

ROLE OF PHARMACOVIGILANCE REGIONAL CENTRES: THE EXPERIENCE IN REGIONE CAMPANIA

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Pharmacovigilance is the science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on Adverse Drug Reactions (ADR) with the aim of identifying new information about hazards associated with medicines and preventing harm to patients. Serious adverse drug reactions worsen the quality of life, require hospital admission or extend hospitalisation length and increase mortality. Spontaneous reporting is the most common method used in Pharmacovigilance and the best one to generate signals on new or rare adverse drug reactions. These individual reports may be the only source of information concerning previously undetected ADR or changes in product safety and effectiveness profiles to marketed health products. Unfortunately, in Italy there is a serious problem of under-reporting. Moreover many differences exist between Italian Regions to recognize this problem.

To potentiate Pharmacovigilance activities, the Italian Drug Regulatory Agency (AIFA) suggested to fund Regional Pharmacovigilance Centres. Many Regions (i.e. Campania Region) adhered to such a proposal. The main objective of Regional Campania Centre is to give independent information on safety and efficacy of medicine products and to encourage the reporting of all suspected adverse reactions to drugs and other medicinal substances including herbal, traditional or alternative remedies. Regional Centre of Regione Campania carries out the following tasks: to correspond with peripheral centres (AASSLL, AAOO, IRCCS), to provide them with technical support, coordinate and monitor their functioning; to ensure quality of data reported by peripheral centres; to organize and attend training programmes/interactive meetings for all peripheral centres; to carry out (and/or review) data causality analysis of all ADR. The *RAF News*, a quarterly publication, alerts health professionals to potential signals detected through the review of case reports occurred in our Region. During its life, the Centre of Regione Campania has carried out different studies of active Pharmacovigilance. At this moment, the Centre is performing an observational study on the use of the antipsychotics in patients with behavioural disorders and dementia, and an observational study on the incidence of adverse events to drugs in the paediatric population.