Open Letter III, to Dr Ian Hudson, Chief Executive of MHRA

16 March 2014

ADHD drugs – MHRA and the Concerta scandal

Dear Dr Hudson,

First I must say I really appreciate getting an answer from you personally. It is important that the information I have given about the Concerta scandal is fully known at the top of MHRA.

Of course I am not, in your answer, expecting you to agree with me, to admit that MHRA has done anything wrong, or to announce some effective actions from the Agency to handle what I have described. I could at best hope that you read the information and acknowledge that you have done so, while at the same time via my open letter informing politicians and media about the scandal.

As you know the Dutch medical agency, CBG, in July 2010 wrote that it *agreed* with MHRA about the assessment of Concerta for adults:

> **"We fully support the position of the RMS [Reference Member State, UK] that the B/R [benefit/risk] of Concerta in the proposed indication [adults] is negative…" (Day 100-comments NL)**

It was at that time also clear that Concerta actually ***caused*** aggression, depression and tics. To quote from the MHRA assessment:

> **"A causal relationship with Concerta was established for aggression, tics and depression."**

I think you agree with me that the table over adverse events presented by Janssen in January 2011, on the request of MHRA, was very clear (see my earlier letter) – and ***alarming***. Here we have the answer from Janssen (with the table on page 84) and a summary of the adverse events reported in Janssen's own studies of Concerta for adults:

> **Response Document from Janssen (Johnson & Johnson) from January 2011**
> **http://jannel.se/Concerta.Janssen.Response.11.01.2011.pdf**

I don't think, Mr Hudson, that you actually have read this document, forming the agreement between MHRA and Janssen about such vital issues as the need for information about what emerged in Janssen's studies of Concerta on adults. If you had, it would be hard to state, as you do in your answer below, that adults are being fully informed about the risks identified in Janssen's studies.

Probably this is the first time that Janssen's "Response Document" is made fully known to the media, politicians and the public in general. Everyone can now verify that Janssen, in the "Response Document" 29 times (!!) repeats a version of the statement: **"The Company no longer seeks an extension of the indication to include adults with ADHD."** And: **"The Company therefore considers that no further action is necessary."**

I would advise you, Mr Hudson, before answering *this* letter, to actually take a look at Janssen's document. In it you will – at these 29 points – see what MHRA and Janssen actually agreed to. After that you cannot any longer state that adults receiving Concerta are being informed about what you and Janssen know.

Do you actually think Mr Hudson that psychiatrists say the following to their adult patients?

> **"I will prescribe Concerta to you. However you should know that Concerta in the Company's best studies had no positive effects after 5 weeks, while *causing* quite some serious harmful ones. Like aggression, depression, anxiety, psychosis, heart disorder. Just so you understand: They have proven that you very likely will not get anything positive out of Concerta after 5 weeks, and that everything after that point is on the minus side. And all this comes from an extensive investigation led by MHRA."**

Of course that would be impossible as MHRA has not communicated the results of the investigation in any official publication reaching doctors and the public.

No, what doctors and patients are being told is another message – a false, misleading and deceitful message from psychiatrists sponsored by Janssen and other pharmaceutical companies.

Don't you personally think it is bizarre that Janssen's sponsored psychiatrists could tell the media, the scientific community and the public the following, two months after the company from MHRA got to know that the Concerta application for adults "should be refused"?

> **"Stimulants are effective in about 70% of [adult] patients with ADHD in controlled trials."** And: **"Stimulants … improves ... anger outbursts, mood swings."** And: **"Side effects are usually mild and transitory ..."** http://www.biomedcentral.com/1471-244X/10/67

Without MHRA doing anything to correct the falsehoods.

These falsehoods are widely distributed in Sweden – and are behind the explosion in the prescription of Concerta to adults. The Medical Products Agency has, in the old and new version of Läkemedelsboken [The Pharmaceutical Book] spread what these psychiatrists have written in their Consensus Statement. This is what all Swedish doctors get to know, what they believe in – and what they say to their patients.

I suppose the situation is the same in UK, with the group member Professor Philip Asherson "advising" the National Institute for Health and Clinical Excellence (NICE) about the good effects of Concerta and about "the mild and transitory" side effects.

You write in your letter: "I understand that you have been in correspondence with other parts of the Agency on these matters." Yes, I have been in contact with the unit for "**Vigilance and Risk Management of Medicines".**

I had earlier read the final assessment of the latest Periodic Safety Update Report (PSUR) for Concerta, from MHRA and the Drug Utilisation Study (DUS) 2011 for Methylphenidate, from the manufacturers – and I could not believe my eyes.

Here we had MHRA stating: **"The usage [of Concerta] may not increase in this time period"** (October 2010-October 2011) http://jannel.se/FVAR.Concerta260511.pdf and then no follow-up whatsoever about this in the PSUR!

Here we had the manufacturers of methylphenidate in Europe giving false information about the prescription of methylphenidate in Sweden in the DUS 2011.

So I thought the reason for MHRA's lack of effective follow-up was false data or no data about the exploding prescriptions of methylphenidate in Sweden. In order to correct that I got several Swedish agencies to send the true data directly to the unit in MHRA handling these matters.

However that did not change anything. I am still waiting for effective actions from this unit.

The latest assessment of the Periodic Safety Update Report for Concerta is soon to be released. It will be very revealing and will answer the question if MHRA *now* has followed up, analysed and recommended effective actions in this area.

It is a bit funny to read in your letter that the exploding prescriptions in Sweden are a matter for the Swedish Medical Products Agency, not for MHRA. Especially considering the fact that the information I get from the Swedish MPA is that the security work about Concerta is led by MHRA – and that the effective actions are supposed to come from that cooperation.

So Mr Hudson, you have a full-fledged medical scandal in your lap. MHRA is *sitting* on the information that a drug proven negative for effect and positive for harm is being heavily marketed and sold to the population (adults) for which it was *disapproved*. The Key Opinion Leaders, hired by the pharmaceutical company, are lying to the public, saying that the drug is effective in "about 70% of [adult] patients", with "mild and transitory" side effects.

I am now expecting you *counter* the misleading marketing campaign from Janssen about Concerta and to actually tell doctors, patients, politicians and the media what was proven in the investigation led by MHRA.

I am expecting MHRA to finally do something *effective* to handle this scandal – we have tens of thousands of patients in Europe right now who are subjected to the *harmful effects* of a drug that you have disapproved, without informing them.

Yours sincerely,

Janne Larsson
Reporter
Sweden
janne.olov.larsson@telia.com

From: MHRA Customer Services

Sent: Thursday, March 06, 2014 5:05 PM

To: 'jan.olov.larsson@telia.com'

Subject: RE: ADHD drugs - MHRA and the Concerta scandal

Dear Mr Larsson,

Thank you for your e-mail of 14 February. I apologise for the delay in responding. I understand that you have been in correspondence with other parts of the Agency on these matters.

I note the action taken against Johnson & Johnson in the USA in relation to risperidone (Risperdal). We work within a different legal framework in the EU. The Marketing Authorisation Holder of Concerta are subject to advertising regulations as set out in Title VIII of Directive 2001/83/EC and are enforced on a national basis within the EU.

As you state in your letter, the public assessment report concerning the variation to include the initiation of treatment of adults diagnosed with ADHD provides information for the general public and is available on the MHRA website. The current Summary of Product Characteristics (SPC) and Patient Information leaflet (PIL) for Concerta does allow use in adults if treatment withdrawal has not been successful when an adolescent has reached 18 years of age, however continued treatment of adults should be reviewed regularly.

The SPC also lists adverse events that are observed in adults who participated in clinical trials, which may also be relevant for children and adolescents. All adverse effects are also listed in the PIL as side effects, written in a language that is easily understood by the layperson.

Both documents contain warnings for all patients (regardless of age) about the risk of underlying mental disorders which can be altered by treatment with methylphenidate. Healthcare professionals and patient carers are directed to monitor patients for adverse events and take the necessary action.

I appreciate that you have concerns about the number of adults treated with methylphenidate, particularly in Sweden. Any concerns about clinical practice and prescribing outside of the licence in Sweden are matters for the MPA and the Swedish medical professional bodies. We will continue to monitor European and international patient exposure and any new information on benefits and risks of methylphenidate through Periodic Safety Update Reports.

Your sincerely,

Dr Ian Hudson

From: Jan Larsson [mailto:jan.olov.larsson@telia.com]
Sent: 14 February 2014 12:02
To: Hudson, Dr Ian
Cc: mailto:%22info@mhra.gsi.gov.uk%22@hosting-e.gsi.gov.uk; nice@nice.org.uk

Open Letter II, to Dr. Ian Hudson, Chief Executive of the MHRA

14 February 2014

ADHD drugs – MHRA and the Concerta scandal

Thank you for the answer (below) on behalf of Dr. Ian Hudson, CEO of the MHRA.

It seems as if my important information is not coming across, so I will try to be a bit more clear in my response.

As you know Johnson & Johnson (and its subsidiary Janssen) in November 2013 agreed with the U.S. Department of Justice to pay 2.2 billion USD, mainly for the illegal marketing of the psychiatric drug Risperdal. The Attorney General of the United States, Eric Holder, said at the press conference presenting the agreement, "these are not victimless crimes" [1].

Let's also look at the case in Texas, where Janssen in early 2012 had to pay 158 million USD [2]. In that case we can, with the words from the State Prosecutor, look at specific examples of *"sophisticated strategies and tactics to disseminate misrepresentations"*, *"a variety of marketing tools disguised as medical education, scientific research and patient advocacy literature"* that the pharmaceutical company used, and how the *company "concealed and failed to disclose information about safety"* of the drug (Risperdal); how it acquired *"key opinion leaders", "advisors"* and *"experts",* and how the company provided inducements including *"research funding", "consulting fees"* and *"enhanced professional reputation"* to these *"experts",* to get *"biased research in favor"* of Janssen's drug. (The quotes from the Complaint against Janssen in Texas [3].)

Let's compare this with Janssen's actions to market and sell Concerta to adults in Europe, despite the agreement with the MHRA and other European drug regulatory agencies *not* to do this.

I refer in my letter below to the secret internal MHRA documents about the Concerta investigation; the documents revealing that Concerta was found to have "negative benefit/risk balance" for adults. I am glad that MHRA now has made the most important of these documents available to the public, even if it is *very* hard to find it. But here it is:
http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con2033483.pdf

The MHRA assessment document about Concerta to adult is dated **14 July 2010**. Janssen had the information that the Concerta application for adults "is not approvable" and "should be refused" (page 18 in the document) in July. But at the same time Janssen sponsored "The European Network Adult ADHD", to produce one for Concerta (methylphenidate) *positive Consensus document,* which the pharmaceutical company could then use in their marketing of Concerta for adults [4]. The group wrote in the document: "We thank Janssen-Cilag who provided support for meeting costs of the European Network Adult ADHD."

So despite knowing about the ***disapproval*** of the Concerta application, the company permitted publication of completely opposite data about the *good effects* and *mild adverse effects* of Concerta in adults in the group's *Consensus document.* The publication of the wide spread document about the good effects of methylphenidate (Concerta, Ritalin) for adults, was done **3 September 2010,** 2 month after MHRA informed the company that the Concerta application "should be refused".

Here is a comparison of the data that emerged in the European study of Concerta, and what was stated in the Consensus document:

Consensus document: “stimulants are by far the best studied and most effective treatment for ADHD.” “Stimulants are effective in about 70% of [adult] patients with ADHD in controlled trials.”
The European study: “B/R [Benefit/Risk] of Concerta in the proposed indication is negative”. Overall, the conclusion of Janssen´s submitted studies were that the company could not demonstrate a beneficial effect even short-term (after seven or thirteen weeks).

Consensus document: “Stimulants … improves ... anger outbursts, mood swings.”
The European study: “A causal relationship with Concerta was established for aggression, tics and depression.”

Consensus document: “Side effects are usually mild and transitory ...”
The European study: “The lack of demonstrated efficacy coupled with the safety issues, especially cardiovascular safety (potential long-term effects of increase in BP [blood pressure]) abuse potential, and psychiatric/aggression AEs [Adverse Events] render the BR [Benefit/Risk] negative for the proposed indication.”

Consensus document: “Importantly, both clinical studies and clinical experience support the view that methylphenidate does not lead to stimulant or drug addiction. On the contrary, it has been shown to have a neutral or reducing impact on substance abuse and the risk of relapse.”
The European study: “It is assessed there is a significant abuse and diversion risk with Concerta.” “... the misuse/abuse potential of methylphenidate is considered a major safety concern: in combination with the concerns regarding the reliability of the diagnosis, adults may try to get diagnosed for ADHD to retrieve methylphenidate in a legalised manner.”

Janssen’s experts concluded that Concerta (methylphenidate) is the **“first choice medication treatment”** for adults with ADHD **“based on an extensive and still growing body of data on efficacy and safety”.** Janssen knew at the time of publication that neither efficacy nor safety was considered to exist for Concerta for adults. Despite that, the company allowed the above false marketing messages to be disseminated to doctors and authorities.

In the group we could also find prominent European psychiatrists, among them **Professor Philip Asherson** (U.K.), advisor to the National Institute for Health and Clinical Excellence (NICE), and a member of the group writing the guidelines for treatment of adults with ADHD in U.K.

The investigation by MHRA and other European agencies showed:

- The combined studies showed that Concerta had no significant positive effects for adults and that the drug caused a number of serious adverse effects, Concerta had a “negative benefit/risk balance” for adults;

- The submitted studies gave clear evidence that Concerta could ***cause*** anxiety and agitated conditions in adults ("evidence for the risk of new-onset anxiety, tension and agitation");

- The submitted studies gave clear evidence of the abuse potential and of the risk of diversion of Concerta;

- A ***causal*** relationship was established for Concerta for aggression, tics, and depression;

- No warnings were to be issued about the fact that it had been proven that Concerta could cause anxiety, agitated conditions and aggression in adults, ***for the simple reason that Concerta should not be prescribed to adults***;

- Concerta could ***only*** be prescribed to adults who before the age of 18 had received methylphenidate (Concerta, Ritalin) and who were judged to have had an "adequate response and acceptable tolerance", ***and*** for which a withdrawal of the drug had been tried without success. The pharmaceutical company Janssen-Cilag declared that it agreed to the following conditions: **"those patients with ADHD who would be considered for continuation of treatment into adulthood *must* have previously been treated with methylphenidate and continue to show adequate response and acceptable tolerability."** [Emphasis here.] No other adults could be considered.

In other words MHRA agreed with Janssen that the company did not need to issue warnings about what emerged in the clinical studies on adults. The company did not need to issue data about the lack of positive effects and the harmful effects proved in Janssen's own studies. MHRA said basically that Janssen did not need to tell this:

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

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

From Janssen's "Response Document" (page 84) to the MHRA, 11 January 2011.

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

- **The persons who received Concerta had a 270% increased risk for heart disorders in form of Arrhythmias;**
- **The persons who received Concerta had a 116% increased risk for Aggression;**
- **The persons who received Concerta had a 62% increased risk for Depression;**

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

And what happened?

After the initial assessment from MHRA (14 July 2010), that Concerta was to be *disapproved* for adults, Janssen and its sponsored psychiatrists issued the misleading data in the Consensus document (2 September 2010).

In January 2011 Janssen declared that the company will withdraw its application – and made the agreement with MHRA *not to* issue warnings about the proven harmful effects.

MHRA agreed with Janssen that Concerta was *not* to be prescribed to adults in Europe. The Agency made the following clear in the Final Variation Assessment Report (FVAR p. 9) from May 2011: (for the period October 2010-October 2011): "The usage [of Concerta] may not increase in this time period." [5]

And Janssen just continued to market and sell Concerta to adults in Europe as if the assessment by MHRA had never been done. In Sweden the company increased its sales of Concerta for adults from 112 million SEK (10.5 million GBP) in 2010 to 180 million SEK (17.0 GBP) in 2013; an increase with 60% (!!) since the drug was disapproved for adults [6].

MHRA is handling the Periodic Safety Update Reports (PSURs) for Concerta in Europe. These reports show that *no effective actions* have been taken by the Agency to enforce the agreements in the years after the disapproval.

***Tens of thousands* of adult patients in Sweden and the rest of Europe have been misinformed and misled about the effects and harmful effects of the drug. MHRA has done nothing to make the real results of Janssen's studies (as written above) known to the patients, while allowing the company and its sponsored psychiatrists to use *"a variety of marketing tools"* to push the drug out on "the adult market".**

So there you have the Concerta scandal. What is MHRA going to do about it?
Yours sincerely,

Janne Larsson
Reporter
Sweden
janne.olov.larsson@telia.com

[1] Department of Justice, Comments by Attorney General, Eric Holder, 4 November 2013, http://www.justice.gov/iso/opa/ag/speeches/2013/ag-speech-131104.html
[2] The New York Times, "J. & J. to Pay $ 158 Million to End Suit Filed by Texas" January 19 2012, http://www.nytimes.com/2012/01/20/business/johnson-johnson-settles-risperdal-claim-in-texas.html
[3] State Prosecutor Greg Abbott, "Plaintiff's Second Amended Petition," December 12, 2008, http://jannel.se/texas-janssen-complaint.pdf
[4] Kooij et al, "European consensus statement on diagnosis and treatment of adult ADHD: The European Network Adult ADHD", *BMC Psychiatry,* September 3, 2010, http://www.biomedcentral.com/1471-244X/10/67
[5] MHRA, Final Variation Assessment Report, FVAR, 26 May 2011, http://jannel.se/FVAR.Concerta260511.pdf
[6] e-Hälsomyndigheten, Prescriptions of ADHD drugs in Sweden 2008-2013, http://jannel.se/N06BA.pdf

From: MHRA Customer Services
Sent: Thursday, February 13, 2014 4:31 PM
To: jan.olov.larsson@telia.com
Subject: Fw: ADHD drugs - Will MHRA handle the Concerta scandal by approving Ritalin for adults?

Dear Mr Larsson,

Thank you for your letter in relation to ADHD drugs with reference to Concerta and Ritalin. With regard to Concerta XL, the MHRA has responded to your previous enquiry on the variation procedure to extend the indication into adults drawing to your attention that the Summary of Product Characteristics (SPC) for Concerta XL contains a clear statement that it is not appropriate to commence methylphenidate treatment in adults. Any adverse events continue to be monitored as part of Pharmacovigilance processes and there are extensive warnings in the SPC already on psychiatric adverse events. Further information on this can be found within the Public Assessment Report for Concerta XL which can be accessed via the link below:

http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con2033483.pdf

With regards to your reference to a Novartis application for use of Ritalin in adults the MHRA has not approved an application such as the one referred to in the Swedish press release from January 2013. For further information in relation to that specific application we would suggest you contact Novartis or the Swedish Medical Products Agency directly.

Kindest Regards,

Yvonne Smith
Customer Services
External Relations
Medicines and Healthcare products Regulatory Agency
Tel: 020 3080 6000

Your views matter. Tell us what you think of the service you have received from us by following the link below:
https://www.surveymonkey.com/s/MHRACustomerServicesFeedback

From: Jan Larsson [mailto:jan.olov.larsson@telia.com]
Sent: 02 February 2014 19:43
To: MHRA Customer Services
Cc: Hudson, Dr Ian; DOH - DHMail (ISD4); nice@nice.org.uk
Subject: Fw: ADHD drugs - Will MHRA handle the Concerta scandal by approving Ritalin for adults?

Open Letter to Dr. Ian Hudson, Chief Executive of the MHRA

(The text below in PDF http://jannel.se/MHRA.Concerta.Ritalin2.pdf)

2 February 2014

ADHD drugs - Will MHRA handle the Concerta scandal by approving Ritalin for adults?

In the beginning of 2011 secret internal MHRA documents revealed: The application to get the ADHD drug Concerta approved for adults was **refused**; Concerta was found to have "negative benefit/risk balance" for adults.

The disapproval of the drug for adults has been a well-kept secret: NO information whatsoever has been issued by the MHRA or the other European medical agencies about the disastrous results.

Let's look on what was hidden for doctors and the public.

This is the not published table over the Adverse Events of Concerta in clinical trials. It is part of the manufacturer Janssen's "Response Document" (page 84) to the MHRA, from 11 January 2011.

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

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

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

The combined studies showed that Concerta had no significant positive effects for adults and that the drug caused a number of serious adverse event – the most important ones described in the table above. Some countries like Holland and France were very negative to the presented evidence from Janssen, while others, like Sweden, wanted to *in some way* get the application through anyway (despite the disastrous results in the trials).

The assessor at the MHRA requested the following in July 2010: "The risks of anxiety/anxiety disorders, depression, aggression, agitation restlessness, suicide related events, psychosis, mania/delusions, decreased appetite, clinically important decreased weight, cardiac arrhythmias, tics/worsening of tics or tourette's syndrome should be added to the Safety Specification as Important Identified Risks."

Janssen had to back down and said: "The Company no longer seeks an extension of the indication to include adults with ADHD." Janssen repeats this statement 29 times (!) in the "Response Document" to the MHRA. And so, no new warnings were issued to other authorities, doctors or patients.

The disapproval was a shock to the ADHD industry and to some medical agencies in Europe. In Sweden the Medical Products Agency (MPA) had for years allowed an explosion in the "off label" prescription of Concerta to adults, with the assumption that the drug was soon to be approved.

And the agency had been assisted by the current Chairman of the **Committee for Medicinal Products for Human Use (CHMP) at the European Medical Agency (EMA), Tomas Salmonson, in his position at the MPA.**

However Concerta was disapproved, found to be harmful and without any significant positive effects for adults. This did not stop the marketing in Sweden.

The prescription of Concerta to adults in Sweden increased with 60% (!!) from 2010 to 2013. Janssen sold the ***disapproved*** drug Concerta to adults in Sweden for 488 million SEK (45 million GBP) in these three years. (See updated figures from Apotekens Service AB http://jannel.se/N06BA.pdf) The highest sales figures for 2013 for methylphenidate in Sweden are for the disapproved drug Concerta to adults.

But now a fantastic "solution" to handle the problem has been presented, having the potential to save the drug manufacturer and all the officials involved in this medical scandal.

And the help for MHRA, MPA and Janssen to handle the scandal comes from an unexpected player – the pharmaceutical company Novartis. The manufacturer of **Ritalin – basically the same drug as Concerta** – has announced its application to get Ritalin approved for adults in Europe. (Swedish press release from 30 January 2013, http://www.cisionwire.se/novartis/r/novartis-ansoker-om-godkannande-for-ritalin-for-behandling-av-vuxna-patienter-med-adhd,c9362988)

Novartis has sought "scientific advice" from some of the more positive countries in Europe, about how to get the drug approved. The company has also chosen to only submit this application for Ritalin approval in *some* countries – the more positive ones. Meaning that the company can avoid the negative statements from the same assessors handling the Concerta application.

A spokesperson from the Swedish Medical Products Agency, Bengt Andrée, announced (!) that Novartis´ application about Ritalin for adults will soon be approved. Andrée said in media: "Everything indicates that treatment for adults will be approved" and that "a statement [about Ritalin] is expected in early summer" (2013).

I am sure Novartis has learned from the failed Concerta submission and that there is a big interest from the officials mentioned above to push through the approval of Ritalin for adults. We can expect that the submitted studies will get a positive assessment this time – no embarrassing questions – and suddenly the concealed and alarming Concerta results can be expected to no longer exist! Janssen will also be saved; no criminal actions will be taken.

But it's hard to see how the above can fit with the MHRA declaration: "We protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research."

So Mr Hudson, will the MHRA take part in this dirty game of approving Ritalin, so that we can forget about the Concerta scandal?

Yours sincerely,

Janne Larsson
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Sweden
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