Drug Safety 2006; 29 (10): 911-1010
0114-5916/06/0010-0911/$39.95/0

3. A National Register for the Monitoring of Adverse Drug Reactions in Children and Adolescents Treated with Psychostimulants

P. Panei, A.L. Knellwolf, R. Arcieri, E. Costabile, R Di Nallo, P. Popoli, S. Vella

Department of Drug Research and Evaluation, Italian National Institute of Health, Rome, Italy

Background: Attention deficit hyperactivity disorder (ADHD) affects today in the UK 366 000 school-aged children and adolescents and 190 900 in France (respective prevalence of 5% and 1.5%). In Italy, the estimates are based on epidemiological studies of mental disorders which are, as in France, rare and carried out locally. The number of children treated with drugs grows up annually. The available data suggest that children and adolescents are at higher risk than adults for experiencing side effects during treatment with psychotropic drugs.

Objective: Assess the long-term incidence and severity of adverse drug reaction specially focused on cardiovascular risk, effect on growth and suicidal behaviour risk.

Methods: The Italian National Institute of Health (ISS) coordinates a national register of ADHD school aged-children. The aim of the register is to monitor ADHD drug prescriptions in this population. Patients will be screened by the neuropsychiatrist for child and adolescent (NPCA) of the local community and addressed to the regional reference centre (RRC) for inclusion in the register. 78 RRC in 20 Italian regions have been accredited by the Italian Ministry of health for ADHD diagnosis according to the DSM-IV criteria and for treatment schedule. The duration of the follow-up is 24 months. The monthly one will be performed by the family paediatrician and the NPCA. Every six months the patient will return to the RRC for a clinical global assessment. The cardiovascular effects, i.e. prolongation of QT interval, will be monitored with ECG, heart rate and blood pressure. The self-harm and suicidal ideation and behaviour will be assessed with the Child-Adolescent Suicidal Potential Index. The growth processes in treated children will be explored by monitoring height and weight curves as compared to theoretical bone aged and growth potential evaluated before treatment and every six months by an X-ray of the left hand. Results: Preliminary results are expected 6 months after the start of the register. Interim analyses are scheduled at month 6, 12, 18.

Discussion: The adverse events influence medication effectiveness, physical and mental health, compliance, and overall outcome. Longer term and larger-scale safety monitoring studies are needed to aware clinicians about the safety profiles of different compounds used in psychiatric disorders.

Conclusion: The register represents a new model of active pharmacovigilance in community setting for establishing the long-term risk-benefit profile of psychostimulants.