

Open letter to: **Professor Kent Woods**  
**Chief Executive**  
**Medicines and Healthcare products Regulatory Agency - MHRA**

August 10, 2008

## **The ADHD drug Strattera and its harmful effects – where is the response from the MHRA?**

In three long letters to the MHRA this year I have given data and asked questions about the harmful effects of the ADHD drug Strattera.

I have got no answers at all.

I now make a summary of the most important points and link to the earlier letters, and look forward to an answer.

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[In the letter January 2, 2008](#), I described the “compelling evidence” for a causal association between Strattera and treatment emergent symptoms of psychosis or mania, as well as other harmful effects. [In the letter March 9, 2008](#), I gave further data about the subject and made an analysis of the reports issued by independent researchers at the FDA, and by the manufacturer, Eli Lilly (the latter being the report used by MHRA in its safety analysis).

### **With reference to these letters:**

The MHRA has made the following promise: “...we take any necessary action to protect the public promptly if there is a problem.” **[1]**

In 2005 researchers at the FDA analysed the psychosis-inducing effects of Strattera and issued its report March 3, 2006 **[2]**. Two years later, February 2008, Eli Lilly issued its “analysis” of the same subject, as part of Periodic Safety Update Report 9, sent from the MHRA **[3]**.

The FDA was very clear about the psychosis-inducing effects of Strattera. The MHRA did not listen. Eli Lilly tried to explain away the results found in its review. (In an article in the Daily Mail this summer, Andrew Herxheimer, editor of the Drug And Therapeutics Bulletin, and emeritus fellow of the Cochrane Centre commented: “Asking a drug company to review its own product is crazy, but it goes on quite a lot”. **[4]**)

But even if it was crazy to ask Eli Lilly to review Strattera, the company reluctantly wrote in its conclusions – and note this was already *in the beginning of the year*: “Nevertheless, Lilly will consider adding language regarding psychotic symptoms including hallucinations” to its product information sheet (p. 1279 of the review).

The Swedish Medical Products Agency (MPA) is obviously also waiting for the MHRA to act. In an answer this summer the agency announced: “...UK has the baton.”

### **[The simple question: How come the MHRA is delaying the issuance of the warnings even more?](#)**

In my letter of [January 2](#), I also took up the forgotten 700 cases of psychomotor hyperactivity. The MHRA assessor was questioning how Eli Lilly could exclude all these reported cases from its review.

I would think you agree with me that this area is of *extreme importance* for the MHRA to handle. We have "700 reported cases of psychomotor hyperactivity [that] were related to an exacerbation of the underlying ADHD".

If we would apply this to the area of diabetes we could say that the patient got a "diabetes medication" with resulting heavy *increase* in blood sugar level. It would probably not take long before such a drug was withdrawn from the market. And considering the accepted rate of underreporting, these reports about Strattera represent an actual incidence of at least between 7000 and 70 000 cases.

***The simple question: Has the MHRA now done an own investigation of these extremely important reports?***

***In the letter May 15, 2008***, I gave updated information about the reported instances of death from Strattera and about the false information provided by Eli Lilly.

***The simple questions: Will the MHRA call in question the false data given by Eli Lilly about instances of death from Strattera and has the agency now started an investigation of all the reported cases of death in connection with Strattera treatment?***

Yours sincerely,

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[1] MHRA, *About us*, <http://www.mhra.gov.uk>

[2] FDA, *Psychiatric Adverse Events Associated with Drug Treatment of ADHD: Review of Postmarketing Safety Data*, released March 3, 2006. [http://www.fda.gov/ohrms/dockets/AC/06/briefing/2006-4210b\\_11\\_01\\_AdverseEvents.pdf](http://www.fda.gov/ohrms/dockets/AC/06/briefing/2006-4210b_11_01_AdverseEvents.pdf)

[3] Eli Lilly, *Cumulative review of Spontaneous Case Reports of Mania, Psychotic Disorders, Hallucinations, and Agitation*, Appendix 16 to Periodic Safety Report 9 for Strattera, 2008, [http://jannel.se/Lilly\\_psychosis\\_strattera.pdf](http://jannel.se/Lilly_psychosis_strattera.pdf)

[4] Daily Mail, *Heart attacks and suicides... yet the dangers were all kept so quiet. So how CAN you trust your medicine?* July 7, 2008,

<http://www.dailymail.co.uk/health/article-1033132/Side-effects-include-suicide-heart-attacks-So-prescribed-drugs.html>