To: Norwegian Medicines Agency,
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New reports about deaths from the ADHD drug Strattera

The Norwegian Medicines Agency has not received the important data about instances of death in connection with prescriptions of the ADHD drug Strattera.

The reason is obvious: Eli Lilly, the manufacturer of Strattera, is only interested in explaining away all instances of death; the responsible medical agency, the UK MHRA, is accepting this and is not requiring that Lilly obtains and submits comprehensive information about all fatal cases.

This is where we stand today as regards deaths in connection with the ADHD drug Strattera:

87 cases of death with Strattera as *Primary Suspect Drug* reported to the FDA, 2004 - September 2008.
See http://www.psychdrugdangers.com/StratteraDeathsPS.html

115 cases of death with Strattera *involved* reported to the FDA 2004 – September 2008 and in Periodic Safety Update Reports from Lilly/MHRA.
See http://www.psychdrugdangers.com/StratteraDeathsAll.html
for FDA reports.

48 children and teenagers have died, 25 of them committed suicide. See summary http://jannel.se/StratteraDeath3.pdf

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Every half year the UK medical agency MHRA is sending out so called Periodic Safety Update Reports (PSURs) to concerned European medical agencies about Strattera. These reports are forming the basis for the "safety work" around this drug. The data are supposed to be commented upon by the medical agencies in the countries where Strattera is approved. And then the report is finalized in UK, conclusions and required actions are issued.

But as you know almost no comments are given from the 25 countries receiving these reports. And if one reads the PSURs about Strattera it is easy to understand why: Every medical agency involved must know that the data presented are more or less worthless, so why comment? Data, analyses and conclusions are from the

manufacturer of the drug Eli Lilly – and then we have the Scientific Assessor at the MHRA giving some comments to what Lilly has offered. If there is a "new safety signal" (meaning new harmful effects reported) Eli Lilly is being asked to give more data and to submit an analysis of the area for a later PSUR. And so, half a year to one year later Lilly submits a "review" of the "safety signal" – *doing what they can to make nothing of the harmful effects in question.*

One very good example of this strange "safety work": The "signal" that Strattera induces mania and psychoses with hallucinations in children. In October 2008 information about this was *finally* included in the European product information (it took an additional four months before it was translated and included in the Norwegian text). But as you know ***everything*** around this "safety signal" was known already in March 2006, when FDA took the unusual step to issue a very clear and honest report about psychosis, suicidality and aggression/hostility in connection with Strattera (and other ADHD drugs). Eli Lilly and MHRA delayed the warning text about this in Europe *for almost three years!* In December 2007 Lilly submitted *its own* "review" about Strattera and psychosis to MHRA – in fact only a long paper defending the drug, explaining away all evidence and blaming the effects on the children themselves. And then it took another year for MHRA to get the warning text out. Read the full background story about this in the article *The ADHD drug Strattera – actions needed now* http://jannel.se/letter.mhra.strattera.jan08.pdf

But let's go back to all the cases of death reported for the drug.

The European countries in which Strattera are marketed have ***never*** got any compilation over fatal cases in connection with Strattera from the responsible medical agency, the UK MHRA – much less a full independent review over these cases. Neither have they asked for such a compilation or review.

The children getting Strattera can be expected to be healthy normal children and in this group of "patients" there ***should be*** extremely low morbidity and mortality. As seen above it is not: 48 children and teenagers getting Strattera "for ADHD" have died. I think we can agree that this is quite a "safety signal"! (It should of course be noted that only a fraction of the serious harmful events caused by psychiatric drugs are reported to the medical agencies; the actual number of deaths can be expected to be much higher.)

I made a FOIA request to MHRA in November 2007 asking for the number of deaths reported for Strattera. The answer was – ***the Agency didn't know.*** They had to ask Eli Lilly.

In its answer, January 2008, Lilly said the company up to 30 November 2007 **"has identified 41 fatal cases in our safety database"**. But as Lilly only accepted deaths reported by a "health care professional (HCP) or regulatory authority", 17 of these cases were right away deducted by the company. They did not count. In Lilly's words: **"Of the 41, only 24 were Adverse Drug Reactions (ADR) with fatal outcomes."** (See the letters: Eli Lilly, Letter to the MHRA, January 2, 2008, (see last 3 pages) http://jannel.se/FOI%2008-011.redacted.letters.Strattera.pdf , where Lilly makes a good job trying to convince MHRA not to release this information.)

The data from Lilly and MHRA didn't make sense as other data indicated that FDA had received at least 61 reports of death with Strattera as *Primary Suspect Drug,* 2004-2007. So how could Lilly state 41 fatal cases of which only 24 should be counted?

As MHRA didn't have any data about the number of children and adults who had died I submitted the information that could be found about this (via FDA and PSURs). This was done in May 2008. MHRA didn't answer. First in October the Scientific Assessor of the Vigilance and Risk Management of Medicines (VRMM) in MHRA sent a reply.

In the answer the Scientific Assessor stated: "*… in order to calculate the total number of reports with a fatal outcome* ***it is not simply a case of adding up reports with a fatal outcome*** *mentioned in our assessment reports of the PSURs [Periodic Safety Update Reports] and those available on the FDA website as these different sources may contain duplicate information." [Emphasis added.]* (MHRA*, Re: letter of 9 September 2008 to "Assessor responsible for Strattera",* 1 October, 2008, http://jannel.se/Reply.from%20MHRA.Assessor.October.pdf)

This was of course very true. But it was also very true that *much care* had been taken to *exclude* possible duplicates. It was quite easy to see that the data presented was NOT "simply a case of adding up reports with a fatal outcome".

From the MHRA letter it looked as if the Scientific Assessor had done some form of investigation to verify the data about the instances of death brought to the Agency's attention. The Assessor wrote: *"We have looked at the data you have sent us to see if they can add insight to the statutory sources of data we have received* ***and do not think that they are of benefit as we cannot verify their source or accuracy."*** (p. 3) [Emphasis added.]

This indicated that MHRA didn't know anything more about these cases in October 2008 than it knew in November 2007, when I first asked questions about the fatal cases!

I found this very strange as there are clear rules for pharmacovigilance in Europe – and *very strict requirements* for both the medical agencies and pharmaceutical companies in investigating reported serious adverse drug reactions – especially fatal drug reactions. I am of course referring to *Volume 9A of The Rules Governing Medicinal Products in the European Union.*
(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)

In order to verify the MHRA's adherence to these rules I made a FOIA request to get the documents that ***should*** exist – had the Agency actually adhered to the rules. I referred very clearly to ***all applicable*** EU rules. (See my FOIA request: *FOIA-request about deaths from Strattera treatment*, 10 January 2009, http://jannel.se/FOIA.strattera.death.pdf **)**

And here is where it stops. MHRA has decided not answer this FOIA request. The Agency has found that asking for this information should be classified as "vexatious". MHRA does not want say anything about the documents requested. And the actual reason is of course: The Agency has failed in its mission, it does not have the documents requested; the rules that all cases of death should be followed up and that comprehensive information should be obtained have simply not been followed.

My investigation about Strattera has been ongoing since 2005 and I have been in contact with MHRA about the harmful effects of Strattera since early 2006. No matter how "vexatious" this can have been for the Agency the "vexatious effects" of the drug revealed in different documents are far worse. **Cardiac disorders, liver disorders, suicidality, aggression, mania, psychosis with hallucinations** – **and many cases of death –** how can a medical agency allow children to be subjected to this?

We can conclude that MHRA, and thus the other European medical agencies, know as little today about all the cases of Strattera death as they did when I started to ask questions.

The only compilation of data in this area available for European medical agencies seems to be the one I have submitted – of which an updated version is found in this report.

No real effort has been done by MHRA, or requested by any other agency, to use the available immense resources to get full information about all these cases of death and to do an independent analysis of that information – not leaving it up to the manufacturer to explain why Strattera *didn't have anything to do* with the deaths of all these children.

The number of deaths is steadily increasing – and the responsible medical agencies have done nothing effective to put an end to that.

I would like to know what the Norwegian Medicines Agency intends to do with reference to the data presented in this report.

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