**Open letter to Department of Health, UK**

**Copy: Professor Kent Woods**
**Medicines and Healthcare products Regulatory Agency – MHRA**
**Copy: European Medical Agencies, including EMEA**
**Copy: The National Collaborating Centre for Mental Health (NCC)**
**Copy: National Institute for Health and Clinical Excellence (NICE)**
**Copy: Media**

November 14, 2008

# MHRA and the Strattera scandal – a request for answers

In a long letter 7th October to the Department of Health I outlined the evidence about MHRA's neglectful handling of the serious harmful effects of the ADHD drug Strattera. (See **http://jannel.se/mhra.strattera.scandal.pdf**) I requested that the DH should take action to protect the children.

In a short, very disinterested letter from 4th November I got the answer that the DH is not to do anything about the evidence and that "there is nothing further to add at present". **http://jannel.se/answer.DH.Nov4.pdf**

Instead of requesting action from the DH I now want to have a clear answer to the questions below. The need for this is obvious: It is important to know that the DH at this stage was fully informed and aware about the facts and evidence but did nothing to handle the situation.

**1. Can the DH acknowledge** that it has received data (in form of a detailed summary of individual cases) about the death of at least 41 children who were under treatment with the ADHD drug Strattera?

**2. Can the DH acknowledge** that the MHRA has not done an investigation into these fatal cases and that the MHRA does not even have a compilation or summary over fatal cases in connection with Strattera treatment?

**3. Can the DH acknowledge** that it is aware of the fact that Eli Lilly has given misleading data about the number of deaths from Strattera treatment to the MHRA?

**4. Can the DH acknowledge** that it is aware of the fact that the MHRA in August 2006 received the data set that formed the basis for the FDA warnings in March 2006 about Strattera induced mania, and psychosis with hallucinations, and that the agency instead of using these data to issue warnings in Europe turned to the manufacturer (Lilly) for analysis and conclusions?

**5. Can the DH acknowledge** that it is aware of the fact that Eli Lilly in the beginning of this year finally submitted its analysis of Strattera induced mania, psychosis with hallucinations, and agitation to the MHRA, saying reluctantly that the company was prepared to issue the warnings, and that the MHRA still almost one year later has not issued any form of warning to parents and doctors?

**6. Can the DH acknowledge** that the promise of the MHRA as stated on its web site is **"**we take any necessary action to protect the public promptly if there is a problem"? (See **http://www.mhra.gov.uk** ) Can the DH explain to me how this applies to the Strattera case?

Yours sincerely,

Janne Larsson

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