

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

From: xx

To: [Janne Larsson](#)

Sent: Friday, May 25, 2007 4:58 PM

Subject: FOI 07/135

Dear Mr Larsson,

Thank you for your further email of 7 May about Strattera. I can assure you this was also received in the Chief Executive's Office and read by him.

Thank you for the further clarification of what your letter of 24 April was about. I still consider that the questions you raised in 07/135 about reviews of psychiatric reactions to Strattera do not differ significantly from those you raised in 07/252 as you are still asking why the MHRA is not commissioning an independent review of such reactions at this present time. On this occasion I will answer your further questions.

1. How come the MHRA is not accepting the conclusions of the FDA assessors in the report above, but instead requests *Eli Lilly* to do a cumulative review of basically the same data already reviewed by the FDA?

Changes to European product information are based on assessment by EU regulators, agreement between member states and in line with legal requirements about product information, not on conclusions of FDA assessors. As you may be aware, product information for many products varies widely in the USA and Europe as they have different criteria for what is to be included in product information.

2. In August 2006 the MHRA got the same data set upon which the FDA made its conclusions above from the MAH, *Eli Lilly*. How come the MHRA – if not accepting the conclusions of the FDA assessors – is not doing an own independent evaluation of this data set instead of leaving it to *Eli Lilly* to do?

The raw data submitted to the FDA and of which we received a copy in August 2006 were of no use to the MHRA in the format they were in due to the different pharmacovigilance systems we have to the FDA. However, we are seeking further and more comprehensive data from the company. A letter has already been sent to the company and they have been asked to respond to the conclusions of the assessment report of the Periodic Safety Update report for the period 27/05/2005 to 26/11/2005, a copy of which you already have.

3. The MHRA is, according to its own texts, supposed to “take any necessary action to protect the public promptly if there is a problem”. The UK SPC for Strattera is stated to be revised January 23, 2007; not a word about the “compelling evidence” above is mentioned [3]. How can the inaction from the MHRA described above be defended considering the purpose of the agency, and how come the already “compelling evidence” does not lead to an issued clear warning in the SPC now?

As I said on 3 May, I do not consider that there have been any inactions on behalf of this Agency with regards to the postmarketing surveillance of Strattera. I hope you will be reassured by my answer to your second question that in the context of ongoing regulatory review, we are taking action to obtain further data from the company.

4. How come the MHRA is asking *Eli Lilly* to do an analysis of these 700 reported cases, after the company has withheld this obviously sensitive information and classified it as “exacerbation of the underlying ADHD”? Why isn't the agency requesting all data about this security risk, followed by an independent review of the data?

When we receive a response from the company we will decide what further review and action is required, in accordance with normal procedures.

Yours sincerely

Xx

xx

Information for Public Health Group, VRMM

Medicines and Healthcare products Regulatory Agency (MHRA)

Market Towers 14-110

1, Nine Elms Lane

London

SW8 5NQ

Tel: 020 7084 2788

www.yellowcard.gov.uk