Patient Health Protection
European Medicines Agency (EMA)
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9 February 2013

Subject: Will Novartis help EMA and Janssen to handle the medical scandal with the ADHD drug Concerta?

Dear Mr. Anthony Humphreys,

Thank you for your letter **http://jannel.se/Methylphenidate.response.to.Mr.Larsson.17.01.2013.pdf**

As you know I have in a 16 pages long report detailed the Concerta scandal, how the pharmaceutical company Janssen increased its sales of the ADHD drug Concerta to adults in Europe, and especially in Sweden, *after* the drug was disapproved. I have compared this scandal with the Mediator scandal in France, forcing the earlier chairman of CHMP, Eric Abadie, to resign, and with "the affairs" in US, where pharmaceutical companies have had to pay billions of dollars for their illegal activities **http://jannel.se/EMA.Concerta.ADHD.pdf**

In your letter you communicate that EMA cannot do more to handle this medical scandal than to send my earlier letters **http://jannel.se/EMA.Concerta.Jan2013.pdf** to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) and MHRA.

I always distrust the *willingness* to act when I hear that medical agencies with huge resources say they cannot do anything effective to handle a medical scandal. So also in this case.

As you have understood from my report, Janssen declared that no new warnings about what emerged in the adult studies were to be issued, as Concerta was not to be prescribed to adult patients anyway. The medical agencies accepted this. This would have been fine if the company, and the medical agencies involved, also had taken actions to make sure that adult patients *were not* prescribed the drug. But as you know Janssen increased its sales to adults in Sweden – in actual fact the sales *exploded* after this agreement, and the involved medical agencies, especially the Medical Products Agency (MPA) in Sweden, did nothing to handle the situation.

From a patient health protection perspective, which you represent, this means that tens of thousands of adult patients in Europe currently are getting Concerta (and other methylphenidate products) without being informed about the serious harmful effects of the drug (see my last letter for Janssen's own table over adverse events). This is, at least in Sweden, *against the law*, as patients should be fully informed about the known effects and harmful effects of drug treatment.

And to this all EMA says is that *nothing* can be done. No "strong recommendations" to the member states or to the Reference Member State (UK) to act; no references to applicable laws protecting patients; no complaints about the criminal actions by Janssen; no criticism whatsoever for allowing this scandal to happen.

In addition to what I have written before it can now be said that the prescription of Concerta to adults in Sweden increased with 47% (!!) in the years 2011-2012. Janssen sold the *disapproved* drug Concerta to adults in Sweden for 308 million SEK (30,5 million GBP) 2011-2012. (See updated figures from Apotekens Service AB **http://jannel.se/N06BA.SWE2008.2012.pdf**)

But at the same time a fantastic "solution" to this problem has been presented, having the potential to save all the officials involved in this medical scandal.

And the help for EMA, MPA and Janssen to handle the scandal comes from an unexpected player – the pharmaceutical company Novartis. The manufacturer of Ritalin (basically the same drug as Concerta) has announced its application to get Ritalin approved for adults in Europe. (See Novartis' Swedish press release from 30 January 2013 **http://www.cisionwire.se/novartis/r/novartis-ansoker-om-godkannande-for-ritalin-for-behandling-av-vuxna-patienter-med-adhd,c9362988**)

I am sure Novartis has learned from the failed Concerta submission and that there is a big interest from the officials mentioned above to push through the approval of Ritalin for adults. We can expect that the submitted short-term studies will get a positive assessment this time (no embarrassing questions), and suddenly the concealed and alarming Concerta results can be expected to no longer exist. Janssen will also be saved; no criminal actions will be taken.

But it's hard to see how the above can fit with the EMA declaration: "The Agency works closely with its European partners to build the best possible regulatory system for medicines for Europe and protect the health of its citizens."

Yours sincerely,

Janne Larsson
Reporter
Sweden