To: Tomas Salmonson, Chairman CHMP (EMA)
Copy: Media

EMA and the medical scandal with Janssen's ADHD drug Concerta

6/1-2013

Dear Tomas,

As you know Janssen's application to get Concerta approved for adults was **disapproved** in Europe early 2011. In Sweden, with approval of you and other responsible persons at the Medical Products Agency, this disapproval led to an **explosion** in the prescription of the drug to adults. This is, as said before, a medical scandal comparable to the Mediator scandal in France.

As you, in your role at the Medical Product Agency, together with some other leading officials, are responsible for decisions creating this medical scandal I think it is time that you as Chair of the Committee for Medicinal Products for Human Use (CHMP) at the European Medical Agency take responsibility for handling the whole situation.

I have already three months ago sent a full report about this scene to you and to the other members of CHMP **http://jannel.se/EMA.ConcertaSept12.pdf** . You have in the beginning of December explained that Concerta is not centrally approved in Europe, saying that EMA is not responsible for handling this. However most of the European countries are involved in the application procedure. We could therefore clearly state that this would very much be something of concern for EMA and CHMP. In your letter you also said that EMA would give me a full answer soon, but I am still waiting for that.

I now want to add some crucial information about what emerged in Janssen's studies of the ADHD drug Concerta. This *is a not published table* over the Adverse Events of Concerta in Janssen's clinical trials. It is part of Janssen's "Response Document" (page 84) to the UK Medicines and Healthcare products Regulatory Agency, from 11 January 2011.

Table 59. Number (%) of Subjects With an Important Adverse Event by Adverse Event Category of Special Interest and by Treatment Group
(CONCERTA EU SCS: All Treated Subjects Analysis Set)

Adverse Event Categories of Special Interest	Placebo (N=309) n (%)	DB CONCERTA (N=596) n (%)	Total CONCERTA (N=1369) n (%)
Total no. subjects with Adverse Events	87 (28.2)	307 (51.5)	815 (59.5)
Hypertension	12 (3.9)	32 (5.4)	136 (9.9)
Tachycardia	0	36 (6.0)	81 (5.9)
Raynaud's phenomenon	2 (0.6)	3 (0.5)	6 (0.4)
Psychosis/mania	3 (1.0)	17 (2.9)	45 (3.3)
Anorexia	23 (7.4)	174 (29.2)	394 (28.8)
Migraine	6 (1.9)	7 (1.2)	25 (1.8)
Repetitive behaviours	0	1 (0.2)	1 (0.1)
QT prolongation	1 (0.3)	0	4 (0.3)
Arrhythmias	11 (3.6)	80 (13.4)	240 (17.5)
Cerebrovascular disorders	0	1 (0.2)	1 (0.1)
Aggression	17 (5.5)	71 (11.9)	202 (14.8)
Hostility	0	3 (0.5)	11 (0.8)
Depression	32 (10.4)	100 (16.8)	270 (19.7)
Suicidality	0	1 (0.2)	3 (0.2)
Tics/tourette's syndrome/dystonias	4 (1.3)	25 (4.2)	72 (5.3)
Carcinogenicity	0	0	5 (0.4)
Withdrawal syndrome	0	1 (0.2)	1 (0.1)

In the Company's **three best** studies of Concerta on adults, the ones **chosen** for Janssen's application, the following harmful events emerged in the short-term studies (up to 13 weeks), where Concerta was compared to placebo:

- The persons who received Concerta had a **270% increased risk for heart disorders in form of Arrhythmias**;
- The persons who received Concerta had a **116% increased risk for Aggression**;
- The persons who received Concerta had a **62% increased risk for Depression**;
- The persons who received Concerta had a **225% increased risk for neurological disorders in form of Tics/Dystonias**;
- The persons who received Concerta had a **190% increased risk for Psychosis/Mania**;
- The persons who received Concerta had a **295% increased risk for Anorexia**;

In its request the MHRA in July 2010 said that new warnings must be issued for the prescription of Concerta to adults. The Agency said: **"The risks of anxiety/anxiety disorders, depression, aggression, agitation restlessness, suicide related events, psychosis, mania/delusions, decreased appetite, clinically important decreased weight, cardiac arrhythmias, tics/worsening of tics or tourette's syndrome should be added to the Safety Specification as Important Identified Risks."**

The response from Janssen was: "**The Company no longer seeks an extension of the indication to include adults with ADHD."** Thus no new warnings about what had emerged in the studies on adults should be issued. Janssen repeats this statement 29 times (!) in the "Response Document". And so, no new warnings were issued to other authorities, doctors or patients.

However, as I have so clearly described in my earlier report, this did not prevent Janssen from increasing its sales of Concerta to adults – without issuing any form of new warnings. In Sweden the increase was **25 % for 2011** **http://jannel.se/EMA.ConcertaSept12.pdf**

In the Response Document Janssen also makes the following clear: "The safety profile of CONCERTA XL in adult subjects with ADHD was generally similar to that seen in children and adolescents with ADHD."

In other words, the same harmful effects described above are also to be seen in children.

I am now looking forward to an answer from you how you as Chair of CHMP, and in your position at the Medical Products Agency in Sweden, can allow this medical scandal without any form of effective actions to handle it.

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