Paediatric Drug Safety Surveillance in Italian Pharmacovigilance Network: an overview of Adverse Drug Reactions in the years 2001-2012

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Background Regulatory actions in paediatrics are mainly based on data mining in Spontaneous Reporting Systems (SRS). Understanding structure and scope of these databases and their strengths and limitations is crucial for their correct use and interpretation for signal detection.
Objective To explore paediatric ADR reports on the Italian SRS database over the last decade.
Methods Reports of suspected ADRs related to children and adolescents (<18 years) were extracted from the Italian SRS over the period 2001-2012. MedDRA® terms and WHO-ATC classification were used to group ADR reports by suspected drug classes and affected system/organ (SOC). Characteristics were analysed within specified paediatric age-categories and compared with adults ADR reports.
Results Among 123,129 selected reports, 8,338 (6.8%) concerned paediatrics, with males more involved than females up to 11 years of age (52% vs. 48%), thereafter reversed. 30% of paediatric reports were serious and of these, 75% required hospitalization, mainly in very young children. Most of the reports were issued by hospital physicians (62%), followed by pharmacists (10%), while reports from family paediatricians accounted only for 8%. Irrespective of the event, the most frequently implicated drug categories were anti-infectives for systemic use (n=3,743, 45%), drugs acting on nervous system (1,304, 15%), and antiinflammatory drugs (849, 10%). As compared to the adult reports, the paediatric group showed a higher proportion of reports concerning respiratory system drugs (7.8 *vs* 2.0%, respectively), and a lower proportion for drugs acting on the blood (1.5 *vs* 10.4%) and on cardiovascular system (1.0% vs. 12.0%). At single compound-level, the mostly suspected drugs were different among children and adults and, in several cases, with respect to the same drug, ADRs were more serious in adults than in children.
Conclusions This descriptive study of Italian SRS reflects real safety concerns for drugs used in paediatrics. Because of the low frequency of reports by paediatricians, specific learning programs should be adopted to stimulate their drug safety monitoring. Since of differences between adults and children, paediatric drug safety needs to be assessed in age-specific setting.