ADVERSE DRUG REACTIONS OF PSYCOPHARMACS

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The importance of adverse drug reactions (ADRs) monitoring was recognized in Croatia early: in 1974 the National Centre for Adverse Drug Reaction was instituted in the University Hospital Zagreb. In March 2005, after new legislation came into force, the obligation of pre- and post- marketing drug surveillance was delegated to the Agency for Medicinal Products and Medicinal Devices. We analyzed ADRs reported to the Agency for the period from March 2005. to December 2008. caused by drugs from ATC group N with special interest to psycholeptics (N05) and antidepressants (N06A). ADRs were evaluated according to their seriousness and expectedness. All ADRs which resulted in death or were life threatening, required inpatient hospitalization/ prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, a congenital anomaly/birth defect or were other important medical event were labeled as serious. ADRs were considered expected if they were described in approved SmPC in Croatia. We found that 15 % of all reported ADRs were caused by drugs from ATC group N. 60% of these were caused by drugs belonging to ATC subgroups N05 and N06A. Additionally, most of the serious ADRs were associated with drugs from ATC group N. These data show importance of ADRs caused by psycopharmacs. Majority of ADRs caused by antipsychotics and antidepressants were reported by psychiatrists, while almost all ADRs caused by anxiolytics and hypnotics and sedatives were reported by primary care physicians.