

## WEB-BASED REPORTING OF ADVERSE DRUG REACTIONS IN ITALY

1)Arzenton E. 2)Sottosanti L. 3)Opri S. 4)Magro L. 5)Viola E. 6)Gonella LA. 7)Stoppa G. 8)Lora R. 9)Pagliarini M. 10)Leone R. 11)Moretti U.

*University of Verona*

Adverse drug reactions (ADRs) are a well-recognized public health problem and a major cause of death and hospitalization. Underreporting is the major issue that undermines the effectiveness of spontaneous reports. Healthcare professionals and consumers can report using paper, telephone or e-mail but in many countries web-based system or specific Apps for smartphone are available for the purpose. The recent European law on Pharmacovigilance (PV) requires National PV Centres to setup web-based systems for reporting. In Italy ADRs reporting via web is now possible thanks to the collaboration between the Italian Medicines Agency (AIFA) and the University of Verona, where the Regional Pharmacovigilance Centre of Veneto region is located. The new web-reporting platform is called VigiFarmaco ([www.vigifarmaco.it](http://www.vigifarmaco.it)). This study aims to verify the impact of its implementation on underreporting in Italy. The web-based system for reporting is available in Veneto Region since January 2014, from September to December 2015 it has been extended to other 7 Italian regions and in 2016 to whole Italy. However, the possibility to use the system for reporting ADRs has been published in the AIFA homepage at the end of February 2017. The number of reports sent through the web constantly increased in the last 3 years. In Veneto Region the web-based reports represent about 50% of total reports in 2016. Up to April 30th 2017 about 19,000 web-based reports were received through VigiFarmaco (11.2% of total reports), respectively 1,073 in 2014, 3,417 in 2015 (+218%) and 9,988 in 2016 (+192%). In the first 4 months of 2017 the number of reports was 4,521, with a 57% increase compared to the same period in 2016. The total number of reporters, however, is similar in the three years (about 13,500 reporters), with a low incidence of reports by consumers. The reporters that use the web-reporting platform were 417 in 2014, 1,020 in 2015 (+145%) and 2,128 in 2016 (+109%). In the first 4 months of 2017 the reporters in VigiFarmaco were 1,572 with an increase of 60% compared to the same period in 2016. The availability of a web-based system for ADRs reporting had a big impact on the Italian spontaneous reporting system, leading to a faster and more efficient evaluation of the report by the local, regional and national Health Authorities and a significant reduction on the work of health operators in Local and Regional PV Centres. However, the diffusion of the system is strictly related to the advertisement on the web, in particular to the link to VigiFarmaco in the AIFA homepage. Since this link has been inserted only two months ago the impact on underreporting is still limited. The number of reporters has had no significant increase in the last three years, even in the Veneto Region, which suggests that the increase of the number of web-based reports is related to a shift of usual reporters from paper to the web, with a limited capability to attract new reporters in the system. The insertion in AIFA homepage of the link to VigiFarmaco could lead to a bigger impact in the next months.