

Toruń, 11.02.2020

Mgr Anna Sporczyk-Popielarczyk
Unit of Civil Law and Civil Procedure Law
Faculty of Law and Administration
Nicolaus Copernicus University in Toruń

Legal status of the entrepreneur operating pharmacies under the Polish law

Summary of the doctoral dissertation

The functioning of the free market economy is inseparably connected with the freedom of business for entrepreneurs. This freedom includes voluntary business activity, its operation and termination. As a rule, the entrepreneur is entitled to choose the market in which he or she shall operate. There are, however, areas in which the economic freedom of an entrepreneur is more or less restricted due to important public interest. One of the markets, under which the freedom of business activity is subject to restrictions, is the pharmacy market.

The issue of the legal status of an entrepreneur running pharmacies under the Polish law has not been researched yet. Publications and monographs available on the market deal primarily with topics related to pharmaceutical law issues in the strict sense, such as trade in medicinal products or reimbursement of medicines. However, one can see a gap in the research in regards to the entrepreneur who runs pharmacies, his/her participation in civil law transactions and the role he/she plays in the medicaments distribution system. At the same time, recently there has been a noticeable increase in interest in these issues, both in literature and journalism. Many issues are arousing more and more interest in mass media (among others the concentration of pharmacies in the hands of one entrepreneur or the prohibition to advertise pharmacies).

This doctoral dissertation aims to provide a detailed analysis of the legal status of the entrepreneur who runs pharmacies. The author makes the thesis that the mentioned

entrepreneur is a special type of an economic operator. On the one hand, his/her activities on the market are monopolistic, since *de lege lata* it is only in pharmacy that are allowed to sell prescribed medicinal products. On the other hand, a number of requirements and obligations have been imposed on the entrepreneur operating pharmacies, which significantly limits his/her full freedom of business. In the content of the dissertation, the author attempts to prove the thesis that the special nature of the business conducted by the pharmaceutical entrepreneur has a fundamental impact on the scope of freedom of this activity.

The subject of discussion in the respective chapters are research problems concerning different aspects of the entrepreneur running pharmacies.

The first chapter presents the historical context and legal basis of regulations related to running pharmacies in Poland from the twenty-year interwar period till the contemporary times. It also presents the development of entrepreneurial activities in the field of pharmacy in the light of EU pharmaceutical law and national health systems in some European countries. This chapter introduces the concepts of a “pharmaceutical entrepreneur” and “pharmaceutical business activity”.

The second chapter encompasses an analysis of the legal situation of the entrepreneur running pharmacies in the civil law transactions. Three stratum of pharmaceutical business activity control have been subjected to detailed research: the subject stratum, the object stratum and the demographic and spatial stratum. In this chapter the author has analyzed the pioneering and not researched so far aspects: the issue of the pharmacy enterprise and its two important components, *i.e.* designation of the pharmaceutical entrepreneur and a license to operate the pharmacy.

The subject of consideration in the third chapter is the Polish system of distribution of medicinal products. This part of doctoral dissertation presents entities participating in a typical distribution chain and analyzes the bond relations between participants in this chain. Particular attention has been paid to the issue of anti-concentration limits in regards to the number of pharmacy companies being operated. The chapter also highlights the franchise as a specific form of performing pharmaceutical business activities.

The fourth chapter is devoted to the issue of the participation of the pharmaceutical entrepreneur in the medicine reimbursement system. This chapter analyzes, in terms of civil law, individual bond relationships between entities participating in the refund system.

The question of contracts for issuing a prescribed refunded medicine has been discussed. A significant part of the chapter is the proposal to confront the medical prescription from the point of view of the structure of the general remittance, and an attempt to classify it as a “reimbursement remittance by name”.

In chapter five, the mail-order form of marketing of medicinal products developed in the last decade has been analyzed. The focus of this research study is determination of the extent to which mail-order sales of medicines in so-called e-pharmacy differs from selling medicinal products in a stationary pharmacy. Indication of the degree of restrictiveness of the requirements for mail-order sales of medicinal products constitute the objective of this chapter.

Chapter six provides a detailed discussion of the issues of advertising the activity of pharmaceutical entrepreneur in the light of the constitutional freedom of conducting business activity. The chapter presents the scope of the prohibition to advertise the pharmacy, and attempts to examine its compliance with the principles of freedom of economic activity, freedom of expression and specificity of legal regulations.

Chapter seven discusses the issue of pharmaceutical confidentiality. The evolution of legal and non-normative regulations related to this issue has been outlined. The subject of precise research in the chapter is the not researched yet issue of the scope of the duty of the pharmaceutical discretion in terms of subject, object and temporal.

Chapter eight is devoted to the issues of civil liability of an entrepreneur operating pharmacies. This chapter details the various regimes for this liability, depending on the event causing the damage. Typical situations are presented in which specific actions or omissions of the pharmaceutical entrepreneur result in tort or contract liability.

Chapter nine summarizes any special characteristics of the entrepreneur who runs pharmacies against the backdrop of the civil law transactions. This chapter contains conclusions and theses that summarize the entire research study comprised in the doctoral dissertation, it also includes some postulates *de lege ferenda*.

In the doctoral dissertation, the research has been conducted using a legal-dogmatic research method based on the analysis of legal provisions, judicial decisions and non-normative acts. A historic method that shows changes in legislation has also been used. The research mainly relates to the Polish legal order, however, in terms of individual

problems, the author also refers to the EU regulations and to national systems of some European countries.

The consideration included in the study are based on the provisions of law dating back to the February 1, 2020.

Anna Sporczyk-Popielarczyk