To: European Commission (Enterprise and Industry, Mr. Martin Terberger**)**

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18 April 2010

Data directly from the Swedish Medical Products Agency (MPA) and from the Risk Management Plan for Concerta, submitted by the pharmaceutical company Johnson & Johnson

A new report about off-label use, abuse, effects and harmful effects, and patterns of use for Ritalin and Concerta in Sweden

This report contains data about the use and abuse of methylphenidate products (Ritalin, Concerta) in Sweden.

It has direct relevance to the decision by the European Commission, from 27 May 2009, about ***the conditions to be fulfilled*** by the pharmaceutical companies producing ADHD drugs ***in order to get continued marketing authorisation*** [1].

With the data below I want to show that it is possible to find and compile important safety data with almost no resources at all – and that it is also possible to find and compile NO data with almost unlimited resources.

I want to put in question the actions taken by the concerned pharmaceutical companies and by the Swedish medical authorities (mainly the Medical Products Agency, MPA). I want to put in question their *willingness to find out and to know,* and I want to claim that the total ineffectiveness shown, in actual fact should be seen as obstructions of the important safety actions decided by the Commission.

This is a follow-up report to my earlier data from 17 January, **http://jannel.se/Report_European_Commission.pdf** – which must be read first in order to understand the data below.

The information I present is compiled from unpublished data in the files of the Swedish Medical Products Agency (MPA) and from stories told by Swedish “users” of Concerta and Ritalin.

The data presented is compared with what the manufacturer of Concerta (Johnson & Johnson; in Sweden Janssen-Cilag AB)) writes in its 319 pages long “Risk Management Plan” (RMP) from 23 November 2009. (Note that ***only*** the parts on off-label use, diversion and abuse are commented upon; the rest of this plan is to be compared with reality later.)

I include a link to the full Risk Management Plan from Johnson & Johnson to make it easy to compare my statements below with the actual plan. I also want to make it easy for all interested persons to access the full plan, to get insight into the distorted

data and evaluations forming the basis for decisions by the medical authorities **http://jannel.se/RMP-ConcertaNov2009.pdf** [2].

In my earlier report I took up the **around 700 cases for 2009** where psychiatrists had explained to the Swedish Medical Products Agency (MPA) that Concerta, Ritalin and Strattera (the approved ADHD drugs) *had no or vanishing effects and/or harmful effects*, and that these psychiatrists, as the next step in the experimentation, wanted to get a license for dexamphetamine (Metamina). The applications (mainly for adults) gave an abundance of evidence about the patterns of use and that the doses of methylphenidate had to be *increased* after a while to uphold the drug effect. They showed that the prescribing psychiatrists in many cases *had to move up to even stronger drugs* (dexamphetamine) when it was no longer possible to increase the dose of methylphenidate.

These data also showed that psychiatrists *continued* to use *similar* drugs in the face of no and/or harmful drug effects, and that discontinuation of the drug experiment did not seem to be an alternative. The continued experimentation despite evidence for non-workability and harm should be compared with the new SPC text for methylphenidate, where it is stated: "Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period … consideration should be given to a possible causal role for methylphenidate, and discontinuation of treatment may be appropriate… consideration should be given to a possible discontinuation of methylphenidate."

I listed 172 examples of the security risks described in the applications.

The Commission 22 January asked the Swedish MPA about their views on the reactions I had listed. And the MPA (Littorin) answered 2 February and wrote: "Larsson's report contains a lot of adverse reactions which in most cases are known for the MPA. The Agency continuously evaluates the risk-benefit profile for each product."

The facts were however that my compilation of security risks – gathered from the descriptions in the individual applications – *was the only one existing*. Thus it was far from the truth to state that the Agency "continuously evaluates the risk-benefit profile for each product". The Agency *had done nothing* with this wealth of information, had not asked further questions to the prescribers about the harmful effects described, had not compiled the data, and had of course not evaluated what they had not even compiled.

The Agency stated in its answer to the Commission that the adverse reactions "in most cases are known for the MPA". That seems like an easy way to avoid responsibility for following-up serious harmful effects, like the ones below (taken from the list I submitted earlier):

> "…very powerful, almost physical anguish"; "severe anxiety"; "joint pain, uncommunicativeness and suicidal thoughts"; a lot of side effects; increased anxiety, even panic attacks; depression and increasing anxiety; "sudden emotional swings from high happiness to sadness and tears"; "headache, increased anxiety and memory disorders"; "sensitive, insecure, paranoid feelings implied in the higher dose"; "a lot of

side effects"; "patient even at a couple of occasions had been confined to bed"; "increased aggression"; "severe side effects such as nausea, vomiting, weight loss, anxiety and depression"; "severe side effects"; "had to be discontinued at a relatively low level due to anxiety attacks"; "very difficult adverse side effects"; "developed a psychosis which led to care in our intensive care department"; "Increased debilitating anxiety"; "adverse events in form of deep depression with apathy"; "intolerable side-effects"; "got anxiety and reinforcement of aggressive feelings"; "sharp and unexpected side effects with all treatments (ranging from allergies to hallucinations)"; "severe side effects were noted"; "got psychotic experiences…Two serious suicide attempt last month"; "severe side effects such as irritability, depression of mood state"; "very strong side effects"; "more speeded up, aggressive".

We had here almost 700 cases where treatment with Concerta, Ritalin and Strattera (often two or three of the drugs) had failed – due to no positive effect or due to intolerable harmful effects.

Further questions to the Medical Products Agency also revealed that many licenses for ***amphetamine*** (the above 700 cases were for *dex*amphetamine) had been granted in 2009. Also in these cases most of them after an initial trial with Concerta, Ritalin and Strattera. It was found that **around 250 of these licenses were for the diagnosis of ADHD** (in the rest of the cases amphetamine was prescribed for tiredness, fatigue in connection with diseases like MS and cancer).

In order to give a picture of the effects of Ritalin and Concerta **in the last 250 cases** now investigated I have listed 80 examples below:

- "Methylphenidate with small to moderate effect ... The treatment can also cause the patient stuck in the activities, as he tends to focus on very narrow areas ..."
- "Concerta 36 mg side effects...."
- "central stimulants ... been depressed, apathetic ... These symptoms disappeared when central stimulants was discontinued ... "
- "Concerta and Strattera, but patient had adverse reactions to this."
- "Tried to Methylphenidate but had severe adverse reactions with rash, swollen lymph glands in the armpits, altered vision, which recurred at each experimental treatment (tested a friend's Concerta earlier this summer) ..."
- "Methylphenidate ... of insufficient effect ... feels side effects such as palpitations."
- "Concerta patient ... just experienced anxiety and had high doses ..."
- "Ritalina Tablets ... significant side effects such as palpitations, restlessness, hypomania, falling asleep with very poor appetite. "
- "Strattera, Concerta…but without achieving a good effect and without being able to tolerate the preparations."
- "Concerta, but was discontinued when the patient became dizzy, had thoughts of harming himself and outbreaks…"
- "Ritalin dose of 45 mg. The effect has been insufficient, also troublesome side effects, sleep disturbance, shaky feeling, unsteady feeling, headache, dry throat, hyperhidrosis, tachycardia, palpation…"
- "Concerta, Ritalin, Strattera and Zyban have not yielded any positive effect ..."
- "Concerta, Ritalin…she becomes very lethargic on this medication ..."
- "Ritalina but then became depressed and had obsessive thoughts, the medication is discontinued."
- "The patient on a maximum of 126 mg Concerta and 20 mg Ritalin, without satisfactory results."
- "Ritalin SR resulted in poor sleep, poor appetite, and the boy became a 'zombie'."
- " ... tried treatment with Ritalin and then showed a paradoxical reaction with exacerbation of hyperactivity, impulsivity. "

- "Concerta prescribed, titrated to 72 mg in the morning. Not experienced relief of symptoms, rather…side effects such as headache. "
- "... ... Concerta, however, got more… speeded and depressed."
- “Strattera, Ritalin and Medikinet with inadequate effect…troublesome side-effects.”
- "... The patient responded with depressive symptoms on methylphenidate."
- "... Concerta side effects such as stomach pain ... ... the Ritalin same side effects."
- "Ritalin ... allergic reaction with severe body itching"
- "... Concerta made him anxious and nervous, insomnia and nausea."
- "... methylphenidate had large, negative effects on appetite and weight."
- "Concerta ... troublesome side effects of anxiety."
- "... Tried Concerta, and Metamina Ritalin, many side effects and with very limited effect."
- "Concerta and Ritalin, but this did not work well."
- "... Ritalin was discontinued due to adverse events."
- "... Concerta, Ritalin and Strattera, but with side effects or insufficient efficacy."
- “Ritalin 30mg, 2 x 1, but unfortunately, altered mood with increased oppositional syndrome and aggression."
- "Concerta 54 mg / d for long periods without significant effect. The next try with short-acting Ritalin was also without significant effect. "
- "... Previously tried Ritalina, but then became depressed and introverted."
- "The patient has tried Concerta…resulted in seizures"
- “Concerta in increasing doses up to 54 mg per day. The patient described that he becomes more anxious, irritable, depressed, restless ... difficult to sleep ... dry mouth and blurred vision ... tense throughout the body and had spasms in shoulders and arms"
- "Treatment with Concerta and Ritalin has been tried without effect."
- "Lack of effect of methylphenidate and relatively pronounced anxiety afternoon / evening."
- “Have tried Ritalin but had seizures."
- “received different doses of Ritalin to 40 mg per day and has not improved, at higher doses rather worsened."
- "Medicated with methylphenidate but previously developed a toxic hepatitis."
- "Ritalin. ... in quite a high dose (1.5 mg / kg / day) developed, however, after about three months of treatment auditory hallucinations that disappeared immediately after discontinuation”
- "Concerta ... troublesome side effects in terms of increased general anxiety that lasts all day, concentration problems, diarrhoea, great concern and anxiety, nervousness and depression and dysphoria and severe loss of appetite."
- "... Has tried Concerta, which only made her sad."
- “Concerta ... did not give an equally good effect ... patient lacks the distinctive sweep of the amphetamine effect compared with Concerta’s discrete onset of action. "
- “Ritalin capsule... but after four days responded with sharp rise in blood pressure ...”
- "Ritalin and Concerta has led to increased tics and Strattera has not had the desired effect over time."
- "... Concerta gave nausea, fainting and dyspepsia."
- "Concerta ... after about a year ago began to perceive an emotional impact that is an unpleasant side effect of Concerta and stopped."
- "Concerta T reacted with fatigue, increased compulsion, and sleep disturbances."
- "Could not stand Concerta due to side effects became aggressive."
- "... Previously tried the long-acting central stimulants medications including Concerta tablet but this has not worked at all."
- "Ritalin dose that gives rise to anxiety”
- "Concerta ... experienced troublesome side effects such as joint pain, muscle pain and swelling in the legs. These symptoms subside the days she does not take her Concerta. "
- "Ritalin SR ... suffered severe side effects such as nausea, which made it impossible to continue treatment."
- "Treatment with Concerta, but with very minimal effect."
- “Ritalin .... was rather more hyperactive and distracted. ... Concerta... once again became more hyperactive and distracted."
- "Concerta not been successful"
- "Concerta. ... No good effect of the drug and he feels mostly tired."

- "Tried Concerta, but was less effective and possible side effects of rash."
- "Concerta escalation of doses, Atomoxetine, Reboxetine and Ritalin capsule and also Tabl. Ritalin in different doses without any particularly good effect on the patient's symptoms. "
- "Initially Ritalin, which however did not work very well. ... Concerta with the same results ... ... Strattera did not work at all, but pronounced impulsivity and increased conflict."
- "Methylphenidate and atomoxetine later without effect "
- "... Failed to respond to methylphenidate."
- "... Both tried Concerta, and Strattera Ritalin. During treatment with Methylphenidate, he became more anxious and restless and his impulsive acts deteriorated. During Strattera, he was totally confused for a short time and stopped immediately. "
- "Ritalin ... Moderate effect on core symptoms of ADHD, but side effects such as severe compulsion and developed phobias. Disappeared after discontinuation."
- "Concerta ... not worked at all."
- "Previous treatment trials with Concerta and Ritalin in the maximum dose did not provide effect."
- "Tried Concerta but he had side effects of this in terms of constant high pulse."
- "Ritalin ... got his impulsivity back. He is very afraid he will harm his children at such occasions. "
- "Tried Ritalin, vulnerable because of side effects."
- "... tried Ritalin, but was clearly sad by treatment and was not feeling well."
- "... Tried both Concerta and Ritalin, but then experienced difficulties to relax."
- "Concerta up to 36 mg ... gave no effect on patient symptomatology ... feeling still tired and distracted ..."
- "... tried other stimulants as Ritalin and Concerta, but the effect has not been satisfactory."
- "... Ritalin 40 mg it was hard to tolerate."
- "On Concerta treatment ... he got many tics. We are now trying to combine Amphetamine-treatment with a low dose of Concerta ... "
- "... been on Concerta up to 72 mg and now on Ritalin 120mg. None of these preparations have had adequate effect. "
- "Ritalin and Concerta ... have been tried without positive effect."
- "... Previously tried Concerta but felt completely paralyzed by the drug."
- "Methylphenidate and atomoxetine have unacceptable side effects such as headache and abdominal pain."
- "Treatment attempts were made with Concerta ... became more compulsive and restless. "
- "Concerta ... severe stomach problems"
- "…treatment trials of Concerta, Ritalin and Strattera have reacted with strong ... hyperactivity, defiance, and possibly mania."

In summary we have here almost 1000 cases (700+250) for 2009, mainly adults, where psychiatrists have prescribed methylphenidate and Strattera, had to end the treatment due to bad effects, and continued the treatment experiment with dexamphetamine or amphetamine. *This is an incredibly important source for safety information – if* the authorities concerned wanted to know.

The Commission in its letter to me 12 February (ENTR F2/JZ/sx D(2010) 4122), with copies to the Head of MPA (Åkerman) and the Head of the National Board of Health and Welfare (Holm), clarified the responsibilities for the national authorities in this area:

> ”The Commission Decision is addressed to the Member States (MSs) and therefore it is the national competent authorities’ responsibility to ensure that the conditions under Annex IV are adhered to and fulfilled.”
>
> ”We would like to recall that methylphenidate containing medicinal products are nationally authorised and therefore, once the review procedure is finalised at Community level, the national competent authorities of the MSs should not only ensure the implementation of the conditions set in the Commission Decision, but also constantly monitor and assess pharmacovigilance data collected to ensure safe and effective use of these medicines.”

It would be very revealing if the Commission *should request actual evidence* about what the Swedish Medical Products Agency and the National Board of Health and Welfare had done to ensure that the conditions under Annex IV are adhered to and fulfilled. *I* have requested the documents showing the actions taken and have only got declarations of good intent as answer.

In a letter to the Head of the MPA (28 February 2010) I strongly suggested that the MPA should cooperate with the National Board of Health and Welfare and with the pharmaceutical companies concerned (paying the research), to fulfil the conditions put up in Annex IV (page 67) as regards drug utilisation and evaluation of off-label use/abuse. I especially indicated the point in the Commission decision:

> **“Where possible, measures of usage including variables such as information on total amount used, patient age, gender, indication dose, duration of use, treatment continuity, comorbidities, concomitant medications, data on patterns of use, physician specialty will be used.”**

I pointed out that the new Swedish Prescribed Drug Register (from 2005) should be fully used to fulfil this requirement. (See the article *The new Swedish Prescribed Drug Register—Opportunities for pharmacoepidemiological research and experience from The first six months,* Pharmacoepidemiology And Drug Safety 2007; 16:726–735, http://www3.interscience.wiley.com/journal/112749905/abstract?CRETRY=1&SRETRY=0

I got no answer from the Head of the MPA, but from the legal department of the Agency (Nordback) I got a thank you, a referral to the Commission decision (which I of course was well conversed with) and a declaration of good intent: “We can ensure that the Medical Products Agency fulfils the obligations resting upon us according to the Commission decision and the other rules.” *No documents* could be produced by the Agency showing that the good intentions were actually followed up with effective actions.

I want to further explain that **full data on the point mentioned above** – **for the last four years** – now could be found in the new Swedish Prescribed Drug Register, if used together with other registers and with the data in the license applications described above.

I would suggest that the Commission asks the responsible Swedish authorities to use what they actually already have access to, in order to fulfil their responsibilities.

Now let's compare the above with what Johnson & Johnson writes in its new "Risk Management Plan" (RMP) for Concerta, from 23 November 2009.

In the RMP it is stated (p. 118) under the heading *Potential for off label-use*:

> "According to IMS covering CONCERTA retail prescriptions in the 4 major European countries where CONCERTA is available (Germany, France, Spain, and United Kingdom), from January 2003 to June 2009, **the vast majority (94.0%) of retail prescriptions of CONCERTA were prescribed to children and adolescents between the ages of 6 and 20 years."** (Emphasis added.)

This is the ***only*** information about off-label prescriptions to adults in this 319 pages long document written by a company with immense resources to investigate and present the facts about prescriptions. Why don't they present the updated information, as I have done in my earlier report to the Commission in February? I then wrote:

> "Regarding the off-label prescriptions I must mention that the newly released statistics from the National Board of Health and Welfare says that 15 580 adults (19-) last year got methylphenidate (13 948) and amphetamine (1632) in Sweden [the figure for amphetamine later showed to be a bit lower as also some children got the drug via license applications]. This is a rise with around 50% (!) compared to 2008; this rise happening in the year when the Commission made it clear that methylphenidate is ***not*** approved for adults."

So 13 948 adults (19-) got methylphenidate (Concerta, Ritalin) in Sweden 2009, while 17 331 children got the same drug. Meaning that 45 % of the prescriptions for methylphenidate were for off-label use, for adults.

While Johnson & Johnson presents data indicating that 94% of the prescriptions of methylphenidate 2003-2009 (in four countries) were for children – meaning this is not a problem at all, I can easily present data showing that 45 % of the prescriptions for methylphenidate in Sweden 2009 were for adults.

Of course this is not a secret for the national authorities concerned. The question is only how they can they accept misleading, outdated information, as the data about off-label prescriptions to adults presented by Johnson & Johnson.

And the simple answer – at least for the Swedish MPA – is that the agency, influenced by its psychiatric consultants with close ties to the manufacturers, think that adults should get methylphenidate drugs, approved or not. The biggest problem for these officials in the MPA and its consultants seem to be what methylphenidate and amphetamine doses they can approve for adults with drug problems. (See my earlier report (p. 11 where the scientific advisor Lars von Knorring asks for a meeting to work out the upper dose levels for the prescription of methylphenidate and amphetamine to drug addicts).

The Commission knows very well that the Swedish MPA objects to the restrictions in the new SPC: "Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders" and instead works to get higher doses of methylphenidate prescribed to adults, addicts and criminals.

It cannot be possible that the Commission can allow these obvious violations of the decided safety measures and I ask the Commission to act to get compliance to the decision.

As for diversion and abuse of methylphenidate it is very interesting to compare *reality* with what Johnson & Johnson says in its RMP.

Misuse and abuse of Concerta is described in the RMP (p. 128-129) under the heading *Drug Abuse and Drug Dependence.* It is stated:

> "CONCERTA has a unique pharmaceutical design that prohibits the dosage form from being crushed, opened, or emptied **making it virtually impossible to abuse it through injection, snorting, or inhalation means.** In addition, it is a long-acting prolonged-release product and **high, spiking blood levels that individuals may perceive as euphoric effects cannot be achieved with an intact dosage form.** Due to these characteristics the CONCERTA formulation would probably not be the preferred choice for methylphenidate abuse." (Emphasis added.)
> …
> "The limited number of paediatric reports in the postmarketing database supports that CONCERTA treatment confers a low risk of drug dependence. **The formulation makes it difficult, if not impossible to effectively abuse; therefore, is not expected to have an impact with respect to overall public health."** (Emphasis added.)

On page 127 in RMP it is said that the total number of postmarketing reports about drug abuse events for Concerta *worldwide* is 16 (!).

In the RMP it is stated (p. 123) under the heading *Important Potential Risk: Diversion:*

> "**Diversion** is understood as the entry of illicit pharmaceutical products onto the unregulated market through a number of channels, eg, thefts of product from the legitimate supply chain, or **product obtained legitimately and subsequently diverted through various means** such as Internet sales." (Emphasis added.)
> …
> "**A total of 3 adverse events with preferred terms of Drug diversion have been received** in the postmarketing database cumulative 01 August 2000 to 10 August 2009 (BRM Report, PSUR 2009). The limited information does not allow conclusions to be made regarding this important potential risk." (Emphasis added.)

Three (!) reports *worldwide* since year 2000?

Some data about diversion of methylphenidate in the US is however presented in the RMP, but about Europe only the following is said (p. 124):

> "From a review of public information sources, it appears that there are currently no databases in place at the EU or national Member State level to directly monitor pharmaceutical product diversion in the EU."

All in all Johnson & Johnson is presenting NO data at all about the abuse and diversion of Concerta in Europe. To make it even worse it is said that Concerta is "**difficult, if not impossible to effectively abuse",** that it is "**virtually impossible to abuse it through injection, snorting, or inhalation means"** and that "**euphoric effects cannot be achieved with an intact dosage form".**

Let's compare what Johnson & Johnson writes in the RMP with some data from the Swedish police and with *extensive* data from the "users" of Concerta in Sweden.

The police department in one district in Sweden reports 2009:

> "In talks police officers have had with Subutex abusers … it has emerged that Concerta is used in connection with drug users' injection of Subutex. Drug users have told they "peel" Concerta tablets and take the content with Subutex. This means that the drug abusers get better effect of the intake of Subutex."

This is for sure an interesting indicator warranting investigation; the very drugs prescribed to addicts to "treat" their drug abuse is *creating a new form of abuse* – which is what has always happened when narcotic drugs have been used as "treatment" for drug abuse.

And this is a story from one of the "users". It is highlighted here because it contains so many of the facts about Concerta denied by the pharmaceutical company – and downplayed by the MPA and its psychiatric consultants. It tells about legally described Concerta "for ADHD", about getting euphoria on the "therapeutic dose", about increasing the dose to get a better high, about dependency and the need to "re-dose", about drug induced repetitive behaviour and over-focussing, and about crashing with anxiety:

> "Concerta is actually a damn fishy substance. Feels like a little love-hate right now. Last time the doctor increased the dosage to 56mg [54mg] and now it has become a bit annoying. I really recognize what you [other users] write about the side effects / withdrawal.
>
> I have the diagnosis ADHD and have really had good and desirable effect earlier. Started at 18 and felt nothing, then 36mg for a while which worked perfectly, except that I was damn tired 10-12 hours after ingestion.

Since I'm very curious about drugs I started with 6 * 18mg as soon as I got the first recipe. The effect was not too good, got damn interested in everything, rang some dodgy calls to friends, some banks were also receiving long-long question-rich conversation. Unable to sleep normally later in the evening.

Now six months later with 56es [54s] got problems at once. When I took them normally in the morning, I got speeded directly, stuck in the bathroom with a book for a few hours, among other things. I am also somewhat absent during the day, everything feels very unreal. Also gets a fairly serious euphoria the first few hours. Euphoria and feelings of unreality do not feel at all funny as I recognize myself from my past opiate abuse.

When this morning's euphoria from the "usual dose" has died down, I am directly discouraged and feel the urge to re-administer, as with past abuse. The last three days I have fallen for the temptation and have chewed more tablets than prescribed.

The first day I studied like a fool in the morning, then I got stuck on wikipedia for a few hours while I had a movie running on the laptop. Slowly came a creeping anxiety, despite re-dosing, after a while it became worse during the night and I was gripped by a compact dark fucking anxiety. Have not felt so bad since my Tramadol withdrawal. Started in the day to write a log when I wanted to see how long the effects of Concerta lasted, but the worse I felt, the more it became a little anxiety story, a declaration to myself that I had to write down how I felt, one welter of emotions, not to succumb from the anxiety. Warned of course my future me to overdose, but now, unfortunately, the roundabout started!

Day two also started with the morning dose, when the effect began to disappear a few hours later the anxiety came directly, so I re-dosed again. The day continued as usual with lectures and study, but as soon as I landed at the computer time just flew away. Around the small hours, I felt tired but now started to look on the [TV] series instead.
...
I took the morning dose, as usual, thoughts swirled in my mind all the time on yesterday's anxiety but damn it one is digging in the cookie jar yet. In addition to the shorter morning euphoria, I just felt unwell today, severe headache and nausea. Purely theoretically, I can see here that there are two solutions for tomorrow: As the good effect wears off I **should** not take more of it, simply not worth it, or just take more, which I unfortunately risk to do if I know myself. "

Johnson & Johnson reports laughable 16 post-marketing events of abuse *worldwide* for Concerta. NO data at all is taken up in the RMP about the scene with abuse of methylphenidate in Europe. The company seems to know nothing about it, and it is the same with the Swedish MPA; the Agency has taken no actions to find out and report about the abuse in Sweden.

The laughable data about 16 cases of abuse worldwide and the efforts of Johnson & Johnson to explain that Concerta *cannot* be abused must be compared with what the “users” in Sweden report in different discussion forums.

Via this link one can read **103 pages** (from Swedish web sites) where the Swedish “users” tell about diversion and abuse of Concerta and Ritalin. The stories are in Swedish **http://jannel.se/concrit.Apr2010.pdf** [3] ***(updated) excerpts are presented in English below*:**

On getting high/getting a buzz on the doses doctors prescribe:

”I think Concerta 36 was excellent to chew ... feel somewhat high on 2”;
”Ritalin 40mg is not so strong, you need 2 such to experience a fairly drunk [state], like Concerta 54mg is much better ...”;
”... Has Ritalin prescribed for my possible ADD and take a total of 40mg in the morning for it ... I am very easily influenced by the Ritalin, I feel very alert and I am almost in a euphoric state the next few hours after I took it. I can sit in trance ... ';
”54-100 mg do I need if I should be high on it”;
”2 40mg now. Damn it is actually power in these. Thought in the beginning that there would be some shit, but they may be called ”good enough”;
”Have a friend who becomes truly stoned at 20mg (and yes, he has taken much drugs too), myself, who need about 40-60”;
”From my own experience you can be stoned if you chew a few 10 mg”;
”Takes conserta 18 mg to concentrate pretty good, I take 18mg 2, then I am just speeded as a parrot”.
”I absolutely become high on Concerta ... 60-100 mg will be good enough ”;
”took 3x36 MG [Concerta] and got a fucking buzz”;
”yes one can get speeded on a 36mg's Concerta, but more is desirable ”;
”I am using conserta 54 mg daily. Well, I can get high on it sometimes. Could be badly speeded”;
”I have at least one friend who I have seen to become *very* speeded on 1 ½ tablet 36mg Concerta ...”;
”Buy Ritalin myself and it's only 10mg, but I'll be right nice on them! but the high will not be for very long ”;
”Is it just 18mg [Concerta] you have to eat 4-6x to get a buzz that works..”;
”You can become sick high by Methylphenidate, I become ”socially high” on a 37mg-tab ”;
”What is a normal dose of ADHD drug (beginners and experienced)?”
[Answer:] ”Something between 40-60mg I would say, more is needed after an hour or so to keep the buzz alive ...”
“ritalin 40 mg are not so strong you need 2 to experience a pretty good buzz, think Concerta 54mg is much better ...The buzz: SPEED, generally happy, want to talk about feelings…”
“54-100 mg do I need to get stoned on. works very well…almost like taking amphetamine but a bit worse because it is shorter and doesn’t give such an intensive high….”
“You don’t fucking need 100 tablets, it was 40mg's capsules. People felt eating 2-3. Then if you injected Ritalin you didn’t even need 40mg, and it was a damn strong shot. So do not talk about stuff you do not have a clue about.”
“I'm no expert on Concerta, but I've taken 90 mg at the most ... On it, and even on a little smaller doses, I got a high that clearly has been in the same class as amphetamine (enormous energy, outward direction, commitment, euphoria…”
“My God .. That's because amphetamines are the drug of choice, in order to feel harmony and euphoria. It is not because you have ADHD that you feel comfortable on amphetamines .. That's because it is a drug that makes you feel like you want to feel. People seem to have incorrect expectations of amphetamine that you should be "nervous" and "running around" - and that it is "unique" that you become concentrated and creative on amphetamine .. Haha. It's a classic effect.”
“From my own experience you can get stoned on nibbling a few 10mg [Ritalin]! The capsules I have never been prescribed so have not actually tested them ..”
“Another thing I noticed is that with Concerta [54 mg] about 20 minutes after I took the pill, I get an extremely pleasant "buzz" feeling. A sort of euphoria. It does not last as long, 1 hour maybe, but it's so fucking beautiful in that first hour! I will be happy, social, energetic, feel good simply! Is that how it feels with “normal” amphetamines too, or?
“I can chew two pieces of 36mg and feel a little speeded. but it always ends with anxiety and shit, hate Concerta.”
“I have eaten Ritalin 30mg for 3 days and has not had the desired effect yet, but feel more merry about 2 hours after eating a tablet. Then go over to where I get my heart rate sky-high and trembling all day and finally a "withdrawal" consisting of nervous twitches

“…euphoric effects cannot be achieved with an intact dosage form”.
Johnson & Johnson, RMP, 23 November 2009

and I get tired. Do hope that it will improve over time ...(Diagnosed with ADD and autism, faint traces of Asperger's.)"

On increasing the dose to get a better buzz:

"I have strong ADHD and Ritalin, 80 mg per day, have never taken it as I should, just abused but if I crush and snort 40mg I get a little power, and I continue then I get greatly speeded ";

"I do not know what Concerta costs on the black market because I have been diagnosed with ADD and get the shit basically free ... This is my speed, can catch balls and count faster than a calculator at doses of 108mg or more ";

"I have concerta prescribed fr 72mg (2 * 36mg daily, to get "high" I take at least 10 54mg chewing of course because it is prolonged";

"I started taking a bit more than I should because I did not know the impact I had at the beginning, and it became just more and more each time. Now I sit here, a monthly ration finished in 3 days";

"Have just managed to get my psychiatrist to prescribe Ritalin to me (rimmed up that I have ADHD etc.), But…capsules tablets of 10 mg. My question to you experts is how many of those should be taken to have a bit fun? ";

"Take Concerta (same as Ritalin) right now, have it prescribed. 1.begins within ten minutes, going up in 30 minutes to. Important: crushed orally if you eat something extra to, a fruit or banana maybe. The increase is VERY nice, I must say, especially if you listen to music. ";

"but I am prescribed 3x 54mg Concerta ... since 2 months back but sometimes it takes 4-5 (not crushed) so you feel good for many hours ";

"The formulation makes it difficult, if not impossible to effectively abuse; therefore, is not expected to have an impact with respect to overall public health."
Johnson & Johnson, RMP, 23 November 2009

"I've had both Concerta and Ritalin prescription since some week even though I have a long addiction behind me with cs. This my psychiatrist knows about. I made the ADHD test and had clear ADHD. The worst thing is that I can not help but chew the capsules in concerta to get a kick effect.. ".

"I ate 8 pieces Concerta 36 mg total, shared and swallowed them last Thursday. Was super sick speeded so I would not even touch one of those pills again ha ha .. it was super sick. Felt so bad on withdrawal 10 times worse than on the ordinary amphetamine cannot even describe the low and tormented myself night until morning without being able to sleep more than maybe 10 minutes all night and just stare at the ceiling and felt bad .. am still not normal after those .. but you know well but never feel normal anyway I really do prefer real amphetamine!"

"yes it is good to have more than two 54mg, but be prepared for a tough withdrawal. Everyone do not get an annoying withdrawal but can imagine that most people get it. I think it is far worse than usual withdrawal from amphetamine."

"Of course to get a good buzz so I need to take 2 and a half Concerta 54mg"

"162 mg of Concerta is sufficient enough to get decently speeded!"

"I have a neuropsychiatric disorder (ADHD) and treated with Ritalin tablets 10 mg orally (active substance: methylphenidate). The dose I really need is about. 2 times less than what I have been prescribed per month (managed to fool my doctor that I need more). The rest I have some fun with after I solve the tablets, filters, etc. so I can shoot it. When I shoot, I am almost always home."

On experimenting with different ways to take the amphetamine preparations to get a better buzz (chew, crush, snort, inject):

"Ritalin is so fucking nice, I love them. Smash balls or snort alternative mix with water the drink kicks in like hell between 20-80mg is usually enough for me one evening ";

"Ritalin is taken up in an excellent way orally and gives effect almost immediately. Ritalin is possible to shoot, and it provides a similarity to cocaine ";

"yes, Ritalin gives a buzz. similar to amphetamine I would say. I am using my medication nasally when I am partying, works fine. but can imagine to crush it and bomb it works very fine ";

”Concerta ... Add tab between 2 spoons, then take a hammer and hit so you get them apart, is also possible to inject this, but sticky, so best to swallow!”;
”You can take it both orally and nasally, of course, different dosing then”.
“Use to be on 40mg tabs [Ritalin] that I crush and take the best way!”
“If it should turn, I usually take between four and eight 36es [Concerta] .. If you do not want to chew them so it's a simple thing to take a knife and split them lengthwise … However the withdrawal is not play with ..”
“I took 80mg and felt a little speeded. Snorted 40mg and felt at least 4-5 times more speeded.”
“It is possible to be stoned and the easiest is to nibble. Personally, I have to take at least 100 mg. [Ritalin] to be speeded, but *the more, the merrier*.”
“I tested my sister's Concerta a few months ago, I think I began with 4*36mg crushed. I got a nice feeling in the body that reminded a bit of tramadol, but less euphoria (though I do not have much to compare with)”
“Agree Concerta works great shit to snort. Do snort half 54 mg and take the other half orally (crushed) then I feel damn good for 2-3 hours.”
“I have Concerta prescribed, most people think it is a pretty fun thing, but withdrawal is bloody boring, and sometimes even more annoying than on true A[mphetamine. By the way I peel them and usually run at 2-3, it makes me a little bit happy…”
“Sitting at the moment and a bit fuzzy on Concerta I came across. Took 3 pieces, because I'm pretty inexperienced. Crunching them btw, tasted shit. Anyway, I got me a decent kick None überrus [big buzz] exactly but will do.”
“Enough to snort about 50mg [Concerta] for me, and then I get totally comfortable "speeded".”
“Well, I know a guy who shoots Ritalin instead of amphetamine and now he also said that he thinks it beats better for him than what amphetamines do.”
“I've always got a really nice buzz from them, and one can only hope that the effect would be there longer. The short half-life similar to that of coffeine makes you have to snort in more every two hours to keep the high. The high, however, is very nice. A completely clean feeling of energy and focus.”
“Concerta is of course true nice to take. Nice buzz, talkative, speeded, emotional (but not so good if you have too many secrets)
The first time I took 2, 36R, crunching them. Felt gold, but was not prepared for withdrawal, so of course it sucked hard. Now I have to take around 100-120mg to get the desired effect.”
“have eaten 5 peeled today and this is a horrible withdrawal.”

“…it is virtually impossible to abuse it through injection, snorting, or inhalation means.”
Johnson & Johnson, RMP, 23 November 2009

On selling or giving away the preparations to others and in that way spreading the abuse:

”Ritalin **...**mates with ADD do not take and I'll get 'them. 2 cans of 30mg 30 buttons in each ie 60 tablets. What are they worth? ”;
”A buddy've fixed up some maps Ritalin that he thought to “feast” on. Is it easy to mix with alcohol, how cautious should you be? ”;
”My buddies poked in the 3 tab of these ADHD medication when he was really drunk because of alchohol. Resulting in that he could [not] breathe, type slobbered all the time, impossible to contact every now and then and lost his breath when he was trying to sleep ”;
”My friend (who…has DAMP) does not like to take his medication, and usually give it to me I do not have huge experience of drugs, just think that it can be fun sometimes. So, if I want to get the maximum effect of Concerta, how should I proceed? ”;
”hey, one buddy has ADHD and is eating Concerta, so I wonder. How many 18mg tablets we need chew / swallow to get us drunk? ”;

“A total of 3 adverse events with…Drug diversion have been received in the postmarketing database cumulative 01 August 2000 to 10 August 2009.”
Johnson & Johnson, RMP, 23 November 2009

”I did try ADHD pills from a friend, Concerta, and yes, I started taking type - 4 pieces, chewed and swallowed, then I took some booze and beer”;
”Have a buddy who had ADHD before. And he kept a jar with Concerta. But not so strong, he says (?). 30 tablets of 200 SEK. Good price? ”;
”A friend has Concerta 18 mg and now, I wonder how the hell I'm going to abuse them (the capsules) like an instruction manual step by step”.
“Remember when I took 300mg of my then girlfriend's Ritalin. There we can we talk about the worst I have experienced in form of withdrawal! Maximum anxiety and quite impossible to sleep even though I was exhausted, succeeded to go to sleep after 18 hours.”
“The girlfriend has ADHD and Concerta 36mg has been prescribed. have tried a few times, even earlier today. There is nothing like pulling a rope in my opinion. Concerta lasts longer. With alcohol, it is actually quite nice. 'll have a great pleasure in the body, with a little shudder very often. Then I chewed the tablet before…Do not get speeded, or something like that, but calmer, and release of some concern. However, I have only taken 38mg at most.”

I have in this report given even more data about off-label prescriptions, effects, use and abuse of methylphenidate in Sweden. And I have compared my findings with what Johnson & Johnson writes to the European medical agencies in its Risk Management Plan, 23 November 2009.

Two important documents have been turned in to the medical authorities in Europe by the pharmaceutical companies about the safety actions ordered by the Commission in May 2009. We have the Feasibility Assessment Study – an aggressive effort, by the manufacturers of methylphenidate in Europe (“the Consortium”) to explain why long-term studies about adverse psychiatric outcomes of methylphenidate treatment *could not and should not* be done. And we have Johnson & Johnson’s Risk Management Plan – with the fraudulent descriptions of the abuse potential and actual abuse of Concerta.

It must be very clear that the concerned pharmaceutical companies are not fulfilling the conditions for continued marketing authorisation decided by the Commission, and it must be clear that the Swedish Medical Products Agency is not taking the responsibility to ensure that the conditions are adhered to and fulfilled.

I therefore ask the Commission to initiate whatever actions necessary within the scope of the authority of the Commission to ensure that effective actions are taken by the Swedish MPA in the matters I have taken up in my report.

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References:

[1] The European Commission, decision and appendixes about methylphenidate products, from 27 May 2009; Decision http://jannel.se/dec_55708_en.pdf Appendixes: http://jannel.se/anx_55708_en.pdf
[2] Johnson & Johnson, Risk Mangement Plan Concerta, 23 November 2009, http://jannel.se/RMP-ConcertaNov2009.pdf
[3] Data from Swedish discussion forums, 2007-2010. http://jannel.se/concrit.Apr2010.pdf