

**International Narcotics Control Board  
Vienna International Centre  
PO Box 500,  
A-1400, Vienna,  
Austria**

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## **The use of central stimulants for medical purposes in Sweden**

### **A report of recent actions taken by psychiatrists and government agencies to further the use of amphetamines and amphetamine-type drugs as treatment for the conditions ADHD and DAMP**

In Sweden the medical use of amphetamine and amphetamine-type drugs has for many years been very low. The background to the Swedish restrictions against such use is well known.

Below is a summary of recent actions taken by psychiatrists and government agencies in Sweden to further the use of amphetamines for medical purposes. The report also takes up how the actions taken by the agencies have resulted in aggressive sales promotion for these internationally controlled substances.

The described plans and actions will lead to – and are already leading to – a strong increase in the use of psychostimulants among children and adults (including drug addicts and criminals).

#### **Actions taken by the National Board of Health and Welfare and by the Medical Products Agency**

In the beginning of the year 2001 a recommendation for the treatment of the so called neuropsychiatric conditions ADHD and DAMP (Deficits in Attention Motor Control and Perception) was turned in to the National Board of Health and Welfare<sup>1</sup>. The report had as originator the Child Neuropsychiatric Section of the Swedish Association for Child and Adolescent Psychiatry, chairman professor Christopher Gillberg. The group (in the association) which had written the report was lead by the psychiatrists Gunilla Thernlund and Björn Kadesjö.

In the report it is written that the time now has come to reach the following aim: “*All children with ADHD/DAMP, who are having so grave problems from attention disorder, hyper activity and/or impulsivity that their *life quality is evidently restricted* and where environmental measures are not sufficient, shall be offered to test if they are helped by central stimulants, as part of the treatment/support.*” It is also said “that if *only* children with very serious ADHD/DAMP should be offered central stimulants it would *with a low count* come

up to 10 000 children” (italics added). The report calls for immediate measures to build up a whole care system to reach the above aim.

One of the leading psychiatrists in the group, Thernlund, stated in a newspaper article in the end of last year her view on the risks with central stimulants<sup>2</sup>. Her statement about this Schedule II substance was: “Central stimulants [with reference to amphetamine] does not only have a documented effect, the side effects are well known and possible to control. If the treatment does not give to a marked degree a positive effect it can just be discontinued, also so if the side effects are getting to troublesome. *Even if the preparations can be abused they are not in a proper medical sense giving addiction, as morphine, benzodiazepines, nicotine or even caffeine.*” (italics added) She considered it “deeply unethical to withhold from them [the children] the possibility of an effective and well proven treatment”.

Concurrently the director-general of the National Board of Health and Welfare, Kerstin Wigzell, wrote an article in the same medical paper<sup>3</sup>. Also she is calling it unethical not to use amphetamine in the treatment of the “neuropsychiatric disorders”: “When we know that a treatment can help a person with difficult functional disorders it is simply unethical not to give that help.” She is nowhere in the article mentioning *any* risks with the (increased) use of amphetamines.

Wigzell is in the article referring to the work done by the National Board of Health and Welfare [hereafter also called the Board] to prepare a document about ADHD/DAMP. It is to be noted that the main contributors to this (not yet released) document are the above mentioned psychiatrists Gillberg and Kadesjö. Their view of the use of amphetamine is clearly stated in the above mentioned suggestions to the Board. The articles by director-general Kerstin Wigzell and psychiatrist Gunilla Thernlund, and the document turned in to the Board by the leading neuropsychiatrists were all answers to and defence against the critique levelled against the Board. The critique had been very intense in the autumn 2000, mainly focusing on the one-sided work of investigation in the matter.

The above mentioned views by director-general and the appointed group of experts should be compared to the official statement done by the National Board of Health and Welfare just some years ago, 1996, regarding suggestions to lessen the restricted use of central stimulants for grownups. The Board then wrote: “The National Board of Health and Welfare is in very strong doubt about widening the indications for treatment with central stimulants, even with the strict rules suggested. The reason for our position is as follows: Many of the around 8000 drug addicts in the country will set great hopes on ‘legal’ prescription. During the 90-ties the National Board of Health and Welfare has only for 4-5 patients supported prescription of central stimulants on license, in statements to the Medical Products Agency. Every matter is requiring lots of resources, often followed by appeal and sometimes even threatening calls from the persons whose applications have been disapproved. It will be possible even for amphetamine addicts to claim that they have a diagnosis requiring treatment and to demand analysis to get license prescription. The boundaries will be hard to tell. Sweden will be considered a more drug liberal country. Increased legal prescription of central stimulants will obstruct the fight against narcotics.”<sup>4</sup>

This position by the Board, just some years ago, should also be compared to the recently given instructions on the work with the document about ADHD/DAMP. The official in charge of the matter, Mats Ribacke, wrote in the instructions<sup>5</sup>: “The present position is that no lower degree of restrictions applies for the group of grownups compared to the group of children

and adolescents.” This must be interpreted so that the restrictions now should be *the same*. (As a comment, there has not for many years now been any *lower* restrictions for grownups compared to those for children.) As there for many years *has been very few grownups* who has got legally prescribed central stimulants, this means that the Board now is opening the door, not only for an increased prescription to children, but also for such prescription to grownups.

In the above mentioned instructions the National Board of Health and Welfare commissioned psychiatrist Björn Kadesjö to put together the document about ADHD/DAMP and the treatment recommendations. Per the Swedish Constitution government agencies are to follow the principle of *objectivity*. All matters should be handled comprehensively and impartially. The critique in the end of the year 2000 took up how the National Board of Health and Welfare *violated* this principle in the work with this document. The appointed group of experts (main contributors Gillberg, Kadesjö, Rasmussen, Modigh and Levander) had *all* a very positive view of the scientific progress regarding ADHD/DAMP and of the use of central stimulants in treating these conditions. *No* persons with deviant view were appointed or heard by the Board. The end result was, with this one-sidedness, clear from the beginning – especially when the director-general also gave voice to this view. The official in charge of the work with the document (beginning 2001), Claes Mebius, gave in January the impression that the Board had listened to the critical voices and was prepared to change the line of investigation. He said: “Now we must of course reconsider our attitude and bring on serious representatives for both schools.”<sup>6</sup> This was however never really done; instead the earlier mentioned Kadesjö was appointed to put together the document.

**The psychiatrist in the group** who has contributed most to the recommendations for grownups is Sten Levander. He turned this year in May in a revised version of a document with treatment recommendations to the Board. It can be expected that his writings will form the basis of the recommendations to be given for grownups by the Board in its end document. It is also so, as will be described below, that several of these recommendations *already* are being used by the Medical Products Agency in their handling of license applications for treatment with central stimulants. It is further so that the report from Levander gives recommendations for the handling of criminals and drug addicts – recommendations which, if put in full use, would *completely* change the traditional Swedish policies in this area – and replace them with drug treatment (central stimulants).

The document is called *ADHD in grownups: analysis and treatment*. (A similar version of the document was written already 27/9-99 and has been used as described below in license application matters to give the “scientific basis” for increased use of central stimulants to grownups.) The recommended use of central stimulants can be read in the following. Levander says (p.22): “There is no reason to wait with the decision about treatment with central stimulants when the diagnosis is established [He is recommending a 45 minutes “testing package”] and no counter indications are at hand. Treatment with central stimulants should not be reserved for the serious cases, as it is likely that moderate symptoms/problems mean the greatest possibility of improvement through treatment with medicine.” This means what it says – that also persons with moderate symptoms should be given central stimulants. Levander is also making the following judgement (p.19): “The key symptom in ADHD is the attention disorder. There is nothing that indicates that this problem can be successfully handled in any other pharmacological way then by central stimulants.” The document gives the following reason for heavily increasing the use of central stimulants (p.20): “It would be

unethical to continue to withhold a potentially effective treatment from a large group of people, despite the relative lack of hard evidence based knowledge.”

The above conclusion (and the ones earlier), about the need for a strong increase in the use of amphetamine, should be compared to the report from INCB of last year, where it was stated (p.4): “19. Scientific progress in understanding the underlying physiological processes of certain health conditions such as obesity and attention deficit disorder (ADD) has been slow in the past few decades. In the absence of effective causal therapies, symptomatic treatment continues, to a large extent using amphetamine and amphetamine-type medicines (amphetamine-type anorectics and methylphenidate). The therapeutic indications and use of those substances had previously fallen to modest levels in recognition of their limited efficacy and safety. Subsequently, they were placed under strict national and international controls. The Board, in its reports, has pointed to the potential problems resulting from the renewed popularity of those substances, as reflected in the unprecedented increases in their manufacture and consumption in some countries. The growing use of those substances for the treatment of school-age and also pre-school children,<sup>10</sup>, <sup>11</sup> in the absence of universally accepted and validated definitions, diagnostic criteria and guidelines for such practice, has recently been the subject of concern.”

The prescriptions in Sweden for grownups diagnosed with ADHD have, as said, increased the latest years from having been very rare (see the statement from the Board from 1996). Last year (2000) 181 grownups in total got amphetamines prescribed, according to data from the Medical Products Agency. This year (2001) 183 new applications for prescription were approved according to the same source. (This should be compared with the figures from 1998. In the autumn that year only 15 persons in total got central stimulants based on their ADHD diagnosis.) Professor Sten Levander has, with his contribution as part of the group of experts appointed by the Board, been a driving force behind this development. He has “guaranteed” license approval for a private practitioner, psychiatrist Ola Lundin. Dr. Lundin had according to information from the Medical Products Agency in the middle of the year 100 patients on license approved prescription. The attitude of Dr. Lundin to the Schedule II substance amphetamine is even more positive than the ones quoted above. In a letter he writes: “The safest, most effective treatment with the smallest side effects and in addition to that the cheapest, is treatment with central stimulants.”<sup>7</sup> Dr. Lundin did not *earlier* get any license approvals for treatment with central stimulants. He then prescribed the amphetamines from a clinic in England and sent his patients with the medication back to Sweden. The Board’s review section for ethical questions criticised his actions and wrote that “the action of the doctor can be seen as complicity to preparation of an unlawful act...”<sup>8</sup> *But* with the help of professor Levander dr. Lundin started to get license approvals in the beginning of year 2000 from the Medical Products Agency. The approvals to grownups starting last year was in accordance with the document written by Levander. It was part of the plan to also get *criminals* treated with central stimulants. Levander wrote (p.22): “In general we should take the step to treat persons with a clear antisocial personality structure and relatively recent criminality with central stimulants first when we have been able to get at least two years of experience from prescription to non-criminals, that is in the end of 2001.” The amount of criminals who could be candidates for drug treatment based on the diagnosis of ADHD is by Levander described as follows (p.8): “In unselected prison materials more than half have had ADHD in childhood and between 20 and 30 percentage have remaining ADHD.”

Consequently the *first* licences for treatment of persons with recent drug addiction and with a criminal background based on their ADHD diagnosis, have been approved this year. Just a

handful of such licenses has been approved to start with. It is also *still* written in the directions for license approvals (for the Medical Products Agency) that counter indications particularly regarding “anamnestic presence of drug and alcohol addiction” and “anamnestic presence of asociality” should be taken into consideration. As seen above the suggestions from professor Levander are to no longer treat these factors as *counter indications* – in fact they are to be treated as *treatment indications*. The first steps in the direction of abolishing these counter indications have been taken this year by the Medical Products Agency. Continued use of the recommendations – especially when these get incorporated in the official end document from the National Board of Health and Welfare – will lead to a *heavily* increased use of amphetamine treatment for (recent) drug addicts and for criminals in the year 2002.

### **Support to groups advocating heavily increased use of central stimulants for medical purposes**

The International Narcotics Control Board describes in various reports its concern about the (financial) support to various advocacy groups fostering the sales of controlled substances. So for example in 1996: “The INCB is also concerned that the use [of methylphenidate] is being actively promoted by an influential parent association, which has received significant financial contributions from the preparation’s leading United States manufacturer.” The INCB report for year 2000 requests the Governments “to strictly implement the provisions of article 10 of the 1971 Convention, which prohibits the advertisement of psychotropic substances to the general public.”

Also Sweden now has “an influential parent association”, with the name of Attention, actively promoting the use of controlled substances. The difference between Sweden and the US is that the group in Sweden has not got any substantial financial support from medical manufacturers. Instead it has been financially built up by support from government agencies and by support from influential psychiatrists.

This advocacy group started with a grant on 50 000 Swedish crowns from the Foundation for Scientific Work within Child Neuropsychiatry, chairman professor Christopher Gillberg. The group got 550 000 from the National Agency for Education (2000-2001). It got 100 000 from the National Board of Health and Welfare in a so called “establishment grant”, for year 2001. The purpose with such a grant is according to the decision (21/12-00) “to make it easier for a small organisation to build up an activity embracing the whole country and to recruit members”. It is also said that the organisation will get 200 000 for year 2002 and 300 000 for year 2003 from the Board. The group is also taking part in a project “Grownups with neuropsychiatric functional disorders which have started in childhood”. This project, led by professor Christopher Gillberg, has got 6 500 000 (for 3 years) from the Social Ministry of the Swedish government.

On the home page of this parent association one can find different tips about ADHD and DAMP. Several of the tips concern how one should go about to get a diagnosis and medical treatment with central stimulants for the alleged disorder. It is impossible for an uninformed person seeking information on this home page not to get the message: amphetamine and amphetamine-type drugs are safe and efficient medicines; the restrictions put on these drugs in Sweden are not in accordance with new scientific discoveries. The articles published on the home page are all in the same line – positive to increased use of central stimulants.

It can be said that the above mentioned psychiatrists and government agencies, with their build-up of a group promoting heavily increased use of central stimulants, have made it possible for pharmaceutical companies to circumvent the prohibitions against advertisement of psychotropic substances to the general public. The effect of the above promotion is probably better than if the companies themselves would have worked out the marketing campaign.

Jan Larsson, writer  
Snöbollsgården 22  
129 45 Hägersten  
Sweden

**Notes:**

1. Treatment with central stimulants of children and adolescents in Sweden, 30/01-01.
2. Dagens Medicin, 5/12-00.
3. Dagens Medicin, 12/12-00.
4. Comments to the suggestions about treatment with central stimulants of grownups with ADHD/ADD-problems, 21/5-96.
5. Paper from National Board of Health and Welfare, 20/9-01.
6. The paper Ordfront, 1-2 2001)
7. Letter to the Medical Products Agency, 24/3-98.
8. Protocol, 9/12-99)