Pharmacovigilance And Drug Safety In Calabria (Italy): 2012 Adverse Events Analysis

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Introduction: Pharmacovigilance (PV) is designed to monitor drugs continuously after their commercialization, assessing and improving their safety profile[1]. The main objective is to increase the spontaneous reporting of adverse drug reactions (ADRs), in order to have a wide variety of information. The Italian Drug Agency (Agenzia Italiana del Farmaco, AIFA) is financing several projects to increase reporting. In Calabria a PV Information Centre has been created in 2010.
Methods: We obtained data using the database of the national New Health Information System (NSIS) AIFA relatively to Italy and Calabria in the year 2012. Descriptive statistics were performed to analyze the ADRs.
Results: A total number of 461 ADRs have been reported in the year 2012 with an increase of 234% compared with 2011 (138 reports)[2]. Hospital doctors are the main source of this reporting (51.62%). Sorafenib (Nexavar®), the combination of amoxicillin/clavulanic acid and ketoprofen represent the drugs most frequently reported causing adverse reactions. Adverse events in female patients (61.83%) were more frequently reported whereas the age groups "41-65" (39.07%) and "over 65" (27.9%) were the most affected.
Conclusions: Calabria has had a positive increase in the number of ADRs reported, although it has not yet reached the gold standard (GD) set by World Health Organization (WHO) (about 600 reports), the data have shown that PV culture is making inroads in this region and that PV projects stimulating and increasing PV knowledge are needed.

References

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