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Portuguese pharmacovigilance system

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Abstract

Pharmacovigilance is related with detection, evaluation, understanding and prevention of adverse drug reactions (ADR) and other drug-related problems and emerged in the beginning of the sixties following the thalidomide tragedy. It is important to promote and disseminate information related with ADR.

The Portuguese National Pharmacovigilance System (PNPvS) was created in 1992. Was implemented as a central structure, and was decentralized in 2000, being created regional units what allowed the approximation of health professionals and involvement of Universities to promote its technical and scientific competences, promoting and increasing ADR reporting.

Pharmacovigilance Systems monitor drug safety with methods as signal hypotheses generators (e.g.: spontaneous reporting), generators and hypotheses verifiers and hypotheses verifiers.

Spontaneous reporting is of major importance to PNPvS, and is an efficient method of signal generation. In Portugal, spontaneous reporting has been evolving positively, being closer to WHO recommendations of 250 reports/million inhabitants, and are from pharmacists, physicians, nurses, pharmaceutical industry, and recently from patients (since July 2012). In 2012, pharmaceutical industry contributed with a significant number of ADR reports.

The European Directive 2010/84/EU added to adverse drug reaction definition suspects of overdose, misuse, abuse and medication errors and occupational exposure, bringing to pharmacovigilance all the risks associated to drugs use. The changes in the pharmacovigilance legislation are conducted aiming the prevention and reduction of the probability of ADR associated with medicines exposure, or in case of occurrence, minimizes its risk. The new legislation turns pharmacovigilance systems more proactive and Risk Management Plans more effective.

Biography

Maria Teresa Herdeiro is a Pharmacist, with European PhD in Public Health (University of Santiago de Compostela) and Master in Food Sciences and Engineering. Is Specialist in Regulatory Affairs (College of Pharmacists). Is Professor Coordinator and Assistant Professor in CESPU, and Invited Assistant Professor in University of Aveiro. Is Scientific Consultant in the North Pharmacovigilance Unit, Medicine Faculty of Oporto.

Has several papers published about Pharmacovigilance, in journals as JAMA, Drug Saf., Int J Antimicrob Agents, Int J Clin Pharm. Has a Post-Doctoral fellowship from Fundação Ciência e Tecnologia (FCT) and is a Principal Investigator in an FCT financed project.