Request for Retraction of Journal Article

21 March 2015

This is a request for *the World Journal of Biological Psychiatry* to withdraw the article "Efficacy and safety of prolonged-release OROS methylphenidate in adults with attention deficit/hyperactivity disorder: A 13-week, randomized, double-blind, placebo-controlled, fixed-dose study", published early online November 2011, in print May 2013 [1].

In the article the following *conclusion* of the study is presented: **"OROS MPH provided overall benefits in the treatment of adults with ADHD"**. As regards safety, the conclusion was: **"OROS MPH was well tolerated in the study."**

The study behind the article (Study 3013) was chosen by the manufacturer of Concerta, Janssen, as the longest of three double-blind studies submitted to European drug regulators for the approval of Concerta for adults in Europe. The UK regulator, Medicines and Healthcare products Regulatory Agency (MHRA), acted as reference member state, leading the assessment of the studies.

In the assessment of Study 3013 the MHRA came to a *diametrically opposed conclusion* about both efficacy and safety compared to what is published in article. The MHRA reached the following conclusion in its Final Assessment Report from April 2011: **"This is clearly a failed study"** [2].

As for safety MHRA's study emphasized that **19 percent of the subjects (34 of 182) receiving Concerta *discontinued* the study (compared to 2 percent in the placebo group) due to adverse effects.**

From the three studies of Concerta the assessment concluded: **"The main new safety concern from the study data is around the frequency of psychiatric adverse events and that this is often de novo [new]. Of note is the incidence of anxiety but also rates of depression and aggressive and hostile behavior are raised." [3]** We could also read: **"A causal relationship with Concerta was established for aggression, tics and depression."** The serious safety concerns stemmed mainly from Study 3013.

We can in the article in *the World Journal of Biological Psychiatry* see that four of the ten listed authors of the study were employees of Janssen (Johnson & Johnson), one was a former employee and the other five authors had been consulting for the pharmaceutical company or had worked in the company's Advisory Board. The clear negative assessment of Study 3013 was known to Janssen and its employees 8 months ahead of the publication in the Journal. Yet the conclusions in the article were not changed.

I hope the Editorial Board of the Journal welcome the above data and request that the article, with its false and misleading presentation and conclusions, is retracted.

Kind Regards,

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[1] Casas, Rösler, Kooij, Ginsberg, Ramos-Quiroga, Heger, Berwaerts, Dejonckheere, van der Vorst, Schäuble. "Efficacy and safety of prolonged-release OROS methylphenidate in adults with attention deficit/hyperactivity disorder: A 13-week, randomized, double-blind, placebo-controlled, fixed-dose study." *The World Journal of Biological Psychiatry*, Early Online November 2011, in print May 2013.
http://informahealthcare.com/doi/abs/10.3109/15622975.2011.600333
[2] MHRA, *Final Variation Assessment Report,* Concerta Day 90, April 26, 2011, see page 5
http://jannel.se/FVAR.Concerta.Day90.260411.pdf
[3] MHRA, *Preliminary Variation Assessment Report,* Concerta, July 2010, see p. 66
http://jannel.se/PVAR.Concerta140710.pdf ,