



ISSN: 1697-090X

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Rev Electron Biomed / Electron J Biomed 2011;2:10-12.

Editorial:

PHARMACOVIGILANCE

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In accordance with the definition established by the World Health Organization (WHO), Pharmacovigilance is the science that collects, monitors, investigates and evaluates the information on the effects of drugs, biological products, medicinal plants, and traditional medicines, in order to identify new adverse reactions, to determine their frequency and prevent danger to patients. To achieve this, WHO established the International Pharmacovigilance Program in 1968 with the idea of pooling all the existing data on adverse drug reactions¹.

Arising from this initiative the Health Authorities of each country have drawn up precise guidelines to protect patients from possible damages from drugs. The Spanish Pharmacovigilance System (SEFV) comprises the Pharmacovigilance Centres of each Autonomous Community, the Spanish Medicines Agency (AEMPS) and health professionals. Royal Decree 711/2002, of 19 July, is the law that regulates the pharmacovigilance of drugs for human use in Spain².

One new aspect of European legislation on Pharmacovigilance is the encouragement of direct notification by the public of suspected adverse

reactions that they detect³; for this reason, notification by patients and users will be of great importance in the future.

In Spain, notification of an adverse reaction is made using a yellow card system communicating this fact to the pharmaceutical industry or to Regional Pharmacovigilance Centres, with the current possibility of on-line notification⁴.

The interest of the scientific community on the problems arising from adverse reactions is obvious by the increased number of publications observed in the last few years. Thus, the publication of suspected adverse drug reactions, which include those found in phytotherapy, alternative medicines, vaccines or other biological or health products is important for post-marketing surveillance. For this reason, it is recommended to follow the directives supported by the International Society for Pharmacoepidemiology (ISPE)¹ and the International Society of Pharmacovigilance (IFoP)⁶.

Another important facet are the activities or projects associated with the teaching and learning of skills by students or health personnel on the subject of Pharmacovigilance, highlighting, within this training dimension, the existence of courses enabling the student to widen these skills by studying for a Master's Degree⁷.

Pharmacovigilance also has a research aspect related to the use of drugs and their impact on the population; this has led to Pharmacovigilance Centres participating in different projects, such as pharmacoepidemiological studies, studies to stimulate notifications, and observational studies on this aspect, and cost-effectiveness studies, where the results would subsequently be communicated in literature sessions, presentations at conferences, and publications.

Among the research projects, highlighted for its relevance, is the "EUDRAGENE project" on the influence of genetic polymorphisms in serious adverse drug reactions⁸; an international project funded by the European Commission, and which attempts to genetically identify populations at risk of developing serious adverse drug reactions; a new working hypothesis that has generated a sense of great expectancy among the scientific community⁹.

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