company up to 30 November 2007 **"has identified 41 fatal cases in our safety database"**. But as Lilly only accepted deaths reported by a "health care professional (HCP) or regulatory authority", 17 of these cases were right away deducted by the company. They did not count as Adverse Drug Reactions. In Lilly's words: **"Of the 41, only 24 were Adverse Drug Reactions (ADR) with fatal outcomes."** (See the letters **[1]**, where Lilly makes a good job trying to convince the Agency not to release this information.)

Other data showed that FDA at that time had received at least 61 reports of death with Strattera as *Primary Suspect Drug,* 2004-2007. (See below.) So how could Lilly state 41 fatal cases of which only 24 should be counted?

In order to help the MHRA to protect children from further harmful effects I compiled detailed data about cases of Strattera death. In May 2008 I submitted this to the Agency (a compilation of data from cases reported to FDA and from the Periodic Safety Update Reports in Europe). I got no answer. Finally 1 October I got a reply from the Scientific Assessor of the Vigilance and Risk Management of Medicines (VRMM) in the MHRA. And 7 October I got an answer from you, Professor Kent Woods, CEO of the MHRA, where you just referred to the letter sent by the Scientific Assessor.

My submitted data about Strattera deaths can be found in the letter *Strattera: Eli Lilly gave false information about deaths from Strattera treatment – a request for full investigation* from 15 May. **[2]**

The Agency was in my letter provided with ***specific data*** (even ICSR [Individual Case Safety Reports] numbers) about instances of death in connection with Strattera treatment.

In the answer 1 October the Scientific Assessor stated **[3]**:

"… in order to calculate the total number of reports with a fatal outcome ***it is not simply a case of adding up reports with a fatal outcome*** *mentioned in our assessment reports of the PSURs [Periodic Safety Update Reports] and those available on the FDA website as these different sources may contain duplicate information." [Emphasis added.]*

I would fully agree to this and it took only a casual reading of my letter from 15 May to find out that *much care* had been taken to *exclude* possible duplicates. It was quite easy to see that the data presented was NOT "simply a case of adding up reports with a fatal outcome".

It was not clear *what* the MHRA had done to verify my data, but the letter from the Scientific Assessor gave the impression that *some form* of investigation had been done about the instances of death brought to the Agency's attention. The Assessor wrote:

"We have looked at the data you have sent us to see if they can add insight to the statutory sources of data we have received ***and do not think that they are of benefit as we cannot verify their source or accuracy."*** (p. 3) [Emphasis added.]

This indicated that the Agency didn't know anything more about these cases in October 2008 than it knew in November 2007, when I first asked questions about the fatal cases.

I found this very strange as there are clear rules for pharmacovigilance in Europe – and *very strict requirements* for both the medical agencies and pharmaceutical companies in investigating reported serious adverse drug reactions – especially fatal drug reactions. I am of course referring to *Volume 9A of The Rules Governing Medicinal Products in the European Union (Guidelines on Pharmacovigilance for Medicinal Products for Human Use)*. **[4]**

In order to verify the MHRA's adherence to these rules I made a FOIA-request to get the documents that ***should*** **exist** – had the Agency actually adhered to the rules. I referred very clearly to *all applicable* EU rules. See my FOIA request. **[5]**

I did not get an answer on the FOIA request within the stipulated 20 working days. Finally, in the end of March, almost three months later, I got the answer. It said I could not get any documents – and the Agency could not even say if any documents existed.

Instead it was decided that my request was "vexatious" – even "obsessive" – and "[we] will not be providing an answer". In an exceptional move the Agency even declared that *future* FOIA-requests would be denied on the subject of Strattera: "We will not engage in any further correspondence with you on Strattera." **[6]** This decision was, as expected, confirmed by an internal reviewer in the Agency.

My investigation about Strattera has been ongoing since 2005 and I have been in contact with the MHRA about the harmful effects of Strattera since early 2006. No matter how "vexatious" this can have been for the Agency the "vexatious effects" of the drug revealed in different documents are far worse. **Cardiac disorders, liver disorders, suicidality, aggression, mania, psychosis with hallucinations** – how can a medical agency allow children to be subjected to these harmful drug effects?

I now realize that it would have been impossible for the Agency to answer my latest FOIA request in this way: NONE of the documents about Strattera deaths you have requested exist. That would have been the same as saying the applicable rules in the EC Pharmacovigilance Directive was not adhered to. So the *only* solution was to declare the requester "obsessive" and so avoid giving any form of answer to the important questions.

We can conclude that the Agency knows as little today about all the cases of Strattera death as it did when I started to ask questions. The only compilation of data in this area available to the Agency seems to be the one I have submitted. No real effort has been done by the Agency itself to find data – much less to take action. The manufacturer (Lilly) has been allowed to get away with "not knowing", "lacking information". The *requirement* in the EC Pharmacovigilance Directive is clear, the manufacturer should *"follow-up all reports of serious adverse reactions to their medicinal product(s) to obtain comprehensive information where available. Additional information not available at the time of the initial report should be provided in the form of follow-up reports".* This is *not* done. And the Agency sends no requests to Lilly to

rectify the situation (letters that *should have been released* as part of my latest FOIA-request – had they existed).

We also know that the data sent out for consideration to other medical agencies in Europe from the MHRA (UK being the Reference Member State, RMS, for Strattera) will never contain anything of real value when it comes to *serious drug reactions*. What is stated in the different Periodic Safety Update Reports (PSURs) sent from the MHRA *is based on data from Lilly* – and Lilly says "not enough information", "details … not provided", "was unknown", "was not identified".

And this is especially clear in fatal cases. It seems in some mysterious way ***impossible*** to get relevant data in these cases; and so no actions can be taken.

We now know why.

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] Larsson, *Strattera: Eli Lilly gave false information about deaths from Strattera treatment – a request for full investigation* http://jannel.se/Strattera.death2.pdf and *StratteraDeath*, May 15, 2008, http://jannel.se/StratteraDeath.pdf
[3] MHRA*, Re: letter of 9th September 2008 to "Assessor responsible for Strattera",* October 1, 2008, http://jannel.se/Reply.from%20MHRA.Assessor.October.pdf
[4] European Commission, Volume 9A of The Rules Governing Medicinal Products in the European Union (Guidelines on Pharmacovigilance for Medicinal Products for Human Use) September 2008, http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-9/pdf/vol9a_09-2008.pdf
[5] Larsson, *FOIA-request about deaths from Strattera treatment*, 10 January 2009, http://jannel.se/FOIA.strattera.death.pdf
[6] MHRA, letter from 25 March http://jannel.se/MHRA.letter.section14.pdf)