

S26-03 - OFF LABEL USE OF DRUGS IN PSYCHIATRY

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Introduction: One type of the treatment interventions is the "off label" use of a drug, which may include the use of a drug in a nonapproved indication, dose range, age group, drug combination and drug formulation. Research in this field is insufficient, while the medical, financial and legal consequences of off label use maybe serious. In case of off label use of a drug the manufacturer does not have any responsibility in case of adverse or serious adverse events.

Methods: Labels (summary of product characteristics) of antipsychotic drugs have been compared for indications and examples of regulations for off label use have been collected.

Results: Labels (summary of product characteristics) very rarely include indications for children, adolescents and for the elderly. A significant proportion of psychotic disorders listed in DSM-IV or in ICD 10 and major clinical syndromes have not been included as indications in the label of antipsychotic drugs. The same compound marketed by different companies under different names may have different labels.

The regulations for off label use of drugs vary between countries and as of today there is no common European regulation for off label drug use. In some countries off label drug prescription is not restricted, these prescriptions maybe reimbursed. Some countries restrict reimbursement of off label prescriptions and there are countries restricting the prescriptions.

Conclusions: More research (especially in young and old age groups) is needed in this field and some European guidelines/regulation would increase the safety of using drugs off label.