

ABSTRACT

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Title of Thesis **Pharmacovigilance: Drug regulation development and legislation overview.**

Introduction: Pharmacovigilance is a scientific discipline relating to the detection and evaluation of adverse drug reactions and other risks associated with the use of the medicinal products after marketing authorisation and implementation of the risk minimisation measures.

Objectives: To analyze the legislation requirements in the area of pharmacovigilance for the medicinal products for human use in the European Union and their implementation in practice. Trends in adverse drug reactions reporting in the various pharmacovigilance systems (United States, Czech Republic, European Union), evaluation of the factors affecting reporting and the main benefits of spontaneous reporting.

Methods: The legal requirements of the European Union, the Czech Republic and the United States was used as the source of information, followed by the official website of the Drug Regulatory Authorities, the best practices guidelines prepared by the European Medicines Agency and by the Food and Drug Administration, the harmonization guidelines issued by the International Council for the Harmonization of Technical Requirements for Registration and recommendations prepared by the Council for the International Organization of Medical Sciences. For the practical part of the thesis, FDA statistics from the FAERS database, EudraVigilance Annual Reports from 2011 until 2016 and the SÚKL report were used.

Results: The thesis presents a comprehensive overview of pharmacovigilance regulatory requirements for human medicinal products. The practical part focuses on the reporting of the adverse drug reactions that is important in the identification of new pharmacovigilance signals and can have an impact on the benefit risk ratio.

Conclusions: Pharmacovigilance contributes to the protection of public health and to the rational pharmacotherapy by ensuring the maximum efficacy of the medicinal product and risk minimisation. Reporting of the adverse drug reactions represents one of the most important pharmacovigilance tool and reflect the effectiveness of the pharmacovigilance system. The collection of these case reports and the use of appropriate statistical and analytical methods enables rapid detection of new safety issues and regulatory action.