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Civil law aspects of pharmaceutical law

Summary of the doctoral dissertation

The dissertation focuses on civil law situation of participants of the pharmaceutical market under the Polish and EU legal systems. Regulations which govern the testing, advertising and trading of medicines are specific. Pharmaceutical law affects not only commercial relations, but also health of many patients. For this reason, pharmaceutical law mainly regulates administrative measures to prevent negative effects of pharmacotherapy and considerations of the representatives of doctrine are focused on public law aspects of pharmaceutical law. However, it should be remembered that even the most-efficient administration can not prevent all illegal practices, their negative effects and damages arising from proper pharmacotherapy. Therefore civil law protection of consumers seems to be equally important. It should be strong, but the legislator also has to take into consideration interests of entrepreneurs. Otherwise, they will be disinterested to operate on the pharmaceutical market and the development of medicine will be stopped.

The dissertation is an attempt to fulfil the gap in research on pharmaceutical law. It is divided into four chapters.

The first chapter consists preliminary considerations. It is divided into three parts. The first part concerns the history of Polish pharmaceutical law, especially from the beginning of the 20th century. In this part, the evolution of legal solutions is presented in order to answer two questions. Firstly, is the axiology of pharmaceutical law universal, independent of political and economic system? Secondly, what is the significance of historical interpretation for the interpretation of the contemporary pharmaceutical law? The second part discusses the sources and systematics of pharmaceutical law and the basic legal definitions which are set out in the Polish law and EU directives from 2001. This analysis is necessary to understand further considerations. The third part analyses liability for damages arising

from medicines. The considerations concerned in this part are devoted to the premises of liability for the medicines as a dangerous products, duties of the manufacturer and duties of the liable entity.

The second chapter concerns civil law aspects of clinical trials. It is divided into three parts. In the first part legal definitions of: clinical trial, investigational medicinal product, subject of clinical trial, informed consent, sponsor, investigator and team of investigators; are analyzed. This is necessary to lay down relations between Polish Pharmaceutical Law Act and EU Regulation 536/2014. The considerations contained in the second part focus on the liability incurred by sponsors and investigators arising from investigational medicinal products. The principles of this liability, duties of the sponsor and the investigator under Polish and EU law are discussed in this part. Based on this, legal protection of subjects of clinical trial is evaluated. The subject of research in the third part is contractual legal relationships related to the conduct of clinical trials. Nowadays, it is difficult to properly perform clinical trials without the help of other entities. Therefore, the scope of freedom of contract in the market of experiments with the use of medicines affects number of experiments, quality of experiments and the progress of medicine.

The third chapter is devoted to advertising medicinal product. This chapter consists three parts. The first part concerns legal definition of the advertisement of medicinal product in order to compare the scopes of the Articles 52-64 of the statute from 2001 and other legal provisions that regulate marketing activities. This analysis makes it possible to determine when the promotion is subject to a special legal regime of the Polish Pharmaceutical Law Act. The considerations contained in the second and third parts focus on the premises of the legality of advertising of medicinal product.

The last chapter concerns civil law relationships related to trade of medicinal products. It is divided into three parts. The first part is devoted to the concept and stages of trading of a medicinal product. It includes also considerations devoted to general principles of trading of medicinal products and pharmaceutical brokerage. The second part concerns wholesale trading of medicinal products, especially obligations of an entrepreneur who runs a pharmaceutical warehouse. The third part is devoted to retail trading of medicinal products, especially to obligations of an entrepreneur who runs a pharmacy.

The analysis leads to the conclusion that pharmaceutical law currently in force corresponds to the needs of participants of the pharmaceutical market in principle, but requires changes in some provisions.

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