

At the Ministerial Conference of the European Office of the WHO the Helsinki declaration was endorsed by all member states of the European Region. The Declaration offered a vision of a comprehensive and inclusive scope of mental health activities. Since then many countries have drafted or scrutinised strategies according to the declaration and activities have been developed in areas ranging from anti-stigma and suicide prevention strategies to the improvement of facilities, development of services and community activities.

There have been numerous successes, but we have also become aware of challenges which need addressing in a variety of ways. These include the absence of evidence in some crucial areas, the cost of service development, health systems not suited to the demands of mental health care, workforce challenges and the stigma and discrimination experienced by users, carers, services and staff.

### PR01.02

The views of European psychiatrists represented in the AEP

C. Hoschl. *Prague Psychiatric Centre and 3rd Medical Faculty, Charles University of Prague, Prague, Czech Republic*

AEP is an organization based on individual membership of those working in the field of mental health care and research in Europe. The role of AEP is changing hand in hand with the harmonization process in European policy including the mental health. The activity of the association as well as the participation of its individual members representing different parts of Europe is to some extent parallel and complementary to the official programs on mental health (WHO a EC projects, STAKES, IMPHA etc.). In addition, there is a significant overlap with such programs, which will be briefly summarized in the forum.

### PR01.03

The views of family organizations in Europe taking into account the recent developments in WHO Europe and the European community

I. Nilsson. *President, EUFAMI, Molkom, Sweden*

Inger Nilsson will speak about how EUFAMI has been involved with the various policy makers and legislators at a European Level over the past number of years and how the Federation has helped to influence policy making. She will also speak how EUFAMI has worked to promote the role of family and carers in order to recognise them as having a central and crucial role in the care and rehabilitation of those who suffer from mental illness.

Specifically Inger will speak about how EUFAMI played a significant role at the WHO European Ministerial Conference on Mental Health in Helsinki in January 2005 and the subsequent Declaration that was produced from the conference.

With regards to the EU Commission Green Paper, Inger will also tell how EUFAMI again has played a pivotal role in the consultative process to date and will continue to fully participate in the next stages of this process.

Finally, Inger will demonstrate how EUFAMI continues to influence mental health policy at both European level and also at national level (through its member associations) by publishing position papers on many related subjects, such as family needs, medication, treatment and care, rehabilitation and care.

### PR01.04

The EU strategy - Green/white paper

J. Scheftlein. *European Commission, DG Health and Consumer Protection, Luxembourg*

The mental health of the EU's population is a value by itself, and a key determinant for health and quality of life. It is an important factor for the realisation of the EU's strategic objectives: prosperity, solidarity and social cohesion, security.

The situation in the EU is marked by significant differences with regard to the mental health status, mental health policies and systems in Member States. At the same time, a commonality across the EU is the increase of diagnosed mental disorders, which severe and growing implications for health, economic and social systems. It can be expected that this trend will continue.

Mental health is a priority of public health policy at Community-level and it is also addressed by other Community policies. Action at EU-level needs to respect subsidiarity and the diversity of situations in Member States. Strengthened exchange and cooperation between Member States can help to tackle the existing inequalities, and action through Community policies can complement measures in Member States.

Experiences through the EU Public Health Programme (2003-2008) showed that responding to the challenges of mental ill health is more effective, if it involves the range of policies and actors who have an influence on the mental health of the population, such as the health, educational and workplaces' areas. The important role of mental health promotion, prevention, early recognition and combating stigma, further to treatment, care and rehabilitation, is now well established.

In October 2005, the European Commission published a consultative Green paper on Mental Health. In this document it proposed the development of a strategy on mental health at EU-level, in line with the competencies established in the European Treaties. The document proposed the following priorities: mental health promotion; prevention of mental disorders and suicidal behaviour; raising the quality of life of people experiencing mental disorders through social inclusion and the protection of their rights and dignity; providing mental health information and research. The document argued that action on mental health at EU-level could promote the exchange and coordination between Member States and between the relevant sectors.

The Green paper initiative attracted much interest and support among EU-institutions, in Member States, in the health and social sectors as well as among patient and family organisations and the civil society. A White Paper to be presented in spring 2007 will draw the conclusions from the consultation.

### PR01.05

The views of the European Brain Council and the various disciplines represented in it

J. Mendlewicz. *President ECNP and Secretary EBC, Belgium*

The European Brain Council (EBC) brings together European based stakeholders in the field of "Brain Research". It is an exceptional organisation as it brings together science, society and industry at the European level.

EBC's scientific member associations are European Association of Neurosurgical Societies (EANS), European Federation of Neurological Societies (EFNS), European College of Neuropsychopharmacology (ECNP), Association of European Psychiatrists (AEP), Federation of European Neuroscience Societies (FENS). The patient associations are European Federation of Neurological Associations (EFNA) for the neurological disease groups and GAMIAN-Europe for the

psychiatric patients. Industry, pharma as well as the device industry, have voted delegates to sit on the EBC board.

EBC actively lobbies at the EC and EP level to promote and enhance research on the brain. This research is not conceivable without considering also the importance of the mental health of Europe's citizens.

Therefore, EBC actively participated in the Green Paper Consultation on Mental Health carried out by DG SANCO. Aware of the challenge such an important initiative poses, EBC pointed out priorities that need to be met and the lack of available evidence for mental health in Europe that needs to be gathered and completed. EBC also strongly suggested not to overlook the importance of diagnosis and treatment as complementary to promotion, prevention and recovery.

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## CS02. Core Symposium: MEASUREMENTS OF OUTCOME IN PSYCHIATRY

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### CS02.01

Why it is sometimes difficult to generalize results from RCT's to everyday clinical practice

W.W. Fleischhacker. *Department of Biological Psychiatry, University Hospital, Innsbruck, Austria*

Randomized controlled clinical trials mostly focus on very specific outcome parameters. These may include symptom relief, psychosocial measures, specific safety issues or compliance, just to name a few. As they often represent early attempt to provide information on new treatments, the homogeneity of the studied population is a crucial study prerequisite. This generally calls for strict inclusion criteria and a large set of exclusion criteria. Understandably, these requirements allow only a certain selection of patients to enter such studies, which, in turn, jeopardizes the generalisability of the obtained results. Alternatives to this approach include so called "large pragmatic clinical trials" with broad inclusion criteria, designed to study a population of patients closer to real life. More comprehensive outcome criteria, such as the effectiveness or remission paradigms, have also contributed to the effort. In the end, results from various types of clinical trials will have to be evaluated in a synthetic fashion in order to enable the clinician to make a rational treatment choice for individual patients.

### CS02.02

Applying pragmatic outcome criteria in clinical trials

R. Kahn. *Department of Psychiatry, University Medical Center Utrecht, Utrecht, The Netherlands*

Abstract not available at the time of printing.

### CS02.03

Adverse events beyond the 'usual suspects'

P. Mohr. *Prague Psychiatric Centre Third Faculty of Medicine, Charles University, Center of Neuropsychiatric Studies, Prague, Czech Republic*

Since the introduction of antipsychotic drugs into schizophrenia treatment patients complained feeling 'fuzzy or dull', of being 'unable to think straight', feeling 'like a zombie'. All these feelings were labeled as a syndrome of 'neuroleptic dysphoria'. Patients may even fail to distinguish adverse events from symptoms of illness; they simply

classify drugs as 'good' or 'bad', or alternatively they believe that medication makes their condition worse. Negative impact of side-effects on quality of life was repeatedly confirmed in various studies. The subjective acceptance of medication is becoming increasingly important outcome measure of tolerability in trials of new drugs, naturalistic observational studies and switch studies. Similarly to the quality of life assessment, impact of drugs on patients' well-being, subjective response to treatment, attitude towards medication, or preference of medication can be measured. Variety of side-effects is associated with antipsychotic treatment. Traditionally, most of the attention is being paid to EPS, akathisia, tardive dyskinesia, and lately weight gain, metabolic, endocrinological, or ECG abnormalities. However, beyond the usual list, largely overlooked adverse events, such as sedation and somnolence, orthostatic hypotension, sexual side-effects may have more severe and direct impact on patient's well-being. The outcome of illness, including treatment compliance, can be negatively affected by the group of clinically highly relevant but mostly ignored side-effects, including sexual dysfunction. Their incidence in clinical trials and everyday practice, together with their consequences, thus deserve closer scrutiny.

### CS02.04

Defining response, remission and recovery in schizophrenia

S. Leucht. *Department of Psychiatry and Psychotherapy, Technische Universität München, Klinikum Rechts der Isar, Munich, Germany*

**Background and Aims:** For a long time it was a problem of treatment research in schizophrenia that uniformly accepted definitions of response, remission and recovery were not available. The presentation will summarize recent reports on these issues and will come up with a number of suggestions.

**Method:** Review of recent publications.

**Results:** Response can be defined as a clinically meaningful improvement of the patient's psychopathology irrespective of whether he is still symptomatic at the end or not. When the BPRS or the PANSS are used for definitions of response, a cutoff of at least 50% reduction of the baseline score should be used for acutely ill, non-refractory patients and a cutoff of at least 25% reduction for refractory patients. A table presenting responder rates in 25% steps covering the whole range up to 100% has been suggested.

Remission is a state in which the patient is free of clinically significant symptoms. A definition based on 8 PANSS items rated mild or better for a duration of at least 6 months has recently been presented. The advantage of these remission criteria is that in contrast to the response cutoffs they show how many patients are still symptomatic at the end of a study or not. Their disadvantage is that they do not reflect the amount of change.

**Conclusion:** Both remission and responder rates could be indicated in future studies. The next challenges are the development of universally accepted definitions of recovery and relapse of schizophrenia.

### CS02.05

Psychosocial reintegration - an overambitious goal in schizophrenia patients?

V. Roder. *University Hospital of Psychiatry, Bern, Switzerland*

Nowadays treatment and rehabilitation of schizophrenia patients demonstrate promising results, especially for symptom remission. E.g. up to 80% of first-episode patients show symptom remission at 1 year after starting pharmacological treatment. But despite initial