Protection Guarantee of Public Health in the Functioning of the Pharmaceutical Market based in the Theory of State Interference in the Economy*

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Abstract:

Purpose: The aim of this article is to analyse legal solutions determining the principles of undertaking and performing pharmacy activities in Poland, with particular emphasis on the importance of these solutions to guarantee the public health protection in terms of theory of state interference in the economy.

Design/Methodology/Approach: The article uses the method of analysis of legal regulation and the descriptive method.

Findings: The object of pharmacy’s activities is the provision of pharmaceutical services that remain in the domain of practising the profession of pharmacist as a profession of public trust. The provisions of Polish Pharmaceutical Law, shaping the principles of rationing pharmaceutical activities in Poland, and thus determining the subjective structure of the pharmacy market, have undergone a particular change, which entered into force on June 25, 2017, giving rise to polarization of participants in the pharmacy market for entrepreneurs.

Practical Implications: Considering the existing differentiation of the pharmaceutical activities model, it is necessary to assess the legal conditions of the public health protection guarantee in the field of the entrepreneur’s social interest. This assessment should concern both running a pharmacy by a non-pharmacist and an entrepreneur with the right to practice as a pharmacist. Recognizing the close correlation between the economic objective and the public objective of the pharmacy activities, the question should also be asked about the significant changes in Pharmaceutical Law aimed at strengthening the pharmacist’s position as an important participant in the market of pharmacy services.

Originality/Value: The implementation of the public health care facility function by the generally accessible pharmacy is in line with the context of public health protection guarantee in the field of the functioning of the pharmacy market, both in terms of the principles of undertaking pharmacy operations as well as legal solutions that determine the pharmacy management model.

Keywords: Economy, pharmacy activities, public health, pharmaceutical law.

JEL Code: E62, K20, K32.

Paper type: Research study.

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1. Introduction

The pharmaceutical service is a special type of benefit aimed at the sphere of basic personal human rights: health and life, covered by the qualifications of practising the profession of pharmacist as a profession of public trust. In the socially most important categories of pharmaceutical services, this benefit remains in the sphere of pharmacies' activities. According to Art. 86 par. 2 of the Act of 6 September 2001 Pharmaceutical Law (consolidated text Journal of Laws of 2020 item 944, as amended – hereinafter: Pharmaceutical Law or a.p.l) the name of the pharmacy is reserved exclusively for the place of rendering pharmaceutical services, including:

- issuing medicinal products and medical devices, specified in separate regulations;
- preparation of prescription drugs within 48 hours from the submission of a prescription by the patient, and in case of prescription for a prescription drug containing narcotic drugs or labelled "to be issued immediately" - within 4 hours;
- preparation of pharmacy drugs;
- providing information on medicinal products and medical devices.

The provision of a pharmaceutical service in the field of services of a generally accessible pharmacy remains subject to the rules of economic activity covered by the constitutional principle of economic activity freedom, which due to the special character and social significance of pharmacies' activities for the public interest, understood as public health protection, remains legally restricted in a significant way. The admissibility of this type of restriction is indicated in Art. 22 of the Constitution of the Republic of Poland (Journal of Laws of 1997 No. 78, item 483, as amended), according to which the restriction of freedom of economic activity is permissible only by law and only for important public reasons. The state's rationing of undertaking pharmacy activity by granting permissions to operate a pharmacy by the authorities of the State Pharmaceutical Inspection is considered to be the most significant indication of the restriction of pharmaceutical activities.

According to Art. 99 par. 1 a.p.l. a generally accessible pharmacy can be run only on the basis of the obtained permission. Carrying out pharmacy activities as part of running generally accessible pharmacy is characterized by a specific dualism of objectives, i.e. an economic objective and a public objective. In economic terms, a generally accessible pharmacy is an enterprise, i.e. in accordance with art. 55\(^1\) of the Act of 23 April 1964 – Civil Code (consolidated text Journal of Laws of 2019, item 1145, as amended – hereinafter: C.c.) an organized set of intangible and tangible assets intended for conducting economic activity. In the above approach, a generally accessible pharmacy is an economic unit whose pursuit is determined by market mechanisms subjected to a certain scope of regulation of public authority organs and aimed at achieving the expected economic effect in the form of profit.
The generally accessible pharmacy activity perceived in this way, however, remains determined and limited by the overriding and statutory public objective, that is public health protection. According to Art. 86 par. 1 a.p.l. the pharmacy is a public health protection facility, in which the entitled persons provide in particular pharmaceutical services, which gives the indicated public objective priority over the economic objective, thus giving the economic conditions and objectives of generally accessible pharmacy activities a subsidiary character. The indicated dualism of the objectives of a generally accessible pharmacy, detailing the absolute priority of the pharmacy's objective of public health protection, makes the question legitimate about guarantee of public health protection in the sphere of functioning of the pharmacy market, both in the context of polarization of the nature and qualifications of business entities running pharmacies, as well as the pharmacy management model in terms of Pharmaceutical Law regulations and judicial decisions. Considering the indicated directing activities of generally accessible pharmacies on the sphere of the public interest protection with simultaneous limitation and subsidiarity of the individual entrepreneur's interest, the above considerations should be referred to the theory of state interference in the economy.

2. Literature Review

In the scope of analysing the admissibility of state interference in market mechanisms, the existing relationships between transaction costs and market failure conditions are important, to which mainstream economics include market strength, external effects, public goods, and imperfect information. Asymmetry, distortion, and interference of information lead to the problem of knowledge about private benefits and costs, i.e. they cause external effects and their special cases in the form of public goods. These factors also raise transaction costs that prevent the solution of the problem of external effects through a private contract, which creates the need for state intervention, however, provided that the benefits of undertaking this intervention outweigh its costs. The concept of transaction cost can be used both to prove premises about market failure and premises about government failure, as restrictions on private contracts are strongly dependent on the quality of formal regulations for which public authorities are responsible. Transaction costs treated as operating costs of the economic system are a more general category than the category of market failure, because in some cases they constitute a blockage for the emergence of markets (Arrow, 1969).

Therefore, the reason for state interference in the economy can be defined as the inability of private markets to supply certain goods in general or in the most expected way, which is connected with the problem of insufficient supply of certain products or services (Pearce, 1992). Market imperfections are often interpreted as situations in which decisions taken by market participants do not lead to maximizing the benefits of the most efficient resource allocation. Market imperfections appear when the market system, unlimited and left to free mechanisms, does not lead to
optimal allocation of resources, appropriate prices or production, generating socially unacceptable results (Wampler and Touchton, 2019). From the point of view of the analysis of state aid institutions, the following market failures are of the greatest importance (Meiklejohn, 1999): market power, external effects, increasing returns to scale, public goods, merit goods, imperfect or asymmetric information, institutional rigidities, imperfect mobility of production’s factors, frictional problems of adjustment to changes in markets, and subsidization by foreign competitors.

Market power is associated with imperfect competition, and especially with the existence of monopolies in some markets, infringement, or distortion of competition. The abuse of market power means a situation in which one or more entities can influence the price system or level of production. As a result of the fact that entities operate in an imperfectly competitive or even monopolized market, they can thus acquire a more privileged market position, which in consequence leads to inefficiency of the allocation system and higher prices (Strebel, Kubler, and Marcinkowski, 2019).

In many cases, the market mechanism is distorted by external effects in the form of social benefits and costs that are related to the fact that the activities of market participants affect external third parties, i.e. persons other than direct producers or consumers (Neven and Verouden, 2008). The effects of positive external effects (benefits) and negative external effects (costs) are borne by third parties and on both the consumer and producer side they are not offset by the price of the goods. Positive external effects are associated with the free-rider problem and occur when entities use the activities of third parties without incurring any costs. In turn, negative external effects occur when third parties bear the costs associated with the activities of other entities (e.g. environmental pollution). This means that the production of such goods by enterprises does not guarantee the fulfillment of the condition of maximizing benefits, which makes it necessary for the state to provide these goods due to the lack of profitability of their production from the point of view of individual producers. Premises for insufficient supply of certain products or services include the inability to allocate private benefits and costs, the difference between social and private benefits, and the existence of benefits and costs also affecting entities other than those directly involved.

In such a situation, state intervention is justified by the need to stimulate the desired allocation of resources and a fair distribution of the costs of goods that are socially important and occur on a sufficiently large scale. In addition, public aid will be acceptable if the effect of support granted from public funds is a surplus of social benefits over private ones due to the phenomenon of diffusion, i.e. the "spreading" of benefits outside the group of direct beneficiaries (Kolstad and Wiig, 2019).

Certain markets may also be inefficient due to the character and nature of broadly understood public goods, which are characterized by the inability to exclude anyone
from their consumption and lack of competition, which means that consumption by a
given entity does not violate the consumer's abilities of other entities (Stiglitz, 2000).
The manifestations of market failure that result from the existence of public goods is,
on the one hand, the insufficient supply of public goods, as they do not allow
economic efficiency to be achieved, and on the other hand it is a "free-rider
problem", which results from limited possibility of exclusion (Kleider, 2018). Lack
of exclusion in the case of public goods or limited possibility of exclusion in the
case of merit goods mean that private entities do not tend to provide them (Font,
Smith, Galais, and Alarcon, 2018). A shortage or even lack of such products and
services would, however, result in the loss of social benefits, which gives grounds
for justifying state interference in the economy (Kasper and Streit, 1998).

In the perfect competition model, market participants have excellent information
(Holzinger and Knill, 2005). In fact, however, this information is often imperfect,
which means that entities have different information, and some market participants
may have better information than others (Midtbø, 2018). This imperfection may
result from incomplete information, lack of access, incorrect transmission, but also
from the occurrence of the phenomenon of uncertainty and risk or the problem of
information asymmetry. Asymmetry and distorted information mean that prices do
not reflect the real value of goods and services (Ferreira da Silva and Costa, 2019).

Empirically it was proved by G. Akerlof by analysing the used car market, where
due to incomplete information on product quality, both valuable products and low-
quality products have similar prices, which ultimately causes defective goods to
dominate in the market (Akerlof, 1970). Akerlof, referring to the law of Copernicus-
Gresham about "money spoilage", described the displacement of inferior goods in
favour of poor quality goods as negative selection, which describes the interaction
between the difference in the quality of goods and the uncertainty regarding this
quality. This means that prices do not provide information between market
participants that guarantees the selection of products and services corresponding to
the offered price and decisions regarding the purchase of specific goods may be
incorrect (Genschel and Jachtenfuchs, 2011).

To indicate the asymmetry of information as a premise for market failure, economic
theory puts an additional condition, i.e. separation of ownership from control.
Relationships regarding the behaviour of entities in this case are explained by the
agency's theory pointing to the relationships between the "agent" and "principal" that
arise when one party (agent) takes action on behalf of another party (principal). In
the principal-agent relationship, the information that is only available to the principal
plays a determining role, and the relationship itself consists in delegating the
principal's powers to the agent. Therefore, it is a contract in which one entity
transfers part of their rights to another, performing services on behalf of the former,
which is the most common codification of the ways of social interaction (Ross,
1973; 1979). In addition, moral hazard may appear in the principal-agent
relationship as a result of information asymmetry. This will happen when the agent acting on behalf of the principal has more information about their actions and intentions, and the principal is not able to completely control the agent who can make risky and incorrect decisions from the principal's point of view. Therefore, moral hazard can result from a situation in which decision makers do not bear the full consequences of these behaviours, hence the actions taken are less cautious and riskier. The moral hazard can be interpreted as behavior that is characterized by a high propensity to take risks in the belief that any consequences of the decisions taken will not be borne at all or will be incurred by another entity, and the potential benefits of these decisions will show high rates of return.

Consequently, the symptoms of information asymmetry are: 1) negative selection, which occurs when, due to a lack of information about a good with greater usability, a good with less usability is chosen (the example of the used car market mentioned above), 2) the opportunism of the agent that occurs when the one with the information advantage in order to maximize their own benefits does not provide the principal with adequate information (e.g. due to the employee's information advantage over the employer as to the value of work and actual effort, similar remuneration may be paid to both valuable and unreliable or not very competitive employees), 3) the danger of abuse, which refers to the situation in which an entity, having more knowledge and not bearing the full costs of their decisions, acts in a manner detrimental to other market participants.

For example, too high interest rate on a bank credit attracts unreliable customers assuming non-payment of debt in advance, which causes banks to reduce interest rates in order to lower the repayment barrier and when the demand for money increases, the necessity to limit the credits granted arises, i.e. the reduction of money supply (Stiglitz, 2002). The task of the state should be to influence the cause and reduce information asymmetry. State intervention is justified because there is a sufficiently large scale and weight of market failure, the inability to ensure the supply of specific goods by the market, and the state has a greater ability to create effective incentives and to apply a mechanism of coercion to suppliers in the field of publishing reliable information about the offer. In addition, public institutions have more complete knowledge and capacity to coordinate the market than individual market participants (Greenwald and Stiglitz, 1986).

When analysing the problem of market failure, the main sources of its imperfections include the lack of institutional rigidities, which is evident, for example, in the field of legislation, low and imperfect mobility of production’s factors, and providing justification for restructuring processes frictional problems of adjustment to changes in markets and subsidization by foreign competitors (Ismer and Piotrowski, 2018). In addition, among the main manifestations of the inefficiency of the market mechanism, in addition to market strength, positive and negative external effects, the occurrence of public goods and the imperfections of the information, one can also
point to the need to redistribute income in society, the emergence of economic imbalance associated with the phenomenon of inflation, unemployment or a decrease in production or market shortages. Market failure may also be caused by problems with the coordination of activities of different participants in such a market, where the costs of concluding contracts, uncertainty as to the result of cooperation and network effects prevent the effective preparation or even the conclusion of contractual agreements, thus leading to inefficiently low levels of coordination and production.

The literature indicates that coordination problems can occur mainly in the mechanism for setting technological standards, in the case of transport infrastructure or in the field of innovation (David, 2002). The essence of this mechanism is the market selection of a good characterized by not more perfect technology and preferred parameters, but a good that is more popular. This means that the preferred standard is not technologically more perfect, but more common, which is the main manifestation of market failure in the perspective of external effects of the network. In such a situation, the justification for public intervention is the state's ability to coordinate the market in order to slow down the adoption of the standard and provide reliable information about the technology, stimulate a standard change for more perfect and protect consumers and enterprises with a weaker market position against monopoly by anti-monopoly regulations and case law.

Given that the existence of market failure is a condition without which it is difficult for Member States to justify the granting of state aid, it should be clearly emphasized that a situation in which an enterprise is unable to undertake specific actions without state aid does not necessarily imply the existence of market failure. This happens when the enterprise's decision not to invest in a low-profitable project, or in a region with low demand or low cost competitiveness, does not have to be the result of market failure, but on the contrary - it can be a sign of a properly functioning market (Kemmerling, 2010). It cannot be assumed that aid aimed at increasing production or lowering prices can be justified by market failure, because overcapacity or excessive consumption may be inefficient from the point of view of market operation or even harmful to the economy and society as a whole.

The existence of a market failure can only be considered if it would not be possible to achieve an effective result alone by market forces without state aid. This principle was referred to by R. Coase, who argued that market failures resulting from external effects may not always be the reason for state intervention, because each party, using them or affected by them, can freely negotiate with others to remove these effects (Coase, 1960). In this case, Coase raised the important issue of the impact of external effects and the resulting social costs, noting the importance of property rights and transaction costs. Coase's theorem assumes that the use of clearly defined and explicitly specified property rights for markets in which external effects occur allows entities to negotiate lower costs, thus transaction costs are insignificant. As a
result, the allocation of resources will be effective, because only in a situation where
transaction costs are high and thus limit the ability of entities to make mutually
beneficial transactions, the market allocation of resources is disturbed by the transfer
of property rights, and state regulation can reduce these costs. However, one should
also consider the situation when the introduction of regulation may limit the benefits
of transaction, if this regulation imposes higher costs on market participants. This
means that state interventionism is effective only when there are transaction costs
and the costs resulting from the need to adapt to regulations do not outweigh the
benefits of regulated behaviour.

Coase's new approach to the problem of social and private production costs leads to
modification of conclusions regarding the state's involvement in the economy. He
undermines the assumptions on which A.C. Pigou analysis was based regarding the
discrepancy between social and private cost, and consequently weakens the
arguments justifying state interference in the market mechanism in the event of
negative external effects. Negative external effects cannot be a determinant of state
interventionism if they are considered as a problem of choice in conditions of
scarcity of resources. This thesis implied that in the absence of transaction costs,
negotiations taking place as part of the exchange process, which is understood as the
exchange of property rights between entities or the transfer of legal rights, lead to
maximization of prosperity, which occurs regardless of the distribution of
responsibility for external effects. Free market allocation of resources is therefore
justified when there are no transaction costs, which in relation to reality is a purely
theoretical assumption.

Therefore, the so-called Coase's theorem should not be equated with the statement
that state interference in economic processes must not lead to an increase in
prosperity, but rather with the statement that the effectiveness of state
interventionism should not be presupposed in advance, because it entails costs that
should be taken into account in relation to the benefits of applying certain state
regulations.

3. Methodology

The aim of this article is to analyse legal solutions determining the principles of
undertaking and performing pharmacy activities in Poland, with particular emphasis
on the importance of these solutions to guarantee the public health protection in
terms of theory of state interference in the economy. The article uses the method of
analysis of legal regulation and the descriptive method.

4. Research Results and Discussion

4.1 Duality of the Position of Participants in the Pharmacy Market
When considering the guarantee of public health protection in the sphere of the functioning of the pharmaceutical market, it is necessary first of all to indicate the rules and limitations of undertaking pharmacy activities as a determinant of the ownership structure of the pharmacies market in Poland. Undertaking pharmacy activities remains conditioned by the verification of the implementation of the conditions formulated by the provisions of the Pharmaceutical Law and the specification of the right to run a pharmacy by a given entrepreneur, made in the form of a decision by a provincial pharmaceutical inspector who is a local government administration authority. The legal principles of undertaking pharmacy operations in Poland have changed fundamentally in 2017 under the Act of 7 April 2017 amending the Act – Pharmaceutical Law (Journal of Laws of 2017, item 1015 – hereinafter referred to as: a.a.p.l.) which entered into force on June 25, 2017. The indicated change in the provisions of the Pharmaceutical Law was aimed at the appreciation of the pharmacist's position as a participant in the pharmacy market, including in particular through the conditioning granting permission to operate a pharmacy from having the right to practice as a pharmacist by the person applying for its issue (or by each partner of the applicant company). According to Art. 99 par. 4 a.a.p.l. the right to obtain a permission for running a generally accessible pharmacy is acquired by:

- a pharmacist holding the right to practice, as referred to in Art. 4 and Art. 4b of the Act of 19 April 1991 on Pharmaceutical Chambers (consolidated text Journal of Laws of 2019, item 1419, as amended), running a sole proprietorship;
- a general partnership or a professional partnership whose subject of activity is solely the management of pharmacies, and in which associates (partners) are only pharmacists with the right to practice.

The above requirement makes it impossible to grant permission to operate a pharmacy to other entities, however, pursuant to Art. 2 par. 2 a.a.p.l. permissions for running generally accessible pharmacies issued before the Act comes into force shall remain valid. The indicated change, referred to in the public discourse as a "pharmacy for a pharmacist", is in essence a highly expected change.

Having regard to the supremacy of the pharmacy's implementation of the objective of protecting public health in relation to the achievement of the economic objective, pursuing the pharmaceutical market's determination by pharmacists as sole owners of newly-opened pharmacies should be considered justified and consistent with the assumptions of the public health protection guarantee in the sphere of functioning of the pharmacy market. The importance of a pharmacist as an important participant of the pharmaceutical market not only in the area of professional activities, but also in the sphere of economic activity, cannot be overestimated in the context of the pharmacist's importance as a guarantor of public health protection.
The indicated change in the principles of undertaking pharmacy operations is not a change of law expressed through an autonomously shaped effect. This change is conditioned by the total of additional statutory regulations and pharmacist's restrictions on undertaking pharmacy activities, the content and importance of which significantly shapes the overall assessment and the dimension of public health protection.

First of all, it should be pointed out that, in accordance with Art. 99 par. 4 a.p.l., a pharmacist seeking to undertake pharmacy activities is obliged to take it in one of the forms of economic activity indicated by the legislator, i.e. in the form of: 1) sole proprietorship, 2) general partnership or 3) professional partnership. What is important, the above restriction does not apply to entrepreneurs who obtained the permission for running pharmacies (or at least have applied for this permission) before the Pharmaceutical Law amendment came into force, i.e. before June 25, 2017. These entrepreneurs remain entitled to perform pharmacy activities in forms relevant to their current activities, including in the form of a limited partnership, limited liability company and joint-stock company.

The indicated distinction of permissible forms of conducting pharmacy operations may result in significant polarization of the participants of the pharmaceutical market to entities authorized to perform this activity in market-more profitable forms, both in the area of financing operations and responsibility for liabilities and to entities authorized to perform this activity in forms that are less economically favourable. It should be emphasized that the performance of pharmacy activities in each of the currently permissible forms of such activities means full economic liability for the entrepreneur, including personal property. For example, in the case of conducting business activity in the form of a general partnership, in accordance with Art. 22 § 2 of the Act of 15 September 2000 Code of Commercial Companies (uniform text Journal of Laws of 2020 item 1526 – hereinafter: C.c.c.), each shareholder is liable for the company's obligations without limitation with all their assets jointly and severally with the other partners and with the company, subject to art. 31 § 1 C.c.c., according to which the creditor of the company may execute the property of a partner in the event that the execution of the company's assets proves to be ineffective (subsidiary liability of the partner).

Recognizing the legislator's desire to limit the forms of undertaking pharmaceutical activity to forms guaranteeing effective exclusion of non-pharmacists from its scope and exclusion of their influence on the entrepreneur running a pharmacy, it is particularly essential to indicate a limited partnership, whose exclusion from the range of permissible forms of undertaking pharmacy activities may remain the most debatable. According to Art. 102 C.c.c. a limited partnership is a partnership aiming at running a business under its own name, where at least one partner is liable to the creditors for the obligations of the company without restriction (general partner), and the liability of at least one partner (limited partner) is limited. A limited partnership
is a special type of business activity in which the overall decision-making and management competencies remain concentrated on the part of the general partner, while the function of the other partner (limited partner) is in particular to make a specific contribution to the company (monetary or non-monetary), while significant limiting its impact on the sphere of company management and conducting its affairs.

It seems, therefore, that the form of a limited partnership, on the one hand, pursues the assumptions underlying the statutory limitation of the forms of undertaking pharmacy activities, and on the other hand would make a significant contribution to the financing of pharmacy activities by the partner in the role of limited partner. Obviously, the legitimacy of undertaking pharmacy activities in the form of a limited partnership would exist only if the legislator, while allowing such a possibility, also took into account the position of a limited partner as not only a person with the right to practice as a pharmacist, but also a person not holding such a right. Considering the current wording of Art. 99 par. 4 a.p.l. the above considerations may be of importance only in the category of conclusions de lege ferenda.

In addition, the undertaking of pharmacy activities is limited by statutory specific considerations: demographic and geographical, in force from June 25, 2017, pursuant to the above-mentioned amendments to the Pharmaceutical Law, and conditioning the issuing of permission to operate a pharmacy with regard to specific population and location requirements. According to Art. 99, par. 3b, a.p.l. permission to operate a generally accessible pharmacy is issued, if on the day of submitting the application for the permission the number of inhabitants in a given municipality, per one generally accessible pharmacy, is at least 3,000 people and distance from the place of the planned location of the pharmacy to the nearest functioning generally accessible pharmacy, counted between the entrances to the dispensing areas of pharmacies in a straight line, it is at least 500 meters. The number of inhabitants as of the day of submitting the application is determined on the basis of current data of the Central Statistical Office.

The obligation of the conjunctive implementation by the applicant of the demographic factor and geographical factor, makes legitimate not only the question of the legitimacy of restricting access to the pharmacies market for pharmacists intending to undertake to run a pharmacy, but also the question of the impact of the indications on the conditions of activity conducted so far. Regardless of the assessment or importance of protecting public health, perceived in the public interest category, justifies legislative interference, and thus also the state's regulation in the structure of the pharmaceutical market so far, to determine the aspect of the location of pharmacies, it should be pointed out that the above limitation was introduced under the amendment of the Pharmaceutical Law, whose main purpose was to strengthen the position of a pharmacist as a participant in the pharmacy market. Meanwhile, it seems that there is a kind of paradox in the sphere of the above
context. On the one hand, pharmacists have become a legitimate professional group authorized on an exclusive basis to undertake new pharmaceutical activities and to obtain a permission for running new pharmacies. On the other hand, simultaneously introduced restrictions on the location of new pharmacies can significantly reduce the importance of the above-mentioned right *per facta* due to the fact that it can not be implemented in the area of a given municipality.

The above conditioning seems to create a specific dissonance between the fundamental and legitimate aim of amending Pharmaceutical Law consisting in increasing the influence of pharmacists on the pharmaceutical market, and thus on the quality of pharmaceutical services and public health protection, and the regulations determining the achievement of this goal. It should be recognized that the pharmacist's right to undertake pharmacy activities, while strengthening the importance and impact of pharmacists' professional group on the pharmaceutical market, would be possible to the fullest extent and with the most significant effect, in the absence of statutory restrictions on the location of pharmacies. Such limitations make the undertaking of pharmacy activities by a pharmacist dependent on the existing state of the structure and location of pharmacies in a given municipality, shaped by the existing participants of the pharmacy market, which in the extreme situation may lead to the inability to open a new pharmacy.

The indicated demographic and geographical limitations may also constitute an important factor conditioning the possibility of conducting pharmacy activities already carried out. If the entrepreneur running the pharmacy is not also the owner of the pharmacy premises, but only has the right to use the premises for the purpose of running it (e.g. under a lease agreement), assuming a possible expiration of the period of disposing of the right or termination of the contract by the landlord which is the basis for administering this right, the requirement to implement the demographic and geographical factor may constitute a significant impediment or an obstacle to the entrepreneur's continued pursuit of pharmacy activities, e.g. due to the inability to open a pharmacy elsewhere.

The obligation to implement the demographic and geographic factor may also have an indirect meaning on the basis of negotiation or renegotiation of the contract conditions, giving the entrepreneur the right to dispose of the premises for the purpose of running a pharmacy (e.g. in the case of expiry of the lease period) consisting in weakening the negotiating position of the entrepreneur running the pharmacy, for possible inability to run a pharmacy elsewhere.

Considering all the above considerations, it should be recognized that the principles of undertaking pharmacy activities shaped by the change of the Pharmaceutical Law have an important, but also complex in the context of the overall assessment, impact and significance for strengthening the public health protection guarantee in the sphere of functioning of the pharmacy market. On the one hand, the adopted
solutions legitimately promote the position and significance of the pharmacist, as a representative of the profession of public trust and the guarantor of public health protection, in the field of the pharmaceutical market by giving the pharmacist's exclusive right to undertake pharmacy activities and run new pharmacies, on the other hand, the introduced solutions seem to tone up the possibility of implementing such a right, both on the basis of acceptable forms of undertaking economic activity, as well as factors limiting the location of new pharmacies.

As a consequence, the competitiveness of the pharmacist's position in relation to the existing and invariably active participants in the pharmaceutical market remains within the scope of conditions that seem to measure to some extent the expected appreciation and progression of the pharmacist's influence and importance in the field of activity of the pharmacy market entities.

4.2 Protection of Public Health in Terms of the Pharmacy Management Model

Running a generally accessible pharmacy constitutes, regardless of the existing profile of the ownership structure, running a public health facility. Both in the case when the entrepreneur running the pharmacy is a pharmacist, as well as when the entrepreneur is an entity not having the right to practice as a pharmacist, running a pharmacy is absolutely pre-eminent to achieve the objective of public health protection, which is reflected in the statutory determined pharmacy management model focused on protecting the interest and the patient's goods. The indicated conditioning finds basis in the distinction between the prerogatives of the pharmacy owner (i.e. the entrepreneur running the pharmacy), which in particular include the duty to properly run a pharmacy expressed in the proper organization of its activity – and the prerogatives of the pharmacy manager, which include in particular the work organization in the pharmacy.

In the above system of subjective dependencies, the pharmacy manager is important from the point of view of the guarantee of protection of public health in the sphere of functioning of the pharmacy market. The pharmacy manager may be only a person who has the right to exercise the profession of pharmacist and has a specific professional work experience in a pharmacy. According to Art. 88 par. 1 and 2 a.p.l. a pharmacist must be established in a generally accessible pharmacy, referred to in Art. 2b par. 1 point 1, 2 and 5-7 of the Act of 19 April 1991 on Pharmaceutical Chambers, responsible for running a pharmacy, whereby you can be the manager of only one pharmacy. The pharmacy manager may be a pharmacist who has at least a 5-year work experience in a pharmacy or a 3-year work experience in a pharmacy if they have a specialization in retail pharmacy.

The Constitutional Tribunal drew attention to the special importance of submitting professional services rendered by the pharmacy to the prerogatives of people with professional qualifications of pharmacists, as guarantors of protection of public
health and patient's goods, pointing out that "the very fact that someone may be subject to rights and obligations resulting from the economic activity in the form of running a pharmacy, cannot conclude that without having specialist knowledge it is dangerous for legally protected goods. Such a danger may result only from factual activities, and these are strictly regulated and reserved for persons with appropriate qualifications in the area of running a pharmacy" (Judgement of the Constitutional Tribunal of 20/08/1992).

In turn, the Supreme Administrative Court drew attention to the position and function of the pharmacy manager, stressing that "pharmacies conduct activities requiring special diligence and high qualifications in the implementation of tasks, as negligence resulting from lack of diligence and high qualifications of personnel may lead to very serious damages to health, and even to the lives of people using their services. Thus, the requirement of constant, ongoing supervision over their activities by persons with special qualifications and professional experience is evident." (Judgement of the Supreme Administrative Court of 20/02/2019). The above position was occupied by the Supreme Administrative Court in a judgement of special importance for the pharmacy management model.

In the final judgement, the Supreme Administrative Court settled a legal issue regarding the rules of entrusting the replacement of the pharmacy manager, which in connection with the validity of the judgement is of preliminary relevance for decisions made by other courts in this matter. According to Art. 92 a.p.l. a pharmacist should be present during pharmacy activities, mentioned in Art. 88 par. 1. a.p.l. Referring to this provision, the Supreme Administrative Court pointed out that "Art. 92 a.p.l., stating that pharmacist should be present in the pharmacy during the pharmacy working hours, mentioned in Art. 88 par. 1 a.p.l., refers not to the general notion of a pharmacist resulting from Art. 2b par. 1 point 1, 2 and 5-7 of the Act on Pharmaceutical Chambers, but to the one defined in Art. 88 par. 1 a.p.l. of the concept of pharmacist responsible for running a pharmacy, that is, one that meets the additional requirements in terms of work experience specified in Art. 88 par. 2 a.p.l. If legislator in Art. 92 a.p.l. was referring to the definition of a pharmacist within the meaning of Art. 2 b of the Act on Pharmaceutical Chambers, it would refer directly to this provision and not to Art. 88 par. 1 specifying the pharmacist responsible for running the pharmacy” (Judgement of the Supreme Administrative Court of 20/02/2019).

As a consequence, the Supreme Administrative Court emphasized that the position taken was also in accordance with the purposive interpretation of Art. 92 a.p.l. indicating that "it should be considered in accordance with the purposive interpretation such reading of the content of Art. 92 a.p.l., which implies the obligation to ensure the permanent presence in the pharmacy of the pharmacy manager within the meaning of Art. 88 par. 1 and 2 a.p.l., or at least another pharmacist with competences required from the pharmacy manager” (Judgement of
the Supreme Administrative Court of 20/02/2019). The final decision is significant for the previous interpretation of the provision of Art. 88 par. 1 and 2 in conjunction with Art. 92 a.p.l., according to which the replacement of the pharmacy manager for a period of up to 30 days could be made to a pharmacist with the right to practice, and only in the case of a replacement entrusted for a period longer than 30 days to a person with managerial competence under Art. 88 par. 2 a.p.l. - i.e. in accordance with § 11 par. 1 of the Ordinance of the Minister of Health of October 18, 2002 on basic conditions for running a pharmacy (Journal of Laws of 2002 No. 187 item 1565).

The decision of the Supreme Administrative Court excludes this kind of subject differentiation and obliges the owners of pharmacies to provide the pharmacy with the employees meeting the requirements of the presence during the working hours of the pharmacy or at least another pharmacist as an assistant manager, however, with the same managerial competence as a result of having the required length of work in a pharmacy. The indicated resolution of the legal issue of entrusting the replacement of the pharmacy manager remains in close correlation with the expected model of pharmacy management as a special type of enterprise constituting a public health protection facility, and thus fits into the expected dimension of public health protection guarantee in the sphere of functioning of the pharmacy market.

5. Discussion

Actions and interventions on the part of the state, as well as their scope and the limits of the public policy are constantly under discussion. It seems that the increase in the State’s function in the economy, as expressed in the growing number of financial activities and involvement, as well as actions taken in the form of various policies, has a quite objective background, showing first and foremost the increasing diversity of problems of collective nature. According to W. Parsons, public policies” live” thanks to the existence of public problems. If the latter did not exist, there would be no reason to pursue policies or concepts of public actions and interventions (Parsons, 2005).

Public policy is a term referring to both redistribution policies and regulatory policies, to the policies of shaping the institutional structure and the sectoral ones. The essence of public policy lies with the combination of legal and regulatory instruments, which public administration authorities have at their disposal to implement specific actions, with the use of selected tools while maintaining proper financing methods. Such a developed and implemented macroeconomic policy becomes a basis for executive actions in relation to a particular area of problems, where the decisive criterion is the recognition of the public – common – property and obtainment of specific social benefits.
Macroeconomic policy has close ties with structural policy, the purpose of which is to affect the supply-side of the economy, and its full effect will be possible to identify only over a longer period. Those areas of State activity are particularly important in the period of economic crisis, economic slowdown, and its effects in the form of a decrease in production and employment, as well as increase in the budget deficit and public debt. Those effects mostly come down to the change of the volume and structure of goods and services supply in the economy, the structure of incentives affecting the decisions of economic entities, and thereby to the creation of conditions favoring a sustainable economic growth.

When determining the scope, form, and goals of activity in individual fields, public authorities decide on what particular public tasks, and to what extent, will be implemented in a given period and at what level of financial involvement. Those initiatives should first and foremost serve to satisfy particular needs of the society, according to the adopted political doctrine and the conducted economic and social policy.

6. Conclusions, Proposals, Recommendations

Running a generally accessible pharmacy is a special type of economic activity shaped on the basis of the duality of objectives, i.e. the objective of protecting public health and the economic objective, with the absolute primacy of the public objective. The implementation of the public health care facility function by the generally accessible pharmacy is in line with the context of public health protection guarantee in the field of the functioning of the pharmacy market, both in terms of the principles of undertaking pharmacy operations as well as legal solutions that determine the pharmacy management model. Particularly noteworthy is a change in the Pharmaceutical Law stipulating the right to obtain a permission to operate a generally accessible pharmacy exclusively for pharmacists, which despite the specific conditions resulting from both limiting the permissible forms of pharmacy operations and the implementation of demographic and geographical factors determining the acceptability of the pharmacy location, is in essence a change in the expected direction and of significant importance for public health protection guarantee.

In addition, the statutory submission of the pharmacy management model to the distinction of owner prerogatives belonging to the entrepreneur running the pharmacy and managerial prerogatives belonging to the pharmacy manager should be highlighted, with emphasis on the autonomy and the role of the pharmacy manager as the basic guarantor of the objective of public health protection by the pharmacy. Therefore, taking into account all legal regulations determining the undertaking and performance of pharmaceutical activities, the state of existing legal solutions should be considered as providing the basis for a guarantee of public health protection in the sphere of functioning of the pharmacy market, whose meaning is
subject to affirmation in the area of proper observance and application of the provisions of the Pharmaceutical Law.

References:

Judgement of the Supreme Administrative Court of 20/02/2019 reference number II GSK 5609/16, publ. Central Database of Decisions of Administrative Courts (CDDAC).
Protection Guarantee of Public Health in the Functioning of the Pharmaceutical Market based in the Theory of State Interference in the Economy


