To: The European Commission (DG SANCO)
Copy: European Medicines Agency, EMA (Committee for Medicinal Products for Human Use, CHMP)
Copy: The Medicines and Healthcare products Regulatory Agency (MHRA)
Copy: Media

15 May 2011

Big Pharma ("The Consortium") obstructing vital safety studies about methylphenidate (Ritalin, Concerta) – and the medical authorities allow it to happen

In November 2009, the manufacturers of methylphenidate in Europe declared in a confidential report that they were **NOT** going to do any safety studies about the long-term effects of the drugs on **"**Cognition and Psychiatric Outcomes".

I did an analysis of the report and requested that the European Commission should take action, and make sure that manufacturers did not obstruct needed safety studies.

See the letter (25 March 2010) here: **http://jannel.se/letter.Consortium.ADHD.pdf**

See the confidential report from "the Consortium" (30 October 2009) here: ***Feasibility Assessment of a Study of Long-term Effects of Methylphenidate on Cognition and Psychiatric Outcomes***, **http://jannel.se/Consortium_ADHD-drugs.pdf**

The Commission answered (5 August 2010) that the Commission decision was "addressed to the Member States and that there is their responsibility to ensure that the decision is complied with". Anyway the Commission had forwarded my letters to the European Medicines Agency (EMA).

The Member State handling the confidential report from "the Consortium" turned out to be UK, and its medical agency, the Medicines and Healthcare products Regulatory Agency (MHRA).

So what did the MHRA do with the attempt by the companies to prevent vital safety studies?

The UK regulator gave a mild answer about the aggressive effort to prevent further studies. The Agency said: "We consider this to be an overly negative conclusion and contend that such a study is achievable." The Agency ended off with the following words: "The MAH should propose how a suitable study could be performed; taking into consideration the comments in this report on how many of the suggested limitations could be overcome." See excerpts (released 25 October 2010) from the MHRA letter to "the Consortium" **http://jannel.se/MHRA.Reply.pdf**

And now we are in May 2011 – two years after the Commission decision about safety actions, four years (!) after the original referral from the Commission to the EMA for recommendations.

And the UK regulator decides that all documents about this affair are confidential, cannot be released, as "The MHRA are at present still in discussion with the

manufacturer, and until such time as a decision is made, this information should not be released". (Decision 18 April 2011.) (The Commission, the EMA and the Swedish Medical Products Agency, say upon request that they don't have any documents about this affair; it's handled by the MHRA. In other words these authorities don't know anything about this important affair.)

The medical authority concerned, the MHRA, is still *"discussing"* if the vital safety studies could be *started!*

I now request that the handling of this matter is reviewed by the Commission. The MHRA, the national authority concerned, has NOT taken the "responsibility to ensure that the [Commission] decision is complied with", but is instead letting the pharmaceutical companies continue to explain why the vital safety studies cannot be done.

May I refer to the Prozac scandal and how the MHRA allowed Eli Lilly to sabotage the vital safety follow-ups about the effects of Prozac on children. See *Prozac for children – what happened with the follow-up?*
http://jannel.se/prozac-children-partII.pdf

Should the Agency be allowed to do the same again?

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