Trends in Spontaneous Adverse Drug Reaction Reporting to a Regional Pharmacovigilance Centre (years 2014-2016)

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Regional Pharmacovigilance Centres (RPCs) represent an important resource to improve the efficiency of National Spontaneous Reporting Systems with a positive impact on reducing ADR under-reporting and improving the relevance and quality of ADR reports. Over the years, various initiatives have been promoted by Italian RPCs in cooperation with Italian Medicines Agency in order to encourage ADR reporting, including active pharmacovigilance projects, provision of feed-back information to reporters and facilitation of online ADR reporting. The aim of this study was to analyze trends in spontaneous ADR reporting in Sicilian RPC over a 3-year period (2014 – 2016) and evaluate the type of ADR reports sent by healthcare professionals and patients.

We analysed all the regional ADR reports over a 3-year period (01/01/2014 - 31/12/2016), with respect to reporting rate (reports/100,000 inhabitants/year), ADR types and suspected medications. Drugs were categorised by ATC classification. ADRs were classified by the Medical Dictionary for Regulatory Activities (MedDRA). Analyses of ADRs were conducted using MedDRA System Organ Classes (SOCs) and Preferred Terms (PTs).

Over the 3-year period 2014-2016, a total of 9534 spontaneous ADR reports were collected in Sicily. Regional ADR reporting rates per 100,000 inhabitants per year rose from 28,3 in 2013 to 77,1 in 2014, corresponding to an increase of 172,8%, and remained almost stable in the following two years. In 2014 Sicily represented the 6th region in Italy in terms of ADR reporting rate and the 8th region in 2015-2016. During the 3-year period 2014-2016, the largest number of reports were received from hospital-based physicians (44.6%), followed by specialists (19.5%). The contribution of general practitioners was significantly increased in the last two-years 2015-2016 (11.62%) compared to 2014 (2.6%). The percentage of reports with serious ADRs was 29,6% in 2014, 33.2% in 2015 and 29.1% in 2016. Overall, the most frequently reported SOCs were general and application site disorders (33.0%), followed by dermatological reactions (24.3%), gastrointestinal disorders (20.3%) and nervous system effects (12.8%). In particular, the largest number of reports concerned pyrexia (n = 1113), erythema (n = 526), diarrhoea (n = 524), urticaria (n = 466), pruritus (n = 435) and vomiting (n = 402). The most frequently medications implicated in ADRs were represented by antineoplastic agents (n=1952; 20.5%) followed by vaccines (n = 1735; 18.2%), immunosuppressants (n = 881; 9.2%) and antithrombotic agents (n = 784; 8.2%).

From 2014 to 2016 the number of ADR reports in Sicily considerably increased when compared to previous years. Italian monitoring registries, online reporting and regional active pharmacovigilance projects concerning vaccines, cancer drugs and drug-induced osteonecrosis of the jaw could have particularly contributed to this increase.