A brief overview of pharmacovigilance in the Molise Region: toward a long-awaited change of pace

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Implementation of pharmacovigilance strategies is essential to reduce adverse drug events (ADEs) and to improve appropriate drug use, thereby achieving more effective and safer therapeutic outcomes in the general population. According to Italian regulations, each Region is in charge of implementing effective pharmacovigilance strategies, under the guidance of the Italian Drug Agency (AIFA), which provides specific resources dedicated to pharmacovigilance activities in each Region. Earlier strategies involved the passive distribution of these resources to the Regions based only on the number of inhabitants, and without any specific pre- or post-hoc monitoring; in the Molise Region, such strategies were poorly effective, and the number of pharmacovigilance reports in the years until 2006 was extremely low (about 4/year, corresponding to about 10/million inhabitants), well below the gold-standard threshold of 300/million inhabitants (WHO, OMS). Starting in 2007, AIFA resources began to be granted to Regions on the basis of specific projects aimed to implement various aspects of active pharmacovigilance, with the explicit intention to promote regional structures specifically involved in pharmacovigilance, and to support the birth of Regional Centers of Pharmacovigilance. The Molise Region, despite being one of the smallest-size in Italy, the infrastructural limitations connected to the relatively small number of permanent employers in charge of such activities, and the complex bureaucracy of the administrative apparatus, responded successfully to these calls, and implemented several active pharmacovigilance projects; among them, one on the use of biologics and biosimilars in the Region, a comparative evaluation of the safety profile of erythropoietins (originator and biosimilars) in dialyzed patients (ESAVIEW; coordinated by the Veneto Region) has been recently completed, and two projects are ongoing, one on the use of drugs for osteoporosis treatment, and the other on the use of antibiotics in the pediatric population between 0 and 2 years of age. Furthermore, the Molise Region has been one of the three Italian Regions selected by the Ministry of Health to implement training and information strategies on medical devices for self-monitoring among the diabetic population. Despite such efforts and the investments in the recruitment of talented and specifically-trained personnel to carry out pharmacovigilance projects within the Region, contracts for non-permanent staff are often activated with rather sporadic and discontinuous timelines, leading to the abrupt interruption of ongoing projects. In the present work, we aimed to investigate whether ongoing pharmacovigilance activities positively correlate with the number of pharmacovigilance reports in the Molise Region. In Fig. 1 are plotted the number of pharmacovigilance reports in the years 2005-2014. The data obtained suggest that the number of reports increase when active pharmacovigilance projects are ongoing (2009-2011), and drop dramatically in years 2012-2013, when activities have been suspended due to the termination of the contracts. Accordingly, the establishment of Regional Center of Pharmacovigilance of the Molise Region, whose activities started in May 2014, along with the recruitment of personnel dedicated to pharmacovigilance, contributed to an increase by about 300% when compared with 2013 in reports number, reaching the gold standard set by the WHO. Overall, the data obtained suggest that the availability of trained personnel is critical to guarantee a continuous flow of records, possibly as a consequence of their direct support to the potential reporters.

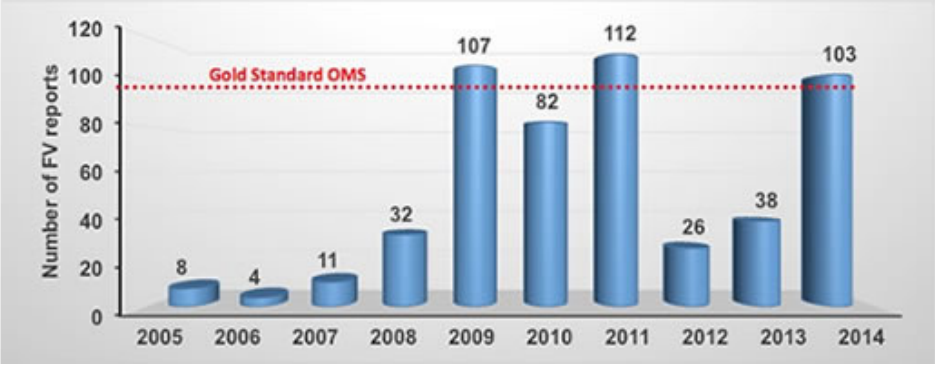

Fig. 1. Number of pharmacovigilance reports in the Molise Region from 2005 to 2014 (source AIFA).