To: European Commission
Copy: Medicines and Healthcare products Regulatory Agency, UK
Copy: WHO Collaborating Centre Uppsala, Sweden
Copy: European Medical Agencies in Concerned Member States

25 March 2009

Additional data about 87 cases of Strattera death and MHRA's violations of important EU-rules about pharmacovigilance

Yesterday I sent a new report about instances of death in connection with Strattera treatment, which revealed:

87 cases of death with Strattera as *Primary Suspect Drug* was reported to the FDA in less than five years (between 2004 and third quarter 2008). See the compilation: http://www.psychdrugdangers.com/StratteraDeaths2008.html

I also sent a formal complaint about MHRA's violations of important EU-rules about pharmacovigilance **http://jannel.se/complaint_Strattera.death.pdf** I submitted the data to the European Commission so that appropriate actions could be taken. I hoped the Commission would make certain that the important rules in the Directive would be followed, for the safety of patients.

As the MHRA today gave additonal data in the case I also want to get that information over to the Commission. In a letter written *today*, the day after I made my complaint to the Commission, the MHRA declares that my request for documents about Strattera deaths and the actions taken by the agency, is deemed to be **"vexatious"** (meaning, what I understand, that it is disturbing and upsetting, causing anger). The request is met with the decision "we will not be providing an answer to them".

As seen in my complaint yesterday to the Commission my FOIA-request to the MHRA was a balanced request based on the rules in *Volume 9A of The Rules Governing Medicinal Products in the European Union (Guidelines on Pharmacovigilance for Medicinal Products for Human Use)* **[1]**. I wanted to get data if the MHRA, responsible for the safety of patients, and in this case mainly of children patients treated with Strattera in Europe, was adhering to the rules, when a large number of fatal results was reported for the drug. This must be seen as one of the most important applications of the FOIA.

But the MHRA characterizes the request as "vexatious" – even "obsessive" – and "will not be providing an answer". In a exceptional move the agency even declares that *future* FOIA-requests will be denied on the subject of Strattera: "We will not engage in any further correspondence with you on Strattera." (See the MHRA letter from 25 March **http://jannel.se/MHRA.letter.section14.pdf**)

One purpose of the FOI Act is to let citizens in on the work done by government agencies; the idea is that openness will make the work of these agencies more effective and prevent abuse of power. The answer provided by the MHRA shows a disrespect to this important law and its purpose. I can understand that the agency does not like that revealed violations of important rules are being exposed in media - but also this must be seen as a vital ingredient in a democracy. Something that in the end will mean better and safer treatment conditions for patients.

I consider that this answer from the MHRA, on an important request for data about Strattera deaths, makes it even more important for the Commssion to investigate the violations of the rules in the EU Directive and to take action, for the safety of patients.

Yours sincerely,

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Reporter

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References:

[1] 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