To: European Medicines Agency (EMEA), all members of the Committee for Medicinal Products for Human Use (CHMP)
Copy: European Commission

The dangers and "safer use" of Ritalin and other ADHD drugs

30 January 2009

Maybe it is my bad command of the English language, maybe it is a lack of experience in reading texts about patient health from the EMEA (based as they are on the business language of the *trade department* in which the agency is located), but I cannot understand the new press release about ADHD drugs
(22 January 2009, http://www.emea.europa.eu/pdfs/human/referral/methylphenidate/2231509en.pdf)

I hope the agency can help in clarifying the points below.

First of all I cannot understand how **"safer use"** can be a fitting expression in this context, like in the headline of the press release: "European Medicines Agency makes recommendations for ***safer use*** of Ritalin and other methylphenidate-containing medicines in the EU." (Emphasis added.)

I get to think of Volvo and the new advertising campaign for the car: *Safest in the world* and *Safety first.* It is a good, honest campaign. An already safe car has been added quite some innovations to make it even better. The dictionary meanings of safe: *"free from danger"* and *"involving no risks",* fit very well.

But how come the expressions **"safe", "safer use"** and **"maximise the safe use"** are used about Ritalin and other ADHD drugs? I thought ***the very reason*** for the press release from the EMEA was to inform doctors and the public about the ***dangers*** with these ADHD drugs; dangers they didn't know about before. What I can see the text takes up ***warnings*** about high blood pressure, increased heart rate, depression, suicidal thoughts, hostility, psychosis, mania, and stunted growth in connection with ADHD drugs.

Volvo was already safe – with the new innovations it is even more safe. Ritalin and other ADHD drugs have known common ***dangers***, common ***risks***.

From the list of harmful effects in the press release one can assume that the EMEA finally tries to make it clear that these risks exist. But how can the action of making doctors and the public aware of these dangers be presented as an action to "maximise the safe use"? Isn't this press release a matter of *trying to* protect children from the known dangers of these drugs? Isn't it a matter of trying to get doctors to take children off these drugs when they present drug induced psychotic symptoms? Isn't it a matter of trying to get doctors to understand that these drugs can ***cause*** depression, suicidal thoughts, hostility, mania, psychosis with hallucinations, and stunted growth – and not always blame it on the kids and the "underlying disease"?

The latest review of 49 randomized clinical trials from FDA (Mosholder et al, *Hallucinations and Other Psychotic Symptoms Associated With the Use of Attention-Deficit/Hyperactivity Disorder Drugs in Children*, PEDIATRICS Vol. 123 No. 2 February 2009) shows that for every

100 children who take ADHD drugs for a year, between one and two experience a drug-related psychotic event. And this is said to be a LOW estimate.

Comparing this again to the car industry, would it be acceptable if for every 100 new cars *two* had a *complete* break failure in a year (psychosis)? Would it be acceptable if in a year a considerable part of these 100 cars suddenly accelerated to a high speed putting the driver and others in severe risk (mania and suicidal behaviour)? Would it be acceptable that the motor in some of these new cars just suddenly explodes while driving on the highway (cardiac arrest, heart failure)?

I guess that Volvo would have some *serious* problems if that would be the case, and that they would have even more problems if they in this situation launched a marketing campaign, claiming that they have now have made the car ***even more safe*****.**

I would like to get a confirmation from the agency that I got this right: that the expression "maximising the safe use" of Ritalin and other ADHD drugs in actual fact is a misprint and that the sentence in the middle of the press release should read "new recommendations on prescribing the medicines and on pre-treatment screening and ongoing monitoring of patients are needed *to not subject so many of these children to the known serious harmful effects from* these medicines".

The second thing I cannot understand is the expression in the press release "there is a lack of information on the long-term effects of methylphenidate". Some lines above this statement the following information is given: "Methylphenidate has been available in the EU since the 1950s." *Normally* the last statement is used by pharmaceutical companies to give the impression that this drug has been with us a long, long time; in other words it is well tested, we should not expect anything bad to happen.

But how does the phrase "since the 1950s" fit with the "lack of information on the long-term effects"?

Should we see the question about long-term effects as an eternal philosophic problem? Why not state the obvious, why not say: 50 years are *enough*! Pharmaceutical companies have tried *hard* to prove "the positive long-term effects" of methylphenidate for 50 years – they have failed. *They have proven that there are no positive long-term effects of Ritalin and other methylphenidate drugs!*

In this process they have also proved *that methylphenidate gives serious adverse effects in long-term use.* I think we can agree about the fact that there are a lot of studies proving the harmful effects in long-term use of ADHD drugs (see also earlier reference to the study in Pediatrics).

And EMEA now at least tries to *lessen* the harm from the drugs, saying that doctors "should interrupt treatment at least once a year".

I would like to get an agreement from the agency that 50 years was the *deadline* for the pharmaceutical companies and their efforts to push forward some kind of evidence for the positive long-term effects of these ADHD drugs.

So can the EMEA now confirm that the misleading expression "lack of information on the long-term effects" from now on will be replaced with the true statements: "*There are no positive long-term effects of methylphenidate*" and *"Methylphenidate gives serious adverse effects in long-term use".*

Yours sincerely,

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