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.

CS02. Core Symposium: MEASUREMENTS OF OUTCOME IN PSYCHIATRY

CS02.01

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

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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

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Abstract not available at the time of printing.

CS02.03

Adverse events beyond the 'usual suspects'

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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 abnormities. 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

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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?

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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

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