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Summary of the doctoral dissertation

Illicit trade of medicinal products as an issue of criminal law and criminal policy.

Following thesis is focused on the issue of illegal trade of medicinal products with special emphasis on the latest trends of this activity. Pharmaceutical crime violates fundamental constitutional rule established in the Article 68 of the Constitution of the Republic of Poland, according to which, every citizen have a right to protection of his health, and public authorities provides equal access to healthcare, regardless of material status. Necessity to provide legal protection for life and public health has been emphasized in the international and European legislation, as well as jurisprudence of the CJEU. This problem affects multiple countries and its effects affect not only consumers, but also governments, producers and suppliers.

The reasons why illicit trade of medicinal products is growing are low costs of producing counterfeit pharmaceuticals and high profit yields, low risk of prosecution and lack of criminal law instruments for countering the phenomena. Demand for illicit medicinal products is growing due to high prices of genuine pharmaceutical, or even lack of availability of genuine products.

Trigger for analysis of this phenomena was lack of comprehensive scientific work on the issue in both Polish and foreign literature.

Aim of the thesis was complex analysis and assessment of criminal law provisions aiming at countering illicit trade of medicinal products in the international law, law of European Union, as legal systems of the select Western European countries. Those regulations were compared to provisions enacted in Polish law and actual operations of law enforcement and judiciary. Main hypothesis is therefore that criminal law provisions and resources on the law enforcement and judiciary side are inadequate to counter pharmaceutical crime.

In order to verify hypothesis three points of view have been considered: criminology, criminal law, and criminal policy, therefore thesis analyses the issue on multiple level. Regarding research methodology, dogmatic-legal and comparative method has been used to

analyse current legal provisions aiming to counter illicit trade of medicinal products, furthermore solutions implemented in selected Western European countries, as well as functioning in international and European law. Historical method has been used as well to analyse development of criminal law provisions used for countering pharmaceutical crime.

In order to confirm or falsify research hypothesis, subsequent steps of research has been described in five chapters.

First chapter deals with phenomenology and theology of illicit trade of medicinal products, describing its scale, current trends and cause of growth of the activity. Those reflections have been preceded by explanation of key definitions important for properly defining criminal liability.

Second chapter presents forms of illegal trade of medicinal products, specifically counterfeiting, theft, supplying products without licence as well as illegal export of the products. Showing different forms of illegal trade of medicinal products aims to present how varied and diverse are criminal activities, leading to significant challenges in countering them. Currently European and international puts most weight on countering counterfeiting of medicinal products. Research however shows that all mentioned forms of pharmaceutical crime pose significant threat to pharmaceutical industry and consumers.

Last 10 years showed significant increase of interest in phenomenon of illegal trade of medicinal products on international stage, with special focus on counterfeiting of medicinal products. In 2011 two important legal instruments have been enacted: European Parliament and Council Directive from 8th of June 2011, introducing multiple provisions aiming at more effective prosecuting relevant criminal activity and controlling legal supply chain, and Medicrime Convention.

In the third chapter most important resolutions of the Directive and Convention are presented, analysed and assessed. Due to legal character of both acts, Directive serves fundamental role in countering pharmaceutical crimes, as it obliges all member states to introduce their articles into national legal systems, on the contrary signing and ratification of the Convention is not obligatory. As such, second part of the third chapter is dedicated to comparative analysis of four European countries: United Kingdom, France, Germany, and Italy with aim of presenting to what degree articles of the Directive have been introduced into legal system in order to assess whether introduced implementations can be especially highlighted and possible introduced similar measures in Polish legal systems.

Continuation of this analysis is chapter four, analysing legal measures enacted in Polish legislation in terms of introducing to distribution medicinal products without license,

counterfeiting them, and illegal export. Presentation of particular legal solutions aims to show whether and to what degree they are adequate to contemporary criminal activity and to what degree resolutions of the Directive have been introduced to Polish legal system. Analysis have been preceded by presenting origins of the legal measures, showing that they are reactive to criminal activity, and novelizations are just response to current state of knowledge of law enforcement about the phenomenon. Furthermore, chapter describes criminal provisions of the Polish Penal Code as well as act on industrial property, which are complementarily used by law enforcement for countering pharmaceutical crime.

Conclusion of the thesis is fifth chapter, dedicated to presentation of empirical research: statistical, analysis of case files and interviews with prosecutors supervising preliminary investigations in case of illicit trade of medicines. Analysis of research aims to show estimated scale of the activity, and more importantly, knowledge and approach of law enforcement and judiciary towards presented phenomenon, but most of all, to confirm or refute established hypothesis.

Keywords: medicinal products, illegal trade, pharmaceutical crime

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