

PSY DREAM – Psychiatric Drug Registration, Evaluation and All-inclusive Monitoring*

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This article gives an overview of how far the movement of (ex-) users and survivors 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 ENUSP position on user involvement and psychiatric drugs

In 1998 the European Network of (ex-) Users and Survivors of Psychiatry (ENUSP) was asked 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* (1997). ENUSP stated that:

There should be bodies including (ex-) users and survivors of psychiatry specifically charged, at national levels, with monitoring how human rights are respected for people with, or who 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)

One of the key points for future ENUSP tasks 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.

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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)

'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' were principles which ENUSP agreed to be part of the Consensus Paper, adopted at the Joint World Health Organization/ European Commission Meeting in Brussels 1999 (World Health Organization 1999, p.9)

Current user involvement in psychiatric drugs issues

The reality differs from this principle of involvement in decision making processes concerning psychiatric drugs. 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 little or no information at the starting point of 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 (1999) 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. The quality of the information given is unknown.

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 was there 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)

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

Survivor-led 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. 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 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; 1996) inclusive alternatives (Kempker and 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 and 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 effects of psychiatric drugs can be (Cobb et al., 2001). In 2004 the Scottish Association for Mental Health (SAMH) published '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 and 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 and 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 damage always come too 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.

Complex medical problems

Sometimes medical problems are too complex so that an uneducated user/survivor of psychiatry could not understand them. 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.

Breast cancer

Breast cancer risk is one 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)

Dependency

Dependency and tolerance building is a dark area not least because psychiatrists strictly deny its existence in public. In their own press 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 and Luxenburger, 1965, p.175)

So-called atypical neuroleptics in general are announced as less harmful drugs.

People will not receive appropriate 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 are not so heavy.' (Ebner, 2003, p.30)

Suicide

Raised suicide rates since the introduction of neuroleptics are well-known. In single cases these rates are explained by reference to symptom-changes. The American psychiatrist Frank J. Ayd says:

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:

Depressive syndromes after the remission of the psychoses and under treatment with psychiatric drugs are not rare, but occur in 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)

Other 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 bad 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, Paroxetine, 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.' (Grimford, 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 patients. 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*.

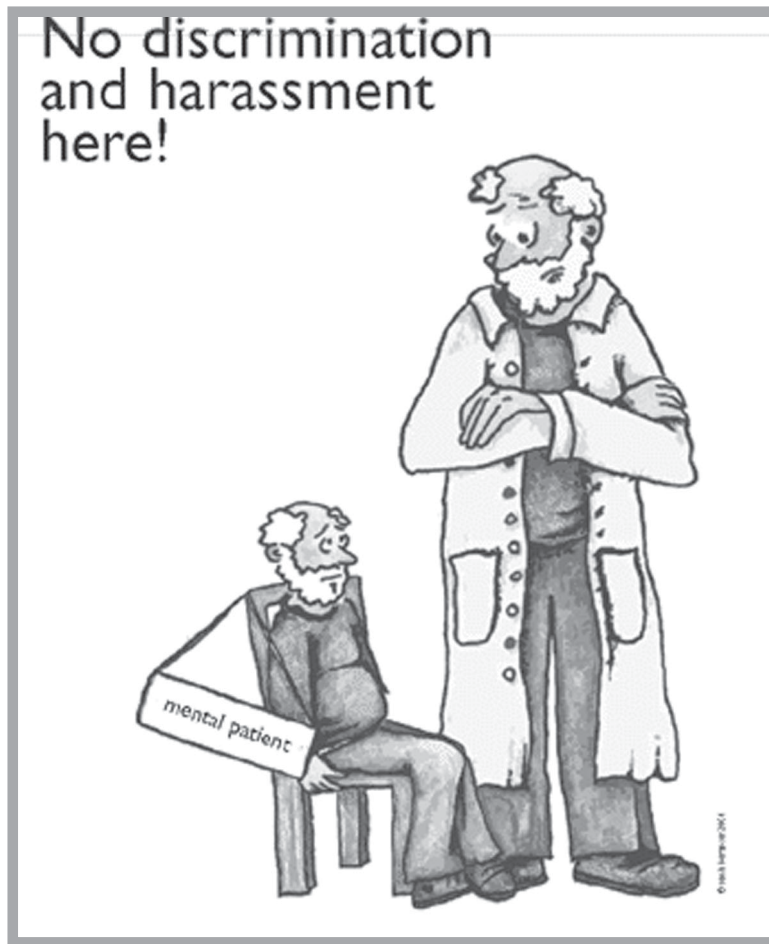
There is clear-cut governmental nonchalance, general disinformation or denial of information, harassment and discrimination towards people with psychiatric diagnoses in all parts of society, including medical and mental health institutions (see Community Action Programme to combat discrimination 2001-2006). Facing the fact, that people with psychiatric diagnoses are the only part of society that has to face the danger of administration of drugs 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 bad effects has been given to doctors and psychiatrists—the ones who often treat by force, deny information and act on a non-egalitarian basis, as the European Commission's anti-discrimination poster illustrates (see over).

Meaningful involvement

Meaningful involvement in drug issues would require involvement in licensing processes in order to participate in decision-making about the granting and withdrawal of licenses. This could start with involvement in ethics' committees followed by 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 Medicine.

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 special involvement of organisations of users and survivors of psychiatry is required. This is due to the current discrimination, the current misinformation and the ongoing forced treatment; even outside madhouses and clinics.

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

- transparency and 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 economic influence, and not replaced by parents' organisations: after all

psychiatrists are never represented by their parents)

- at least double representation on the user/survivor side
- the possibility 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)
- the combination of national and international aspects.

Suicide register

A special form of monitoring psychiatric drugs is the suicide register, as demanded for some years 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.' Neuroleptics with their proven suicide risks are the main treatment for people with the 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

We need meaningful involvement of users and survivors of psychiatry in all aspects of psychiatric drug issues – especially registration and monitoring of psychiatric drugs. Involvement is needed 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 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 competencies. Better cooperation of user-controlled initiatives for research and training is urgently required.

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