All about PSY DREAM. Psychiatric Drug Registration, Evaluation & All-inclusive Monitoring*

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SUMMARY. **Aims** — In this article the author - board-member of the European Network of (ex-) Users and Survivors of Psychiatry (ENUSP) -explains, what is needed to guarantee a minimal level of involvement of users and survivors of psychiatry into issues relating to psychiatric drugs. **Methods** — He reflects demands of their organisations, and compares these demands with the current involvement level. Considering the concrete circumstances in psychiatry, he reflects the risks and dangers of the administered drugs -especially the widely used neuroleptics -for example enhanced breast cancer risk in women, suicidal effects, receptor changes, tardive dyskinesia and other toxic reactions. **Results** — Considering the unique situation of psychiatric patients to receive treatment in general without informed consent and in a violent way or through bullying and threat, he argues for to provide their involvement in all aspects of psychiatric drug issues -especially registration and monitoring, for example by their involvement in creating and running a suicide register. And he argues for involvement in ethics committees, licensing processes and providing guidelines and decision making about effectiveness and reimbursement of costs. **Conclusions** — As first steps towards these aims he proposes independent and user-controlled research, independent and user-controlled education and independent and user-controlled information about the effects of psychiatric drugs.

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This paper gives an overview of how far the movement of (ex-) users and survivors[1] of psychiatry in Europe has to go to achieve the aim of full involvement in two key aspects of psychiatric drug use; the registration of drugs and monitoring of drug effects. In general the *European Network for Mental Health Service Evaluation* (ENMESH) has a quite optimistic view on user involvement:

"User and consumer involvement is arguably the most exciting recent development in mental health services across Europe. The inclusion of service users as equal partners in all aspects of delivery and development is perhaps the greatest challenge facing services today." (ENMESH, 2004, p. 6)

THE POSITION OF ENUSP ON USER INVOLVEMENT AND PSYCHIATRIC DRUGS

The European Network of (ex-) Users and Survivors of Psychiatry (ENUSP) was asked in 1988 to write a commentary on the World Health Organization's (WHO) Quality Assurance in Mental Health Care, Draft-Human rights of people with mental disorders (World Health Organization, 1997). ENUSP stated that:

There should be bodies including (ex-) users and sur-

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vivors of psychiatry specifically charged, at national levels, with monitoring how human rights are respected for people with, or are said to have, mental disorders. The task of these bodies should include the registration of new treatment measures and decisions of ethics' committees in research fields. (Lehmann, 1999, p. 6).

For future ENUSP tasks, one of the key points was decided, at its congress *Into the Next Millennium -Moving Forward to Our Own Future* 1999 in Luxembourg:

ENUSP should demand that the drug companies are forced by law to pay reparations. These reparations should be held in a fund administered by (ex-) users and survivors of psychiatry to research, develop, publicise and run alternatives to psychiatry. (ENUSP, 1999)

In the same year ENUSP agreed to a Consensus Paper, which was adopted at the *Joint World Health Organization/European Commission Meeting* in Brussels 1999. "Developing innovative and comprehensive, explicit mental health policies in consultation with all stakeholders, including users" and "Highlighting research and development, establishing mental health information and monitoring" (World Health Organization, 1999, p. 9) were principles, which have been welcomed by ENUSP.

USER INVOLVEMENT IN PSYCHIATRIC DRUGS ISSUES NOWADAYS

From this principle of involvement in decision making processes concerning psychiatric drugs issues the reality differs. Currently the main involvement of users of psychiatry is opening the mouth and swallowing administered drugs or presenting the buttocks to receive an injection. There is no involvement in any form of decision making, neither in licensing psychiatric drugs or monitoring, nor in individual decision making. Complete and understandable information, the basis for meaningful involvement, does not exist. Often psychiatric drugs are administered in a violent way or through bullying and threat.

There is no information at the starting point of the drug administration, nor during the course of treatment in a psychiatric clinic, nor at that point when people are discharged from psychiatric wards and long-term treatment starts. Psychiatric and medical publications unanimously support this position. Researchers from psychosocial organisations like the mental health charity Mind (England & Wales) came to similar conclusions; Margaret Pedler from Mind suggested that 71% of patients receiving SSRIs, were not informed about so-called side-effects, nor were 77% of patients who received neuroleptics (Pedler, 1999). The quality of the information given is unknown.

Ten years ago the *Bundesverband Psychiatrie-Erfahrener* (the German Association of Users and Survivors of Psychiatry) participated in a study on quality of psychiatric care. Its members were asked: "Have you been informed about risks and so-called side-effects completely and comprehensibly?" In the, about, 105 returned answer-sheets not in one case there was a positive answer (Peeck *et al.*, 1995).

German psychiatrist Hanfried Helmchen philosophized about the appropriate time for information about irreversible risks in neuroleptics. With reference to the ideas of his colleagues he suggested that information should be given either one year after starting the drug or when the first signs of tardive dyskinesia appear, because:

The percentage of refusal would probably be very high, if all acute schizophrenic patients were to be informed about this risk before the start of a necessary neuroleptic treatment. (Helmchen, 1981, p. 83)

This psychiatrist was not unrepresentative of his psychiatric colleagues; he was the President of the German Association of Psychiatrists and Neurologists at the time.

USER-LED AND SURVIVOR-CONTROLLED INFORMATION

Users and survivors of psychiatry started to publish independent information about risks of psychiatric treatment. Leonard Roy Frank with *The History of Shock Treatment* set the example in 1978 (Frank, 1978). The author of this article, Peter Lehmann, started independent publications about psychiatric drugs in 1981 with his article "What you always wanted to know about psychiatric

[1] The term "user of psychiatry" refers to people who have mainly experienced psychiatric treatment as helpful. The term "survivor of psychiatry" in turn refers to those who have mainly experienced psychiatric treatment as being a danger to their health. These definitions are often misunderstood: to "survive psychiatry" does not mean that psychiatrists are being accused of trying to intentionally kill people. But it does mean that diagnoses such as "schizophrenia" or "psychosis" very often have a depressing and stigmatising effect, leading to resignation and chronic hospitalisation. And it means that drug-effects such as neuroleptic malignant syndrome or tardive dyskinesia or dystonic or epileptic attacks can be a danger to health and life, which have to be survived.

drugs" (Lehmann, 1981). In the USA David Oaks, now working for MindFreedom, followed with his article "Thorazine, Mellaril, Haldol, Prolixin: bizarre facts about neuroleptics" (Oaks, 1982/83). Finally the author set up his own publishing house to publish different books in German and (since 2004) in English about: the effects of psychiatric drugs on the metabolism and the mental, psychic and organ system (Lehmann, 1986; 1996a, b) inclusive alternatives (Kempker & Lehmann, 1993) and successful withdrawal from neuroleptics, antidepressants, lithium, carbamazepine and tranquilizers (Lehmann, 1998; 2004).

To enable users of psychiatric drugs and their supporters to find information independently, the author provides online information in English, German, Italian and French about helpful sources: www.peter-lehmann-publishing.com/info.htm. The Berlin organisation *In Any Case* provides training & research from the user/survivor perspective in psychiatric drug matters, both in English and German for professionals and users/survivors (see www.faelle.org/fortbildung.htm#english).

Meanwhile psychosocial organisations also publish information about psychiatric drug so-called side effects. An example is Mind's report on the yellow card project which showed how unpleasant, disabling and, in some cases, life-threatening the so-called side effects of psychiatric drugs can be (Cobb *et al.*, 2001). In 2004 the *Scottish Association for Mental Health* (SAMH) published with "All you need to know?" a user-orientated survey of psychiatric drugs based on a survey of people's experience of psychiatric drugs. Because such organisations are not user-controlled, and many members are providers of mental health services, there is a tendency to comply with the dominant psychiatric view that medication is basically safe. This compliance is found in both those patients, who contribute to such reviews or in the people who edit them. SAMH for example warns:

Don't be put off seeking help because of some of the comments in their reports. Very many people who returned forms said they found medication helpful. (Bradstreet & Norris, 2004, p. 99)

A neutral person would add: *Don't lose caution because other people report positively. We may have a tendency to be compliant patients, but nobody knows beforehand how psychiatric drugs work in your individual and special body.*

Reports, if critical, are helpful, and they might, as the law requires, give a part or all the information psychiatrists deny users. Online information reaches only a privileged number of service users. Few psychiatric institutions have service user access to the internet (a notable exception is Shelton Hospital in Shropshire, England). Mind-altering effects ("Zombie syndrome") prevent people giving reports on the bad effects of psychiatric drugs or understanding those reports. Reports on risks and damages always come to late, when the damage is already done, when severe and irreversible damage has developed, when dependency has developed, or when people are simply already dead.

COMPLEXITY OF MEDICAL PROBLEMS

Sometimes uneducated user and survivors of psychiatry could not understand medical problems because those problems are complex. They cannot be noted in individual anecdotal reports; they should be addressed in governmental and administrative monitoring bodies. Four examples of neuroleptic toxicity shall illustrate the difficulty.

Dependency

Dependency and tolerance building is a dark area not least because psychiatrists strictly deny its existence in public. In their own magazines they speak differently, as the example of the German psychiatrists Rudolf Degkwitz and Otto Luxenburger shows, which stated:

We now know that it is extremely difficult, if not impossible, for many of the chronic patients to stop neuroleptics because of the unbearable withdrawal-symptoms. (Degkwitz & Luxenburger, 1965, p. 175)

Ever since the emergence of psychiatric drugs, many people who have taken prescriptions have made their own decision to quit. One can only speculate how many people have attempted to quit after having been exposed to the idea in an uninformed way only to experience a "relapse" and eventually another prolonged administration of the drugs. I think it is safe to say that a great number of attempts to quit would have been more successful if those wishing to quit and those around them had been better informed as to the potential problems that may arise as well as of means for preventing the often-prophesied relapse. Psychiatrists have reported the following psychological withdrawal symptoms: a depressed mood, fear, a desire to run away, and fits of crying. Because a reduced dosage may result in motor disturbances and emotional pain caused by the neuroleptics becoming more pronounced and/or particularly intense (due to the fact that the emotional numbing of the drugs has subsided), a temporary -but nonetheless serious -risk of suicide may arise during withdrawal. How often are these

withdrawal-problems misdiagnosed as relapse into psychoses?

Tension, restlessness, destructiveness, aggression, irritability, and excitability may develop into withdrawal psychoses and delirious states. Fritz Reimer, like Degkwitz a former President of the *German Association for Psychiatry and Neurology*, concluded the following concerning the possibility of post- withdrawal delirium that may last several days:

The ultimate factor in the delirium syndrome is certain to be the psychoactive pharmaceuticals. On the surface, it appears to compare to the withdrawal delirium of the alcoholic. (Reimer, 1965, pp. 446f.)

Vegetative withdrawal symptoms that may occur include anorexia (or a lesser loss of appetite), binging, nausea, vomiting, gastritis, diarrhea, stomach ache, colic, pronounced nasal discharge, sebaceous gland discharge, hot flashes, freezing, pronounced sweating, cardiovascular (i.e. heart and circulatory system) problems such as a racing heartbeat, dizziness and physical collapse. The dangers that proceed from the habituation of a vegetative state and a physical dependence on neuroleptics have been shown in a rabbit study by Helma Sommer and Jochen Quandt at the Psychiatric Clinic in Bernburg/Saale. Their observations were based on noted metabolic changes induced by chlorpromazine that caused a circulatory collapse after withdrawal from the neuroleptic, despite the fact that metabolism was in fact returning to normal. For six months, Sommer and Quandt administered neuroleptics to 20 rabbits. The four animals that had received the highest dosage (16.7 mg/kg) died after a brief fit of cramping:

At a dosage of 13.3 mg/kg of chlorpromazine, abrupt withdrawal led to a sudden death within 14 days, probably due to irreversibly blocked metabolic processes that stopped functioning (similar observations in human beings have been published in which death followed a brief stage of cramping). (Sommer & Quandt, 1970, p. 487)

In 1997 Urban Ungerstedt und Tomas Ljungberg at the Karolinska Institute in Stockholm published results of studies in which rats were administered the conventional neuroleptic haloperidol and as a comparison the "atypical" clozapine. They believe that "atypical" neuroleptics modify subtypes of specific dopamine-receptors, produce their supersensitivity and contribute to the risk of new, increasing, or chronically powerful psychoses of organic origin, which can be understood as "counterpart to tardive dyskinesia" (Ungerstedt & Ljungberg, 1977, p. 199). Since then, medical journals have steadily published findings on supersensitivity, rebound and withdrawal psychoses (see Lehmann, 2004, pp. 32ff.).

The frequent damage caused by typical neuroleptics like haloperidol arises from changes in dopamine-D2-metabolism, observable as motor disturbances; the usual damage caused by "atypical" neuroleptics like clozapine, sertindole or quetiapine goes in the direction of changing the metabolism of special subtypes of dopamine-receptors, dopamine-D_1 and -D_4, seen as producing or increasing mid- and long-term psychotic syndromes of organic origin. Frank Tornatore and his colleagues at the University of Southern California School of Pharmacy in Los Angeles warned of the development of supersensitivity psychoses:

There is a worsening of the psychosis (delusions, hallucinations, suspiciousness) induced by Iong-term use of neuroleptic drugs. Typically, those who develop supersensitivity psychosis respond well initially to low or moderate doses of antipsychotics, but with time seem to require larger doses after each relapse and ultimately megadoses to control symptoms (Tornatore *et al.*, 1987, p. 44).

Supersensitivty should be understood as the result of an increased tolerance to the drugs, as they point out in an additional citation in the German translation of the book four years later: "Thus, a tolerance to the antipsychotic effect seems to develop" (Tornatore *et al.*, 1991, p. 53).

"Atypical" neuroleptics in general are announced as less harmful drugs. People will not receive necessary information to come to an informed decision when these drugs are offered. Gerhard Ebner, Chairman of the Swiss Association of psychiatric chief doctors and member of the Advisory Board of Janssen Cilag for the introduction of Risperdal Consta, stated:

We do not have less side-effects, but other ones. They can also be very drastic, even when the patients do not perceive them directly. For that reason the patients can be motivated to take the antipsychotics more easily, the excruciating dyskinesias/extrapyramidal side-effects do not occur or not so heavy (Ebner, 2003, p. 30).

Breast cancer

Breast cancer risk is another example. Uriel Halbreich and colleagues from the Gynaecological Department of the State University of New York in Buffalo compared mammograms of 275 female patients over 40 treated between 1988 and 1993 at the Buffalo Psychiatric Center, with mammograms from 928 patients from the Erie County Medical Center, a General Hospital. In 1996 they reported in the *American Journal of Psychiatry*, that the risk of breast cancer in female psychiatric patients was

3.5 times higher than in general patients, and 9.5 times higher than the average. The main and only explanation they had was the carcinogenic effect of raised levels of the hormone prolactin. Raised prolactin levels are common even in small doses of psychiatric drugs and suspected to be responsible for one third of female breast cancers. They conclude:

If confirmed, the suspected higher incidence of breast cancer among the psychiatric patients might be due to medications and further underscores the need for screening mammograms for breast cancer in these patients (Halbreich *et al.*, 1996, p. 559).

Suicide

Raised suicide rates since the introduction of neuroleptics are well-known -for psychiatrists. In single cases these rates are explained by reference to symptom-changes. In the *American Journal of Psychiatry*, which in general is not read by users and survivors of psychiatry, the American psychiatrist Frank J. Ayd says openly:

There is now general agreement that mild to severe depressions that may lead to suicide may happen during treatment with any depot neuroleptic, just as they may occur during treatment with any oral neuroleptic (Ayd, 1975, p. 497).

His German colleague Peter Müller explained in his specialists's book:

Depressive syndromes after the remission of the psychoses and under treatment with psychiatric drugs are not rare, but occur on about two thirds of the patients, and sometimes even more frequently. (…) Without treatment with psychiatric drugs, depressive syndromes after a complete remission are only found in exceptional cases (Müller, 1981, p. 72).

Benkert & Hippius (1980), two other German psychiatrists, answered the question, whether suicidality perhaps could be caused by an excessive dosage:

Depression, suicidality, states of excitement and delirium under the influence of drugs generally occur during doses prescribed by the treating physician (Benkert & Hippius, 1980, p. 258)

"Atypical" psychiatric drugs have also suicidal effects, as the report of Ursula Froehlich, living in Austria, shows:

Since I began taking Leponex (clozapine), I do not want sex anymore, did not feel like moving and had no joy in life. A life without joy is, however, worse than death. All that remained with me is watching TV, where I have watched others living for seven years. I am still alive biologically, but my senses are long since dead, everything that I former enjoyed I am not able to do anymore. In a way, my life does not exist anymore, I feel so empty and unimportant. In the mornings, the feeling is the worst. Every day I intend to start a healthy life the following day, to throw away the drugs, to drink many vitamins and fruit juices and to start with a daily fitness routine. The psychiatric drugs cause a feeling as if it was possible for me to start with a completely different, a new life the following day. But when I wake up in the morning I feel like smashed, and I never come out of bed before 9 o'clock, my depressions are so extreme that I think of suicide every day (Froehlich, quoted from Lehmann, 1996a, p. 70ff.).

Further toxic reactions

There are more severe effects which might occur, but risks like receptor changes, pancreatitis, agranulocytosis, malignant hyperthermia, malignant neuroleptic syndrome etc. are never spoken of, so no early warning signs of iatrogenesis are explained. There is much information available on risks of psychiatric drugs. This is already well known to the pharmaceutical industry and in medical science; to gather this again on the basis of reports of the user experience is not the way to implement fair user-involvement.

Sometimes drug companies simply hide negative drug effects. One example appeared in the British newspaper *The Independent* on August 27, 2004. Writing about problems with the antidepressant paroxetine (marketed as Allenopar, Aropax, Aroxat, Aroxetin, Casbol, Daparox, Deroxat, Ennos, Euplix, Frosinor, Motivan, Oxet, Oxetine, ParoLich, Paroxat, paroxedura, Paroxetin, Paxil, Paxtine, Sereupin, Seroxat or Tagonis) the journalist claims:

The Anglo-American drugs giant (GlaxoSmithKline) has agreed to pay $2.5m (£1.4m) in settlement of a court case brought by Mr Spitzer, who claimed GSK had suppressed data suggesting its anti-depressant drug Paxil (called Seroxat in the UK) could cause suicidal tendencies when prescribed to children ... had published only one of five trials on Paxil ... effectively suppressing results that did not favour the drug (Grimond, 2004).

Officially reported unwanted effects of psychiatric drugs might be only the tip of an iceberg. Sometimes not even proven information about deadly effects are considered a problem for governmental bodies, as the example of Richard Brook, chief executive of Mind, shows. Brook was representative for *Mind in the Medicines and Healthcare products Regulatory Agency* (MHRA), an expert group set up by the UK's Committee on Safety of

Medicines to review the safety of drugs. Brook had to face the nonchalance of MHRA over years referring to suicidal effects of paroxetine in young patient. When he broke the silence about the lack of initiative from the governmental body and made the scandal public, the consequence was heavy criticism by the government.

There is clear-cut governmental nonchalance, general disinformation or denial of information, harassment and discrimination of people with psychiatric diagnoses in all parts of society, including medical and mental health institutions (ENUSP, 2003a, b). Facing the fact, that people with psychiatric diagnoses are the only part of society that has to face the danger of administration of drugs against by force, wouldn't it be appropriate and necessary to ensure a minimum of user-involvement? At the very least this should enable their organizations to be part of decision-making about licensing of psychiatric drugs and part of monitoring bodies.

Where is any form of user-involvement in gathering and judging reports about psychiatric drugs? How can they trust that their interest is meaningfully considered? Until now, there has not been an opportunity for users or survivors of psychiatric drugs to report bad effects to governmental bodies or manufacturers of psychiatric drugs. The only systematic opportunity to report the negative effects has been given to doctors and psychiatrists - the ones who often treat by force, deny information and act on a non-egalitarian basis.

ALL-INCLUSIVE INVOLVEMENT

Meaningful involvement in drug issues would require the involvement in licensing processes in order to participate in decision-making about the granting and withdrawal of licenses. This involvement could start with involvement in ethics' committees and be followed by involvement in clinical studies on psychiatric drugs in the form of involvement in the assessment of studies on new psychiatric drugs. This might be directly or via trusted experts and end with recommendations to the governmental Committee on the Safety of Medicines.

Involvement in the key aspects of psychiatric drug use; the registration and monitoring of psychiatric drugs (PSY DREAM; Psychiatric Drug Registration, Evaluation & All-inclusive Monitoring) would deliver involvement in discussion and decision about guidelines and reimbursement of costs through health insurance institutions (the UK equivalent might be seen as the National Institute for Clinical Excellence). Compared to other medical patients, a specific involvement of organisations of users and survivors of psychiatry is required. This is due to the current discrimination, the current misinformation and because of the ongoing and developing forced treatment; even outside madhouses and clinics.

Meaningful involvement in PSY DREAM (Psychiatric Drug Registration, Evaluation & All-inclusive Monitoring) would require:

- transparency & access to information
- the chance to invite single users/survivors of psychiatry to give direct information
- the possibility to order reports
- consulting specialists selected by survivors
- direct representation of legitimate representatives of autonomous organisations of users and survivors of psychiatry (i.e. independent from drug company economical influence, and not replaced by parents' organisations: after all psychiatrists never are represented by their parents)
- at least double representation on the users/survivors side
- the requirement to publish and reveal minority votes
- economic equality (for example, self employed persons who give up paid work to attend PSY DREAM meetings need fees for attending those meetings)
- combination of national and international aspects.

A specific form of monitoring psychiatric drugs: the suicide register

A specific form of monitoring psychiatric drugs is the suicide register, as demanded some years ago by ENUSP and the German Association of Users and Survivors of Psychiatry. Suicide is the primary cause of death in people with the diagnosis "schizophrenia", and neuroleptics with their proven suicide risks are the main treatment for people with the mentioned diagnosis (Müller, 1981, p. 1f.). Such a suicide register could enable means for discovering the connection between suicidality and neuroleptics, antidepressants, electroshocks, and other forms of psychiatric compulsion (see www.enusp.org/suicideregister.htm).

CONCLUSION

To provide meaningful involvement of users and survivors of psychiatry in all aspects of psychiatric drug issues - especially registration and monitoring of psychiatric drugs, we must have involvement in ethics committees, licencing processes and providing guidelines and decision making about effectiveness and reimbursement of costs. Where such conditions do not exist, independent

and user-controlled research is needed on independent and user-controlled education and independent and user-controlled information about effects of psychiatric drugs.

Facing linked associations of psychiatrists and international drug companies, users and survivors have to improve their efforts to cooperate internationally to exchange information, best practice examples and to combine their special compentencies. Better cooperation of user-controlled initiatives for research and training is urgently required.

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