EVALUATION OF ADVERSE DRUG REACTION REPORTING IN THE SICILIAN REGIONAL PHARMACOVIGILANCE CENTER OVER A 3-YEAR PERIOD

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Introduction: The Italian Spontaneous Reporting System is based on a decentralized network of several Regional Pharmacovigilance Centers (RPVCs). The RPCV activities has significantly improved the efficiency of the national system with a positive impact on reducing adverse drug reaction (ADR) under-reporting and improving the quality of ADR reports. The Sicilian Regional Pharmacovigilance Center was officially established in 2011, based on four qualified Units, three of which located in university hospitals, and coordinated by a Regional Pharmacovigilance Office. The aim of this study was to provide an overview of ADR reporting in Sicily over a 3-year period, evaluating the type of ADR reports sent by healthcare professionals and patients.

Material and methods: We analysed all the regional ADR reports collected from January 2016to December 2018, describing reporting rates (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) and stratified by System Organ Classes (SOCs) and Preferred Terms (PTs).

Results: During the study period, a total of 8414spontaneous ADR reports were collected in Sicily. Regional ADR reporting rates per 100,000 inhabitants was 60.2in 2016, 58.0 in 2017and 48.3in 2018. The largest number of reports were received from physicians (67.3%), followed by other healthcare professionals (24.72%). The contribution of patients was significantly increased during the study period (5.2%) compared to previous three years (1.7%). The percentage of serious ADR reports was 25.1% in 2016, 22.3% in 2017and 20.9% in 2018. The most commonly reported SOCs were general and application site disorders (42.3%), dermatological reactions (19.0%), gastrointestinal disorders (17.5%), musculoskeletal and connective tissue disorders (13.9%) and nervous system effects (11.7%). In particular, the largest number of reports concerned ADRs, such as pyrexia, lack of therapeutic efficacy, myalgia, diarrhea. The medications most frequently implicated in ADRs were represented by vaccines (22.5%), immunosuppressants (20.6%), antineoplastics (14.9%), lipid modifying agents (7.6%) and antithrombotics (4.4%). Over the study period, there was an increased reporting of ADRs due to biological agents and, concerning pediatric age, to psychotropic drugs,

Discussion and conclusions: From 2016to 2018, the reporting trend in Sicily remained substantially stable and largely exceeded the WHO's gold standard. Most ADR reports concerned biological agents and vaccines. Active pharmacovigilance projects have presumably contributed to these results. Moreover, during the study period, patient reporting considerably increased when compared to previous years.