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Data from the Swedish Medical Products Agency (MPA)

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

This is a report about ADHD drugs based on data directly from the Swedish Medical Products Agency (MPA).

The European Commission has in its decision from 27 May 2009, about marketing authorisation for methylphenidate products (like Ritalin and Concerta), put up clear conditions to be fulfilled by the pharmaceutical companies producing ADHD drugs [1]. So for example should studies about drug utilisation, "including evaluation of Off-Label use/Abuse" be done, as well as studies about "Long-Term Use effects" (for adverse cognitive outcomes and adverse psychiatric outcomes), "Growth, Development and Sexual Maturation" and "Cardiovascular and Cerebrovascular effects".

Per the latest data I have from the MPA the only document having relevance to the studies above that has been submitted to the Agency is the so called *Feasibility Assessment of a Study of Long-term Effects of Methylphenidate on Cognition and Psychiatric Outcomes.* This document, presented by the "The Consortium" (as the manufacturers of methylphenidate drugs call themselves in the document), can only be characterised as an aggressive effort to explain why long-term studies about adverse psychiatric outcomes of methylphenidate treatment could not and should not be done, together with distorted facts about the beneficial long-term outcomes of drug treatment. The intention with the feasibility assessment study is clearly to delay needed safety actions for methylphenidate drugs.

Considering the above it is my hope that *this* report with data directly from the Medical Products Agency in Sweden about off-label use, abuse, effects and harmful effects will be of real value for the Commission and the EMEA.

The PR campaign selling the message that methylphenidate drugs are "safe and effective" – and creating an explosion in off-label prescriptions

The official message from the pharmaceutical companies and psychiatrists working with the industry is that methylphenidate (in Sweden mainly Ritalin and Concerta) is *"safe and effective".* The message has also been the same from concerned government agencies in Sweden, as these agencies mainly take advice from the psychiatric authorities working with the manufacturers. This PR campaign – which

have included the creation of an advocacy group ("patient organisation") called Attention, demanding ADHD drugs for children and adults – has lead to a heavy increase in the off-label prescription of ADHD drugs to adults. In 2008 around **14 000 adults got ADHD drugs** (from the class N06BA) in Sweden **in off-label prescriptions** (according to data from the National Board of Health).

Part of the message to doctors and the public in Sweden is also that all persons prescribed methylphenidate *get a low dose* – far from the doses causing euphoria and far from the doses used by drug addicts.

We have heard the following*: "Treatment of ADHD with stimulant medications is supported by hundreds of research studies during 30 years, showing their safety and efficacy",* said Janssen-Cilag, Sweden [2]. *"Hopefully it can mean that many thousands of adult Swedes get access to medications that can facilitate their life tremendously"*, Janssen-Cilag, psychiatrist Niels Guldberg and patient group Attention in a press release about adults and Concerta [3]. "*Serious adverse effects have not been demonstrated",* said expert consultant for the Medical Products Agency, psychiatrist Lars-Olof Janols in a newspaper article [4]. *"The daily doses are in general 1-5 percent of what is needed to get 'high'",* said Professor Christopher Gillberg [5]. *"It's a dose around one hundredth [of the one abused] and it need not to be increased",* said the patient group Attention [6]. *"…it's important to know that the medical treatment with the doses used does not give an euphoric experience and that there is no tendency for dose increase"*, said Björn Kadesjö, scientific advisor to the National Board of Health and welfare and coordinating author of the Board's main ADHD text in Sweden [7]. *"No risk for dependency or abuse",* said leading expert and lecturer Agneta Hellström from Stockholm County Council to hundreds of listeners about methylphenidate [8]. *"…an effective and well proven treatment",* where *"the adverse effects are well known and possible to control",* and where the drugs *"are not in a proper medical sense giving addiction, as morphine, benzodiazepines, nicotine or even caffeine"*, said leading psychiatrist Gunilla Thernlund, who has also been responsible for the Quality Registry for stimulant drugs, administered by the National Board of Health and Welfare [9]. On the question if ADHD drugs are in any way dangerous the National Psychiatric Coordinator Anders Milton said, *"On the contrary…for those who need them it is a miracle."* [10] Milton led a national project under the Ministry of Health where one important action was to set aside millions of tax payers money to make sure that adults got drugs for ADHD – despite *none* of these drugs being approved for adults.

The information from the manufacturers and leading psychiatrists has been clear and simple, and doctors and the public have not missed this message.

At the same time the reporting of adverse drug reactions to the Adverse Events Registry of the Swedish Medical Agency, by the psychiatrists who prescribe methylphenidate and Strattera, has been *very* low. For 2009 the following number of adverse event reports was submitted to the Adverse Events Registry: Concerta 16 reports, Ritalin 9 reports, Metamina (dextroamphetamine) 2 reports, Strattera (atomoxetine) 14 reports.

Based on the "safe and effective" PR message and on the small number of adverse event reports from prescribing psychiatrists one could almost get the false idea that

very few persons were subjected to security risks from these drugs. We obviously need another source of information to get the some real facts about the effects of methylphenidate drugs.

What the information from the Medical Products Agency shows about effects and harmful effects of Concerta and Ritalin

As said the Adverse Events Registry contains very little of value – as in other similar systems security risks with different drugs are not reported. But there is another department in the Medical Products Agency containing a wealth of information about the *true effects* of methylphenidate products (and of Strattera): the department dealing with clinical trials and licenses.

In Sweden Concerta, Ritalin and Strattera are the only drugs *approved* for the treatment of what is called ADHD (two other methylphenidate products are also approved, but not really used). This means that when psychiatrists for any reason wants to prescribe another drug, as the dextroamphetamine drug Metamina (manufactured by Recip), they need to have a license approval from the MPA for the prescription, and they can only get that approval *after having prescribed approved drugs first* (Ritalin, Concerta, Strattera). This means, in its turn, that psychiatrists wanting to get an approval to prescribe Metamina must give good and clear arguments why they want or need to do that.

And from this we get the wealth of information existing in the License section of the MPA. A request, per the Swedish Freedom of Information Act, to get a copy of *all licenses approved for 2009 for Metamina* (the latest for each patient), gives the following result:

695 patients got an approval for Metamina in 2009. And remember, that almost all of these persons first had been treated with the *approved* drugs: Ritalin, Concerta, Strattera.

In the license application we can see – maybe for the first time – the prescribing psychiatrists describing the **real effects** of Ritalin, Concerta, Strattera.

We could sum these license applications up by saying: **Here we have almost 700 cases where the security risks (no or vanishing effects, harmful effects) with these drugs are eloquently expressed.**

We have an abundance of evidence that the doses of methylphenidate for adults – around 650 of the license applications concern adults – have to be *increased* after a while to uphold the drug effect. We have very good evidence that the prescribing psychiatrists then *have to move up to even stronger drugs*: when it is no longer possible to increase the dose of methylphenidate they have to transfer the patient to increasing doses of dextroamphetamine (Metamina).

Below is a list of **examples** – directly from the license applications – of what the prescribing psychiatrists have found about the effects of Ritalin, Concerta and Strattera:

- Ritalin & Zoloft ”insufficient effect”
- ”Ritalin / Concerta without satisfactory effect”
- Concerta and Ritalina. ”Residual effects in the form of very powerful, almost physical anguish. Palpitations, numbness and tremors. Earlier tried Strattera without effect. ”
- ”Patient has been treated with methylphenidate in increasing doses, without significant clinical effect at lower doses and severe side effects such as increased agitation, sleep disturbance, muscle aches and tachycardia at doses above 30 mg.”
- ”Concerta up to 72mg. Is improved but have gone down very much in weight and have trouble sleeping. ”
- ”Tried Ritalin, Concerta and Strattera without success.”
- ”Earlier treatment trial…Concerta and Ritalin for several years proved insufficient effect.”
- ”Tried methylphenidate but due to of insufficient efficacy and side effects now been on Metamina over half a year.”
- ”Concerta has been tested in dose increase to 54mg/d with some effect, but growing anxiety. A switch to Strattera, which already at a low dose resulted in severe nausea, dizziness and loss of appetite.”
- ”Tried both Concerta and Strattera, but abandoned both treatments due to side effects, despite a good effect on ADHD symptoms. ”Concerta dysphoria and anxiety. Strattera sexual problems.”
- Concerta. ”Perennial history of depressive illness ... Concerta, but given the side effects such as agitation, anxiety and insomnia, stressed feeling. Had these side effects even at low dosage”
- Ritalin, Equasym, Strattera. ”Some, but not enough effect ... side effects of both Strattera and CS [central stimulants]. ”
- ”The effect of Ritalin has been limited and the patient has also become more depressed.”
- Concerta. ”Bothersome dry cough which is clearly related to this medication.”
- ”We've tried with different stimulants such as Concerta and others. The results were very meager. ”
- Strattera and Ritalin. (Ritalin), ”pulse rise that is troublesome and he may also get an increased tic problem which is also troublesome, ... Pulse increase has been around 100 beats per minute instead of the normal resting heart rate around 70 in both controls by nurses and doctors. ”
- ”Tried Ritalin which made her depressed.”
- Methylphenidate. ”Got troublesome side effects.”
- Concerta, Ritalin. ”Allergic reactions in the form of shortness of breath.”
- Treatment for depression, ”not improved by the comprehensive treatment ... methylphenidate in gently increasing dose but responded with nausea, dizziness, feeling stress, which can easily escalate to severe anxiety, which has made increasing the dose of 45mg Concerta impossible.” ... Experiment with the addition of Strattera has also been made without positive effect. ”
- Methylphenidate. ”After examination, the patient treated with methylphenidate, dose about 60mg positive effect. The patient thinks that the effect is insufficient and would therefore want to try Metamina instead. ”
- Concerta, Ritalin. ”…was discontinued due to a suspected allergic reaction.”
- ”Ritalin ... arose reaction (rash, itching), Strattera is not successful: sleep problems, emotional blunting”
- ”Not previously tolerated Concerta.”
- “Maximum dose of Concerta was 72 mg and the maximum dose of Ritalin was 40mg 2 in the morning ... In higher doses, he has been rather over-stimulated, without reaching full symptomatic relief. ”
- ”Ritalina and Concerta, which had to be discontinued due to side effects.”
- “…we notice that the effect of Concert 2 pills 36 mg daily is inadequate ... We have had to increase the dose Concerta, been up to 126mg daily, and she has also got the addition of Ritalin in pill form, but continues to experience tremendous fatigue and difficulty starting. By

now wondering …if Metmina may be an option ... Due to insufficient efficacy of methylphenidate wish to test the Metmina in order to optimize (!) the treatment as the patient experiences hopelessness as regards the bettering of her condition."

- Concerta, Ritalin, Strattera. "The patient has not been able to continue with these medications due to side effects of the preparations, and sometimes because he had no benefit from them ... one may give the patient a chance to try Metamina too."
- "Strattera, Concerta and Ritalin is not giving effect ..."
- "Treatment trials with methylphenidate up to 90mg daily, a relatively high dose given that the patient weighs about 60 kg. Medication had no significant effect, so the test was discontinued after a few months ... internal stress and significant difficulties in getting started with tasks and complete unfinished projects prevents both work ... social contacts ... do treatment trials with Metamina. "
- Concerta and Strattera. "Had to be terminated due to depression, insomnia and a feeling that does not recognize himself."
- Methylphenidate. "Difficult to evaluate the treatment ... What he particularly seems to have achieved is an improved ability to handle the contact with 'difficult people'... Side effects occur in the form of headaches, motion sickness-like nausea…Furthermore, the patient ticslike blinking of a similar level. "
- Ritalin. "His motor tics got worse and he also got side effects in form of double vision"
- "Tried all of central stimulant drugs on the market in Sweden, but without the desired effect and side effect severe headache."
- "Only a small effect of Ritalin"
- Methylphenidate and antidepressants. "An adequate dose has had limited effect."
- Methylphenidate. "Got…intolerable side effects."
- Concerta "not significantly positive result"
- Concerta and Ritalin. "…intolerable side effects such as anxiety, nausea, increased pain and fatigue." With Metamina "improvement in endurance."
- Methylphenidate "without experiencing a satisfactory effect"
- Concerta "effect .. decreased ... associated with depression"
- Concerta and Ritalin. "Side effects"
- Methylphenidate "without enough effect"
- Concerta, Ritalin. "had to end this after a few months because of severe side effects such as muscle and joint pain, uncommunicativeness and suicidal thoughts ... I tried Ritalin ... same side effects, although to a lesser extent."
- Concerta "without any significant effect"
- Ritalin "discontinued because of side effects "
- Concerta "largely ineffective"
- Concerta, Ritalin "annoyed by muscular side effects, he clearly puts in connection with the medication."
- Ritalin "with side ... increased muscle tone, abdominal pain"
- "Ritalin 40mg in the morning, Metamina T 0 +3 +3
- "Necessary to bring the day to work"
- Methylphenidate "gave…dermatitis"
- Methylphenidate "became hyper-focused in some way"
- Ritalin "palpitations and muscle pain "
- Ritalin, Strattera. (Ritalin) effects completely subsided. Gives lowering of mood. "
- Methylphenidate "at 3.5-4 tablets very good effect, but at the same time grandiose feeling."
- Methylphenidate "no beneficial effect"
- Methylphenidate "not given adequate effect, but with side effects in the form of fever, blurred vision."
- "Tried similar products to Metamina but had not sufficient effect"
- Ritalin "insufficient treatment effect resulted in more side effects, palpation, fatigue, poor concentration skills clearly with Ritalin. "
- "Strattera has not worked. Concerta, Ritalin works ... .. but may display adverse reactions in the form of particular anxiety why it has been difficult to take the medication in the dose he would need."
- "Absent effect of both Ritalin and Concerta" (dose up to 100mg in previous treatment)

- ”Treatment with Metamina discontinued because of obvious difficulties with compliance ... even committed crimes ... treatment in hospital for an unspecified time ...wish it now, under more controlled conditions to resume treatment with Metamina.”
- ”Concerta…gave a lot of side effects.”
- ”Concerta and Ritalin without effect.”
- ”Emotional unstable personality disorder, recurrent depression and ADHD ... tested Concerta, Ritalin and Strattera, without success. Primarily got side effects.”
- ”Methylphenidate ... developed relatively troublesome side effects in the form of mainly abdominal discomfort, nausea and vomiting.”
- ”Tried to medicate approved preparations without significant effect.”
- ”Concerta / Ritalin gave lots of uncharacteristic side effects.”
- ”For which Ritalin was not working and have had adverse reactions.”
- ”Methylphenidate previously tested with considerably less effect.”
- ”Methylphenidate ... effect was insufficient. Adverse reactions, irritability, anxiety, impaired verbal flow. ”
- ”Methylphenidate ... many side effects such as gastrointestinal upset, malaise, apathy, muscle cramps... history of many years of abuse of amphetamines, in small doses…Dose: 100 mg /day”
- ”72mg Concerta without significant effect and with increased anxiety, even panic attacks ... Given the patient's very ambitious and recurring experiences of failures and unfinished projects, it is considered of great value to her to make a treatment trial with Metamina.”
- ”Concerta and Ritalin have been stopped due to side effects in the form of…depression and increasing anxiety, and inadequate efficacy”
- ”Concerta ... dizziness and low blood pressure.”
- ”Formerly with Concerta, Ritalin and Strattera without effect.”
- ”Significantly more side effects from methylphenidate and much less effective.”
- ”Ritalin ... elevated heart rate was unacceptably high.”
- ”For a short period self-medicated with small doses of amphetamine and the better she felt.”
- ”Ritalin and Concerta ... intolerable side effects ... sudden emotional swings from high happiness to sadness and tears. Strattera was tested which gave great concern and anxiety.”
- ”Concerta and Ritalin ... implied a positive effect in terms of reducing anxiety. In raising the dose ... headache, increased sweating, indigestion, and some increase in anxiety.”
- ”Concerta ... severe side effects as nausea and increasing abdominal discomfort. Changed since Ritalin dose up to 140mg daily. Has left much of the difficulty in concentration, despite this dose ... would like to try Metamina treatment... was also found…recurrent depression, emotionally unstable personality ... also a polydrug use.”
- ”Tried Ritalin and Concerta, but had no good effect, however, a lot of troublesome side effects, with headache, increased anxiety and memory disorders.”
- ”Concerta ... bad effect and headache.”
- ”Ritalin ... 110mg ... not had full effect ... experience some residual attention deficit disorder.”
- ”Diagnosis of recurrent depression ... tried all the treatments available to us including SSRIs, tricyclic drugs, MAOIs, ECT, and various combination treatments ... no treatment trial gave a significant effect.”
- ”Methylphenidate ... sensitive, insecure, paranoid feelings implied in the higher dose.”
- ”Tried both Ritalin and Concerta and had very high doses, however not felt totally helped and is now set to Metamina in the above dosage ... question is whether she now needs to increase the dose.” Dose 80mg/dag
- ”Tried both Strattera to Ritalin and Concerta without any effect. On the other hand ... a lot of side effects. ”
- ”Tried Concerta, Ritalin and Strattera and all with pretty bad results.”
- ”... Concerta side effect in the form of headache which patient even at a couple of occasions had been confined to bed.”
- ”Tried both Ritalin, Concerta and Strattera ... allergic reaction on both Concerta and Ritalin. Strattera did not have any effect except to increase the patient's anxiety.”
- ”Concerta then Strattera... without clear effect, however, with troublesome side effects (agitation, irritablitity, sleep disturbance). Subsequently put on Amphetamine ... despite dose adjustments have had increasing problems associated with coming down (!!) at any doses, especially after the last dose (rapid severe mood swings, increased psychological fatigue, poor concentration) ... As dextroampfetamine have slightly longer half-life and better half-life

than amphetamine the coming-down period (!!) can be tolerated better... The patient should have the opportunity to test dextroampfetamine. ”

- ”Ritalin ... was discontinued for about a week due to increased aggression ... Also tried with Concerta but also then got increased aggressiveness in a similar manner as with Ritalin.”
- ”Tried every drug on the market available to for his disability ... Ritalin, then ... tried Concerta long-acting Ritalin, as well as Equsaysm Depot, with side effects such as loss of appetite and insomnia. Also felt anxious and depressed ... tried Strattera ... very moderate effect ... tried combining Strattera 60mg (evenings) with 36mg Concerta in the morning ... there are experiences among practitioners colleagues (in both child and adult psychiatry) that Metamina can work a little bit better in this patient group [ADHD, Asperger's].”
- ”For many years in maintenance treatment for opiate dependence ... currently Methadone ... also diagnosed with ADHD ... medicated with Strattera ... was not feeling well from this and have been prescribed Concerta ... works well during the day but makes him uneasy in the late afternoon. ... he has tried both amphetamine and Metamina and describes the effect of this that it has the advantage that it disappears in the afternoon and make him sleep well at night ... therapy trial with Metamina.” Dose “increase to the appropriate level”.
- ”Concerta increase without significant effect, then Ritalin increase to 50mgx4!, With some effect, but not optimum ... Also tried Strattera, which the patient has not tolerated, nor been able to wait for effect due to earlier irritability returned. Wish now to try Metamina, as I could not get the full effect of methylphenidate, despite extreme doses. ”
- ”Treated with short-acting Ritalin, Concerta, and with the two preparations in combination, and troubled by a sense of medication influence, why he wishes to try Metamina.”
- ”Patient has a history of depression fatigue probably due to her ADHD problems.”
- ”Both Concerta and Ritalin has caused severe side effects such as nausea, vomiting, weight loss, anxiety and depression.”
- ”Earlier a multi-year dependence on amphetamines ... medicated with methylphenidate, Concerta earlier, now Ritalin ... not felt good, is irritable, depressed. Examined the addition of antidepressants, Sertalin, Cymbalta, even tested Lamictal without any improvement of mood.”
- ”Concerta with insufficient effect, and had increased anxiety ... now applying for a license for Metamina to optimize the effect of CS.” N
- “Metamina dosage has been increased to 11-13 [55-65mg] tablets a day.”
- ”Diagnosis fatigue syndrome, generalized anxiety disorder treated with Metamina as Ritalin has not given effect and causes side effects.”
- ”tried Concerta and Strattera but reacted with severe side effects.”
- ”Medication with methylphenidate ... had to be discontinued at a relatively low level due to anxiety attacks ... even an attempt with Strattera ... discontinued for the same reasons as before.”
- ”Tried T Metamin in increasing dose.”
- ”Concerta resulted in insomnia and anxiety, and changing to Strattera resulted in increased anxiety.”
- ”Tried Ritalin and Concerta respectively and improved significantly concerning concentration. Had to discontinue both treatments due to very difficult adverse side effects.”
- ”Now on Concerta, but can not take more than 18-36mg/dag, giving insufficient effect. If she takes more she gets palpitations and becomes sick. ”
- ”Treated with methylphenidate, up to 70mg/d positive results but clearly insufficient effect. Why switch to Metamina is recommended.”
- ”Treated with methylphenidate ... The effect has been poor, only positive effect has been that she has not been so irritable.”
- ”Methylphenidate without effect.”
- ”Treated with methylphenidate in relatively high doses. 70mg/d without adequate efficacy and side effects in form of tachycardia and tremour. ”
- ”Examined at our specialist clinic for addiction disorders and he has been prescribed Ritalin and then he developed a psychosis which led to care in our intensive care department ... switch to Concerta improved .. could be managed in outpatient settings. He has experienced a non-sound effect of Concerta why we are now seeking Metamina... previously treated with high doses of Ritalin and Concerta (216mg per day) without real effect. ”
- ”Tried the treatment with all the options available: Concerta, Equasysm, Ritalin, but the effect has not been there and patient had a lot of side effects.”
- ”Dosage 8 +8 +8 DAILY” gives 120mg Metamina per day.

- ”Metamina ... contributed to an increase in waking, reduced start-up difficulties, which made life more bearable for the patient.”
- ”Tried Ritalin and Concerta, but was not happy when he took those preparations ... Strattera a good effect on ADHD ... stomach pain ... The pain got worse.” (School-age children)
- ”Tried methylphenidate, which has not helped, and gave reactions at moderate dose.”
- ”Diagnosis: Protracted severe depression ... bipolar disorder, with primarily very lengthy and difficult to treat chronic depression ... suicide risk ... treated with a wide range of psychotropic drugs without any tangible positive results. Earlier possibly some effect of ECT ... ordained forced medication with ECT. Since November methylphenidate with a weak to possibly small effect. To this difficult to treat patient, I think it's worth making an effort with Metamina when we have so far failed to help her with any other medicine. ”
- ”Not had adequate efficacy with antidepressants ... trying Concerta and Ritalin, and he felt the effect on concentration and work. Pretty soon, he gets anxiety, depression, sadness of life... Patient can probably find it helpful to test Metamina. ”
- ”Concerta 18mg. Increased debilitating anxiety ... Some nights ... could not sleep at all. ”
- ”Incomplete response to Ritalin in high doses.”
- ”Methylphenidate ... not optimum effect ... was troubled by repeated anxiety attacks ... Not offered support in medication ... relapse to amphetamine use ... ... detoxified…inportant that he be given the opportunity to try Metamina. Methylphenidate has given adverse events in form of deep depression with apathy, lack of confidence in the future. ”Dose 15-18 tablets per day” [75-90mg]
- ”Tried both Ritalin and Concerta... moderate efficacy, side effect in form of depression, discomfort.” Metamina ”18-20 tablets a day” [90-100mg]
- ”Constant tendency to push forward various projects ... talented and high probability is that he with adequate treatment with stimulants would have a better chance to cope with these ... methylphenidate tested and got… anxiety and worry.”
- ”Ritalin ... severe side effects such as palpitations, headaches, increased anxiety, loss of appetite and difficulty sleeping.”
- ”Tried both Strattera and Ritalin but had intolerable side-effects.”
- ”Tried Ritalin with bad effect.”
- ”Concerta resulted in severe anxiety ... ... Ritalin as yet yielded no effect. When the dose was increased the patient got anxiety and reinforcement of aggressive feelings. Plan to start with dexampfetamine sulphate [Metamina]. ”
- ”Medicated with Concerta with poor treatment outcomes.”
- ”Complex psychiatric problems both with an emotionally unstable personality, past alcohol and drug abuse in combination with ADHD ... In recent times ... had a few relapses, drunk alcohol and smoked cannabis. Despite this, the patient experienced a decrease in drug want when she takes stimulants ... very important that the patient may continue with Metamina. ”
- ”... Family history of ADHD… treatment with Ritalin. It turned out that patient was slightly depressed, leading to that patient got treatment with antidepressants. It turned out ultimately that patient is not very depressed and that her symptoms can be fully explained by the basic diagnosis of ADHD ... tried unsuccessfully treated with T Concerta 36mg/dygn ... not tolerate T Strattera. ”
- ”Tried methylphenidate but developed side effects with increased anxiety, feeling of being drug influenced and strong itching.”
- ”Concerta in dose up to 54 mg/day ... depressed mood and feeling of being screened off ... Ritalin ... had recurring problems with blurred vision and double vision ... ophthalmologist ... 'some accomodation influence can be caused by Ritalin’ ”
- ”Tried adequate doses of Concerta and Ritalin and had side effects such as anxiety, when the medication effect subsided. Even tried Strattera, but had major side effects.”
- “Treated with Ritalin in high dose (160mg/d) ... Very good treatment outcomes but, strong anorexia ... lost weight from 64 to 54 kg. Lower dose has been tried… absence of the positive effect of methylphenidate. ”
- ”Concerta and Ritalin, both of which resulted in many adverse reactions in the form of anxiety and palpitations.”
- ”ADHD and drug dependence in remission ... In the past, treatment trials done with Concerta, Ritalin and Strattera. The patient has shown sharp and unexpected side effects with all treatments (ranging from allergies to hallucinations). A last attempt to treat the patient's restlessness is planned with Metamina. ”

- ”Concerta ... got behavioral disturbances. Switched to Ritalin but got depressed thoughts, became more impulsive, intoxicated with Ritalin tablets 5 pieces ... On another occasion, climbed up on the facade on a high building on the roof. Inhibitions were completely missing and he had a kind of high feeling in the body ... tested with Strattera treatment and was up at 40 mg when he received somatic side effects such as severe fatigue, sleepiness, severe abdominal pain, flu-esteem, varying activity level, etc. ”
- ”Tried both T Concerta and T Ritalin without effect…severe side effects were noted.”
- ”A hefty ADHD as well as related amphetamine abuse ... tried both Concerta and Ritalin. Concerta did not work at all as he got psychotic experiences. Ritalin tested also in reasonable hefty doses without adequate effect. Two serious suicide attempt last month and I can not see that we can refrain from also trying Metamina when it almost feels like the last opportunity to save his life. ”
- ”Trials with Concerta has been done… increase up to 36 mg without effect…numbness, dizziness and headache”
- ”Concerta treatment ... get uncomfortable side effects of dizziness.”
- ”Medication also with 12 mg of Subutex.” Dosage 12 tablets 3 times daily (180mg)
- ”Tried Ritalina and Concerta, but experienced severe side effects.”
- ”Concerta ... dose 54 mg in the morning and 18 mg in the day ... not particularly good effect on his mood and his ability to concentrate. He wants to test Amphetamine. ”
- ”Methylphenidate has had moderate, clearly insufficient effect why treatment wih dexampfetamine is recommended.”
- ”Concerta slow dose increase up to 54 mg. Inititally the patient experienced a good mood, he became calmer, he could sit still and less impulse breakthrough. When the dose was not sufficient for the afternoon, dose increase to 54 mg in the morning and 54 mg in the afternoon ... still had a hard time in the afternoon / evening, we raised the dose to 162 mg ... still did not have significant improvement or effect we transferred him to the capsule of Ritalin…with gradual dose increase to 160 mg ... relapsed, however, in an alcohol abuse ... New assault and binge ... put in Medikinet dose of 160 mg with an improvement in concentration, and restlessness, but the patient experienced headache, which disappeared when the medicine was discontinued which led to the cognitive deterioration coming back. ”Dosage 14 tablets, 70 mg.
- ”Tried all on the market available methylphenidate preparations such as Medikinet, Ritalin, Concerta and also Atomoxetine - Strattera. All preparations have given him side effects and he has not seen any good effect of any of these. ”
- ”Concerta treatment with bad results.”
- ”Previous abuse history is ... iatrogene benzodiazepine dependence ... tried Concerta up to 36 mg with severe side effects such as irritability, depression of mood state, and fatigue combined with sleep disturbance, he discontinued himself.”
- ”Concerta has been inadequate.”
- ”Tried Concerta and Ritalin (methylphenidate) but have had a rash and had no effect. Is as restless as ever. ”
- ”Ritalin, Concerta and Strattera had insufficient efficacy and unacceptable side effects.”
- ”…on the medication Concerta 7 x 36 mg + 18 mg, which seems to be insufficient in effect.” (270 mg of Concerta a day)
- “Concerta with no effect, however, with very strong side effects.”
- ”Ritalin ... The effect has been insufficient, also troublesome side effects.”
- ”Tried treatment with Ritalin, but not tolerated this, become more speeded up, aggressive, etc.”

We could easily extend this list of security risks by adding data from the other license applications, and we would find descriptions of security risks for almost 700 cases. In a great majority of these cases the persons have not only been treated with *one* drug (as Ritalin), they have also been given Concerta and/or Strattera, meaning that we for each person treated have described security risks from several ADHD drugs.

Data about heavily increased doses of stimulant drugs – and replacing one form of abuse with another

In the official guidelines for ADHD treatment in Sweden, the scientific advisor to the National Board of Health and Welfare, Björn Kadesjö, wrote: *"…it's important to know that the medical treatment with the doses used does not give an euphoric experience and that there is no tendency for dose increase"* [7].

The data from the license applications for Metamina tell another story, as we have seen in the examples above. For a great majority of the adults prescribed Concerta, and Ritalin the doses have had to be continually increased in order to uphold the drug effect – and when it is no longer possible to increase the dose of methylphenidate a switch to the even stronger drug dextroamphetamine (Metamina) had to be done. The data from the License Section of the MPA give clear evidence that the statement *"no tendency for dose increase"* is simply not true.

And even if we don't get the full treatment history of the persons we get a good view of the actual huge doses used of Concerta and Ritalin – and the horrifying doses of pure dextroamphetamine (Metamina) that the psychiatric consultants for the MPA are introducing in Sweden.

In the license application we find that prescribing psychiatrists have used **huge** doses of Concerta and Ritalin. We find that patients have got:

- "126 mg [Concerta] daily…also addition of Ritalin";
- "changed to Ritalin up to a dose of 140mg daily";
- "Ritalin…110mg…not good enough effect";
- "Ritalin increase to 50mgx4! [200mg!]";
- "previously treated with high doses of Ritalin and Concerta (216mg per day) without real effect";
- "Treated with Ritalin in high dose (160mg/d)";
- "we raised the dose to 162 mg ... still did not have significant improvement";
- "Concerta 7 x 36 mg + 18 mg, which seems to be insufficient in effect [270 mg of Concerta a day!]".

And as we have seen even these doses are not high enough! In order to maintain the *drug effect* in adults the prescribing psychiatrists are requesting a switch to even stronger drugs, like the dextroamphetamine Metamina.

We get in the license applications insight into the **horrifying** doses the psychiatric consultants for the MPA are now introducing in Sweden – we can clearly see that this is just a matter of replacing one form of (illegal) abuse with another (legal) abuse. The activity has nothing to do with "treating ADHD", it is instead a "substitute treatment" where drug addicts are getting steeply escalating doses of methylphenidate and then moving onto dexamphetamine.

The main psychiatric consultant for the Licensing Section is the scientific advisor for adult psychiatry for the MPA and for the National Board of Health and Welfare, professor Lars von Knorring. In a "landmark decision" professor von Knorring has approved a license application for Metamina with such horrifying doses that it is doubtful if a drug naïve person would survive one day's use.

In his decision, in the internal document, professor von Knorring is clearly saying the opposite to the adopted PR message of the *low dose.* He says (in translation):

> **"There is an overwhelming agreement among the specialists on adults with ADHD and drug abuse that these require high doses."** [11]

And with this he approves a "treatment dosage" of dextroamphetamine (Metamina) of **"45 mg X 5" – 225mg/day!**

The prescribing psychiatrist in this extreme case seems to be Bo Söderpalm, specialist doctor at the Sahlgrenska University Hospital, Dependency Clinic, and group leader for The Department of Neuroscience and Physiology at the University of Gothenburg.

Söderpalm maintains the position that 40% of persons abusing drugs have ADHD, and that prescription of methylphenidate and amphetamine to these addicts does not increase the abuse, *"everything points instead towards that it decreases"* [12]. According to the advocacy group Attention´s summary of his presentation from 2009 he is also of the view that it should be *"a requirement for the social services, when they buy services [from private treatment centers] that there is an opportunity to go through examination [for ADHD] and to get drug treatment started"* [13]. In other words NO drug-free treatment centers for drug addicts should be allowed to exist with support from society – only centers offering "off-label" prescriptions of amphetamine type drugs and Strattera. According to the press release Söderpalm also claims that *"ADHD is life threatening"* if not treated.

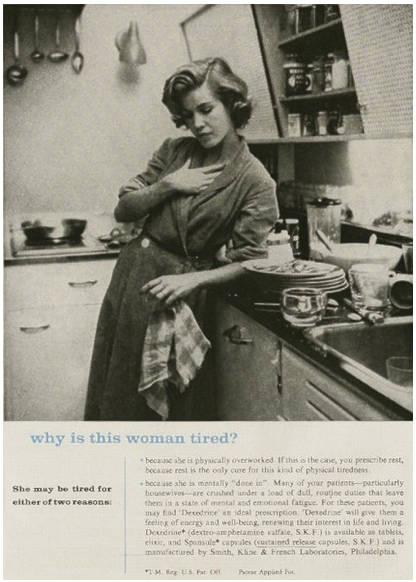
What is interesting **on a national level** about this is that doctor Söderpalm is one of the "specialists" that the scientific advisor Lars von Knorring requires should be invited to the Medical Products Agency to work out the upper dose levels for the prescription of methylphenidate and amphetamine to drug addicts – "with ADHD" [11]. What is even more interesting is that Söderpalm is part of the expert group, under SBU, The Swedish Council on Technology Assessment in Health Care [14], which should establish what is scientifically proven for what is called ADHD and its treatments [15]. It could be said that the very special ideological positions of Söderpalm, together with his dangerous off-label prescriptions of huge doses of amphetamine to drug addicts, should make national agencies, governed by objectivity and impartiality, very careful to use his services.

What are the prescribing psychiatrists really treating – what do the data from the MPA show?

In reading the license applications for Metamina one of the first questions that come to mind is: **What are they actually treating in these adults?**

It seems to be everything from *"problems starting tasks"* to difficulties *"completing started projects"*; it seems to be to support the persons *"very high ambition level",* and to get the effect of *"decreased starting problems",* to assist the person who delays projects and give him *"a better chance to succeed with these",* to give *"a better mood".*

In short, it is difficult to differentiate between what these psychiatrists are treating and what Ciba-Geigy (now Novartis) said in its marketing of Ritalin in the 50-ties and 60-ties.



Dexedrine [dextroamphetamine] advertisement, 1956.
Journal of the American Medical Association, Vol. 160, No. 10.

why is this woman tired?

She may be tired for either of two reasons:
* because she is physically overworked. If this is the case, you prescribe rest, because rest is the only cure for this kind of physical problem.
* because she is mentally "done in." Many of your patients -- particularly housewives -- are crushed under a load of dull, routine duties that leave them in a state of mental and emotional fatigue. For these patients, you may find 'Dexedrine' an ideal prescription.
'Dexedrine' will give them a feeling of energy and well-being, renewing their interest in life and living.
Dexedrine* (dextro-amphetamine sulfate, S.K.F.) is available as tablets, elixir, and Spansule* capsules (sustained release capsules, S.K.F.) and is manufactured by Smith, Kline & French Laboratories, Philadelphia



Ritalin advertisement, 1967. *JAMA, the Journal of the American Medical Association*, Vol. 199, No. 11, pp. 250-252.

RITALIN® (methylphenidate CIBA) **sparks energy ~ relieves chronic fatigue and mild depression**
Certainly Ritalin isn't going to make a sprinter out of the man barely able to drag himself through the day. But this gentle stimulant can spark energy -- and enthusiasm -- in the chronically fatigued, mildly depressed patient. With vitality increased and outlook brightened, the patient finds daily tasks no longer loom so large, nor do life's problems seem so serious.
Unlike most antidepressants, Ritalin acts promptly -- is less likely than amphetamines to cause excessive stimulation, sudden letdown, appetite suppression, alterations in pulse rate or blood pressure. Ritalin is widely cited for its outstanding safety record; untoward effects on blood, urine, or liver and kidney function are not to be anticipated. Side effects, if they occur, are generally mild….

The diagnosis mentioned in most of the license applications to the MPA is ADHD, but this concept seems to embrace most of what is unwanted in life for a person. And as in these old advertisements, the main good effect sought for these adults seems to be **more energy and a better mood**. And when the "uplifting" effect of one methylphenidate drug has vanished despite dose increase it's time to test another, and then when even more effect is needed (and as the harmful effects have become

more clear) it's time to try pure amphetamine. And for persons already abusing amphetamine the legal prescriptions of methylphenidate and dexamphetamine is just a "substitute treatment" – replacing illegal drug abuse with abuse sanctioned by society.

This is a scene quickly developing into a similar situation as in the 60-ties, when serious abuse problems were created with legal prescriptions of Ritalin, which in its turn led to the withdrawal of Ritalin and similar drugs from the market in Sweden [16].

What do the "users" themselves say about Concerta and Ritalin – non intended use, abuse and diversion?

The source of information so far has been the Medical Products Agency. In this end part the source becomes the "users" themselves, as they present their stories on Swedish web sites. These stories are included here to get a glimpse of "the other side of the coin", what these "users" – often younger adults – say about Ritalin and Concerta outside the doctor's office. The stories are far from scientific but indicate the alarming need for intensive research into non intended use, abuse and diversion of methylphenidate drugs prescribed for ADHD [17].

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 ..."

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 ”;
”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 know 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.. ”.

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 altenative 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”.

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? ”;
”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”.

In other words, adolescents and adults will get a high, get a buzz, become badly speeded from the doses prescribed to even small children. It is therefore no real difference between what is claimed to be "a dose of medicine" and what can be "a drug dose", creating euphoria. There is also an abundance of evidence that the prescribed methylphenidate is being used at higher doses than intended, that it is taken in ways not intended and that it is being diverted (sold, exchanged, given away) to person abusing the drugs.

It is my hope that this information will be used by the Commission and the EMEA to take quick actions to protect the public and to prevent the spreading of abuse of amphetamine type drugs in the society. It is my hope that the new directives that pharmaceutical questions should be handled by Health and Consumer Policy directorate, DG Sanco, will mean that consumer safety now should take precedence over the protection of profits for the pharmaceutical companies.

It cannot be expected that the manufacturers of these drugs will take any effective actions *by themselves,* to get the needed safety data asked for in the decision by the Commission 27 May 2009, proven by the fact that nothing effective has been done about this since the time of the decision (in actual fact the only visible action taken by the manufacturers is the aggressive effort, in the Feasibility Assessment Study, to explain why long-term studies about adverse psychiatric outcomes of methylphenidate treatment could not and should not be done).

I have in this report shown parts of the wealth of information existing about the true effects of methylphenidate products. The archives and registries of the Medical Products Agency and the National Board of Health and Welfare contain huge amounts of valuable data about use, abuse, (long-term) effects, and off-label prescriptions of methylphenidate and other drugs prescribed for what is called ADHD. But these sources are not being used to collect the safety data asked for by the Commission. There are most certainly many officials working in these agencies who want to collect and present the valuable data in order to protect the health of the public. But instead of initiating studies to that purpose the responsible government agencies, taking advice from outside experts sponsored by the pharmaceutical companies, have acted to create an explosion in prescriptions of methylphenidate drugs – even in off-label use.

I assume that the Commission now, in accordance with the intention in the decision, will make sure that the responsible national agencies, as the Swedish Medical Products Agency, collect and present all needed safety data about these products in the very near future.

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