

Concentration of entrepreneurs on the pharmaceutical market: selected issues

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Abstract:

Aim: The article has been selected due to the need to determine the legal basis for the consolidation of entrepreneurs on the pharmaceutical market and to identify the difference from the common pattern established by the regulations set forth in the Competition and Consumer Protection Act dated 16 February 2007. The selection of an enactment (the Competition and Consumer Protection Act or the Pharmaceutical Law Act) as the appropriate basis for ruling shapes the legal status of an entrepreneur on the pharmaceutical market, in particular with respect to selecting specific remedies.

Design / Research methods: The text of enactments was analyzed using mainly the linguistic method. The aim of the analyzed regulations and the system of values protected by law were also investigated.

Conclusions / findings: The regulations concerning anti-competition consolidation on the pharmaceutical market set forth in the Pharmaceutical Law Act are *lex specialis* with respect to solutions adopted in the Competition and Consumer Protection Act (this applies only to issuing a permit for running a retail pharmacy and a limited service pharmacy). These regulations are related with respect to content but, simultaneously, they differ with respect to the adopted consolidation criteria (qualitative criterion: the Competition and Consumer Protection Act, and quantitative criterion: the Pharmaceutical Law Act). The regulations set forth in the Competition and Consumer Protection Act apply also to consolidation on the pharmaceutical market since the obligation to report a consolidation intent is not specific to the industry in which the consolidation takes place. It means that President of the Office of Competition and Consumer Protection is competent to study the consolidation status and issue decisions related to consolidation on the pharmaceutical market, and entrepreneurs can appeal from the President's decisions to the Regional Court in Warsaw.

Originality / value of the article: The approach presented is not present in the current literature which is the main value of the article. The subject matter of the article can be interesting for entrepreneurs present on the pharmaceutical market and law practitioners.

Keywords: concentration, competition protection, medicinal product, President of the Office of Competition and Consumer Protection, pharmacy, pharmaceutical market, pharmaceutical industry, Voivodship Pharmaceutical Inspector.

JEL: K21, K23

1. Introduction

The fair competition principle, which is one of the essential business principles, has been expressed by the legislator in the provisions of Article 17 of the Act of July 2, 2004 on the Freedom of Business Activity (consolidated text: Dz.U. [Journal of Laws] of 2016, item 1829 as amended) and expanded also in the Competition and Consumer Protection Act of February 16, 2007 (consolidated text: Dz.U. [Journal of Laws] of 2017, item 229; hereinafter: CCPA). The essence of freedom of enterprise gives rise to two specific types of freedom described as freedom in competing with other entrepreneurs (Walaszek-Pyziół 1994: 45) and concentration of entrepreneurs which is an emanation of the freedom to choose the legal and organisational form of business (Klecha 2009: 152; cf. judgement of the Constitutional Court of January 19, 2010, file ref. no. SK 35/08). In case of a business initiated and conducted according to the Pharmaceutical Law of 6 September 2001 (consolidated text: Dz.U. [Journal of Laws] of 2016, item 2142 as amended), two divergent values clash. First of them springs from the principle of freedom of enterprise (which is the principle of the economic system of the Republic of Poland), while the second is rooted in the need to create conditions supporting starting and running a business “in a manner free from a number of hazards for life and health” (Szydło 2002: 16).

The aim of the article is to establish the legal basis for concentration of entrepreneurs on the Pharmaceutical market and identification of the extent of difference from the common pattern shaped by the CCPA provisions. For this reason, I am going to list the key traits characteristic for the relationship between entities operating on the pharmaceutical market. The article consists of two main parts, i.e.: Uniqueness of the Pharmaceutical Market and Concentration of Entrepreneurs on the Pharmaceutical Market

2. Uniqueness of the Pharmaceutical Market

First, it is worth noting that the term “pharmaceutical market” is a complex term with a concept of a “medicinal product” playing an important role as its component.¹ According to the

¹ “Medicinal product” is the core term used in the Pharmaceutical Law. It is defined in the provisions of Article 2 item 32 as “a substance or a blend of substances presented as having properties preventing or curing diseases in humans or animals or administered for diagnostic purposes or to restore, improve or modify physiological functions of the body through pharmacological,

elementary division of the pharmaceutical market,² regulated by the Pharmaceutical Law, the sector is divided into the medicinal product manufacturing sector and the medicinal product trading sector, further divided into the wholesale medicinal product sector³ and the retail medicinal product sector.⁴

There is no doubt that the pharmaceutical sector is characterised by very strict administrative and legal control of economic behaviour related to the sphere of starting, running and closing a business (Stankiewicz 2014: 77; Podleś 2011: 11 ff.), manifesting itself predominantly in the requirement to obtain a respective administrative decision.⁵ In the Pharmaceutical Law, the restriction on the freedom of enterprise is justified essentially with the need to protect the public health, which boils down to “the important public interest” (mentioned in the provisions of the Article 22 of the Constitution of the Republic of Poland). While an extensive process of adapting the national pharmaceutical law to the requirements of the EU law is observed on the pharmaceutical market coupled with interpretation of regulations in line with the EU laws (cf. Kondrat 2009: 11–26; Wołoszyn, Lubeńczuk 2011: 583 ff.; Stankiewicz 2011: 489 ff.; Kopec 2008: 246 ff.), due to a strong attachment the market has to the national healthcare systems, it is difficult to say that there is a single pharmaceutical market in the EU as such (cf. decision of the President of the Office of Competition and Consumer Protection of March 2012 26, No. KDD-23/2012: 13). The root cause for division of the pharmaceutical sector into as many separate parts as many states form the EU is largely attributed to a mechanism of financing

immunological or metabolic performance”. Moreover, it is correlated with the EU law (cf. Article 1 item 1 letter b) of the directive 2004/27/EC of the European Parliament and of the Council amending directive 2001/83/EC on the Community code relating to medicinal products for human use (O.J. Official Journal EU L 136: 58). Such product categories as dietary supplements, cosmetics and medical devices should be distinguished from a medicinal product. However, the term “drug”, according to the applicable law, is recognised as a synonym of a “medicinal products”. Cf. Article 2 item 10 of the Act of May 12, 2011 on Refunding Drugs, Food for Special Medical Purposes and Medicinal Products (consolidated text: Dz.U. [Journal of Laws] of 2016, item 1536 as amended).

² R. Stankiewicz defines the “pharmaceutical market” as a “system of relations between entities participating in manufacturing a medicinal product, entities involved in its wholesale and retail sale and consumers” and differentiates it from the “pharmaceutical sector”, identifying the latter solely with the medicinal product manufacturing segment (Stankiewicz 2014: 77, 88). It seems that M. Krekora’s use of the notion of “pharmaceutical market” is boarder and it is referred to the “medicinal product market” (Krekora 2006: 15 ff.).

³ At present, according to the provisions of Article 72 par. 1 of the Pharmaceutical Law, “medicinal product wholesale (...) is only allowed by pharmaceutical wholesalers”. Before the Pharmaceutical Law was amended on December, 12 2014 (the Act of December 19, 2014 concerning the amending of the Pharmaceutical Law and other acts (Dz.U. [Journal of Laws] of 2015, item 28), medicinal product wholesale was also allowed as a customs and consignment warehouse.

⁴ Retail trade of medicinal product is allowed through or in the following organisations: a retail pharmacy (cf. Article 68 par. 1 of the Pharmaceutical Law), a limited service pharmacy (cf. Article 70 par. 1 of the Pharmaceutical Law), non-pharmacy outlets i.e. herbal and medicinal shop, specialist medicinal supply shop, retail store (cf. Article 71 par. 1 item 1–3 of the Pharmaceutical Law).

⁵ Provisions of Article 75 par. 1 item 17 of Act of July 2, 2004 on the Freedom of Business Activity is the basic regulation here. As an example, the following decisions authorising starting and running a business on the pharmaceutical market should be mentioned: a permit to manufacture or import a medicinal product (cf. Article 38 par. 1 of the Pharmaceutical Law), a license to run a pharmaceutical wholesale store (Cf. art. 74 par. 1 of the Pharmaceutical Law, a permit to run a retail pharmacy (cf. Article 99 par. 1 of the Pharmaceutical Law), a permit to run a limited service pharmacy (cf. Article 70 par. 4 of the Pharmaceutical Law).

medicinal products from the national health insurance system and developing prices of medicinal products by competent national bodies on different levels (judgement of TPICE of September 27, 2006 in the case no. T-168/01, GlaxoSmithKline Services Unlimited v. the Commission, [2006] ECR p. II-2969). Moreover, this phenomenon is inseparably related with another feature of the pharmaceutical sector which is demand for medicinal product since the decision is made by the doctor and not by the patient, in particular where prescription-only medicinal products are concerned (Announcement of the Commission – Executive Summary of the Pharmaceutical Sector Audit Report: 9). For this reason, we may recognise some non-price related competition elements (the main pressure is put on the preferred course of treatment) as the price of a medicinal product is not the decisive element, i.e. predominantly affecting the decision to buy a medicinal product.

A concise presentation of the key features of the pharmaceutical sector was needed and essential for the sake of clarity and understanding author's analyses presented below, concerning the mechanisms of entrepreneurs' concentration on the pharmaceutical market.

3. Concentration of Entrepreneurs on the Pharmaceutical Market

The fundamental act of law containing provisions related to the concentration of entrepreneurs and its control is the CCPA. In the provisions of Article 1, the legislator, defining the subject-related scope of its applicability, stated that it governs “the rules and procedure for counteracting (...) anti-competitive concentrations of entrepreneurs and their unions if the practices or concentrations cause or may cause effects on the territory of the Republic of Poland”. However, in order to report an EU-level concentration and assess its grounds, the provisions of Council Regulation (EC) No 139/2004 of January 20, 2004 on the control of concentrations between undertakings (the EC Merger Regulation, Official Journal L 24: 1) should be referred to.

The author of the paper does not intend to analyse in detail some positive premises which may necessitate notification of a concentration (cf. Article 13 of the CCPA) and a catalogue of exemptions from the obligation to notify about the intention of such concentration (cf. Article 14 of the CCPA) or methods for defining the size of sales (cf. Article 16 of the CCPA), neither wishes she to analyse provisions containing competence standards with regard to issuing decisions on

concentrations (cf. Articles 18–21 of the CCPA Law; cf. Skoczny 2014; Kohutek, Sieradzka 2008; Kępiński 2013).

The approach to treat the provisions of Article 99 par. 3 of the Pharmaceutical Law as *lex specialis* provision with regard to the solutions used in the CCPA may be considered uniform (Stankiewicz 2014: 496; Kruszyński 2010). The present phrasing of the provisions of Article 99 par. 3 of the Pharmaceutical Law is a consequence of adopting the Act of April, 20, 2004 concerning the Amendments to Pharmaceutical Law, Law on the Profession of a Doctor and the Pharmaceutical Law, Medicinal Product Law and the Law on the Office for Registration of Medicinal Products, Medical Devices and Biocides (Dz.U. [Journal of Laws], No. 92, item 882). It is worth noting that anti-concentration restrictions on the pharmaceutical market were introduced to the national legislature less than one year from adopting the original version of the Pharmaceutical Law.⁶

According to the provisions of Article 99 par. 3 of the Pharmaceutical Law, “the permit (...) shall not be issued when the applicant: 1) runs or has applied for permit to run medicinal product wholesale or act as an agent in selling medical devices or b) runs more than 1% of retail pharmacies on the territory of a region or entity which he controls, directly or indirectly, in particular subsidiaries defined in the CCPA, run jointly more than 1% of pharmacies in a region; 3) is a member of a capital group as defined in the CCPA, members of which run more than 1% of retail pharmacies in a region”.⁷ T. Skoczny rightly points out that a referral to the provisions of the CCPA causes some issues with interpretation since the piece of legislature lacks direct definition of such terms as “a controlled entity” and “a subsidiary”. What is more, following Skoczny’s line of reasoning, a flaw of the provisions of Article 99 par. 3 of the Pharmaceutical Law consists of applying the subject (quantitative) criterion when, according to the provisions of the CCPA, “protection against an excessive concentration on the competent markets is helped by the quantitative criterion of the market power, arising not from the number of market participants but,

⁶ By virtue of the Act of August 30, 2002 on amending the Pharmaceutical Law (Dz. U. [Journal of Laws] No. 152, item 1265), the following provisions of Article 99 par. 3 were introduced: “The permits mentioned in par. 1 shall not be issued when the applicant: 1) runs or has applied for permit to run medicinal product wholesale or 2) runs more than 10% of retail pharmacies on the territory of the Republic of Poland or is an entrepreneur dependent on such entity according to the provisions of Article 4 item 3 of the Competition and Consumer Protection Act of December 15, 2000 or 3) is a member of a capital group running more than 10% of retail pharmacies on the territory of the Republic of Poland according to the provisions of Article 4 item 14 of the Competition and Consumer Protection Act of December 15, 2000”. It is worth to add that the amendment emerged as late as when amending the bill in the Higher Chamber of the Polish Parliament.

⁷ R. Stankiewicz points out that the provisions of Article 99 par. 3 of the Pharmaceutical Law allow for distinguishing two types of prohibitions to concentrate, i.e. prohibition of the so-called vertical concentration (Article 99 par. 3 item 1) and prohibition of the so-called horizontal concentration (Article 99 par. 3 items 2 and 3) (Stankiewicz 2014: 493).

first and foremost, from the size of the share in the market, measured with the sales volume” (Skoczny 2015: 7).

Provisions of Article 99 par. 3 of the Pharmaceutical Law are addressed at the Regional Pharmaceutical Inspector enjoying, on top of that, the authority to give, refuse to give, modify, change, withdraw and declare expiration of a permit to run a pharmacy (Article 99 par. 2) and a permit to run a limited service pharmacy (Article 70 par. 4 in relation to Article 99 par. 2 of the Pharmaceutical Law)⁸, and the Chief Pharmaceutical Inspector who is the body (institution) of appeal (cf. Article 112 par. 3 of the Pharmaceutical Law). In case of finding, at the stage of issuing a permit to run a retail pharmacy (a limited service pharmacy), that the established facts of the case correspond to the standards implied by the provisions of Article 99 par. 3 of the Pharmaceutical Law, the Regional Pharmaceutical Inspector cannot issue a permit to run a retail pharmacy (a limited service pharmacy). R. J. Kruszyński analyses whether such form of a negative examination of the application, i.e. non-issuing the permit, is identical with the refusal to issue the permit (Article 101 of the Pharmaceutical Law). I share the opinion of the author that a decision issued on the basis of provisions of Article 99 par. 3 and Article 101 of the Pharmaceutical Law are not different from each other in terms of procedural consequences and, therefore, there is no normative rationale for their differentiation and the incompatible content of the two provisions based only on historical reasons (Kruszyński 2014: 143).

The present status of the regulation governing the anti-competitive concentration in the Pharmaceutical Law is commonly criticised as failing to achieve the purposes for which it was adopted. In the doctrine, it is claimed that the legislator intended to prevent an excessive concentration of retail pharmacies in the hands of one entity (Skoczny 2015: 7; Krekora 2012: 404–405). When analysing the provision, there are some doubts about the type of values that the legislator intended to protect. Are they the values characteristic for the police function of the state (health and life) or rather for the control function of the state in economic relations (competition)?⁹In the legal opinion dated March 30, 2004 (Krawczyk 2004: 2), it was recognised directly that the provisions of Article 99 par. 3 of the Pharmaceutical Law did not protect any important public interest and, therefore, some doubts were raised about the rationale behind

⁸ It should be concluded on the basis of the provisions of Article 70 par. 4 sentence 2 of the Pharmaceutical Law (through intra-system referral), provisions of Article 99 par. 3 of the same act should be applied respectively in the proceedings for issuing a permit to run a limited service pharmacy (cf. judgement of the Supreme Administrative Court [NSA] of June 26, 2008, file ref. no. II GSK 201/08; judgement of the Regional Administrative Court [WSA] in Warsaw of 26 June 2007, file ref. no. VII SA/Wa 582/07).

⁹ On the police and control functions, see the relevant legal literature (Kocowski 2009a; Kocowski 2009b).

introducing such method for restricting the freedom of enterprise introduced in the provision of Article 22 of the Constitution of the Republic of Poland. In turn, T. Skoczny expresses his opinion about the objective shared by the provisions of Article 99 par. 3 of the Pharmaceutical Law and the CCPA, referring to limiting an excessive competition on the retail market for the medicinal products (Skoczny 2015: 9).

It must be noted that the governing bodies of the national Pharmaceutical Inspection (Regional Pharmaceutical Inspector and Chief Pharmaceutical Inspector; cf. Article 112 par. 1 of the Pharmaceutical Law) exercise supervision “for the purpose of protecting a public interest of human health and safety” (Article 108 par 1 of the Pharmaceutical Law) and one should assess whether they are equipped with tools adequate for analysing ownership dependencies among entrepreneurs. In my opinion, the practice will show whether declarations and statements filed with the application for the permit represent a sufficient and effective source of information for the Regional Pharmaceutical Inspector (Article 100 par. 2 items 6 and 7 of the Pharmaceutical Law; the statements contain information about entities controlled directly or indirectly by applicants and about entities which are member of a capital group together with the applicant).

In my view, the conditions described in the provisions of Article 99 par. 3 of the Pharmaceutical Law should be classified to the arguments for withdrawing the permit. Such an approach would make *de legeferenda* arguments discussed in the literature realistic and lead to ending the uncertainty with regard to interpretation of regulations. However, on the other hand, in letter of the Chief Pharmaceutical Inspector of June 28, 2004 (GIF-P-L-01-58/RS/04) to Regional Pharmaceutical Inspectors, the importance of observing regulations of Article 99 par. 2 of the Pharmaceutical Law was emphasized (“In-depth analysis of the area is important because of a potential take-over of retail pharmacies and, in particular, shares in pharmacies operating as commercial law companies, by other entrepreneurs consolidated in capital groups, without a formal change of the owner and, consequently, the requirement to change licenses and permits to run retail pharmacies and a related potential bypassing of the anti-concentration regulations...”). Moreover, the provisions of Article 32 par. 1 items 2 of the Business Operation Act of November 19, 1999 (Dz.U. [Journal of Laws], No. 101, item 1178), which was repealed, were pointed out as the basis for obligatory withdrawal of the permit or license to run a retail pharmacy (Pismo Głównego Inspektora Farmaceutycznego z 28 czerwca 2004 r.). This article corresponds to the provisions of Article 37 par. 1 item 2 of the Pharmaceutical Law, being now in force. The key role should be

also attributed to the opinion expressed by the Undersecretary of State at the Ministry of Health, dated October 15, 2004, in response to the interpellation no. 7885 on anti-concentration regulations of the Pharmaceutical Law in the context of the current and planned acquisitions of PolskaGrupaFarmaceutyczna (Odpowiedź podsekretarza stanu w Ministerstwie Zdrowiana interpelację nr 7885). According to this opinion, exceeding 1% threshold of ownership of pharmacies operating in a region is fully sufficient to apply provisions of Article 37 par. 1 item 2 of the Pharmaceutical Law. The conclusion is consequent upon the argumentation that “the acquisition of shares (stock), resulting in exceeding the threshold, causes a change in the factual and legal status. Entrepreneurs who, as a result of buying shares (stock), combined their efforts as a group of related entities ceased to meet conditions for receiving a permit to run retail pharmacies and, consequently, run a business specified in the permit”.

In the light of the above, it must be considered that the provisions of the CCPA – being a general law – will be applied further on, as the correct substantive basis for decisions on anti-competitive concentration of entrepreneurs on the pharmaceutical market. In consequence, it is assumed that the preventive obligation to notify the intention to concentrate is not dependent on the sector of the anticipated concentration (Kohutek 2008: 448). Consequently, a general competence is stipulated for the President of the Office of Competition and Consumer Protection (hereinafter: President of OCCP) to analyse the status of concentration in the economy and behaviour of entrepreneurs on the pharmaceutical market and issue the decisions on entrepreneur concentration (cf. Article 31 par. 2 and 3 of the CCPA).¹⁰ Entities operating on the pharmaceutical market are subject to the CCPA. A manufacturer or a producer of a medicinal product, an importer of a medical device, a medicinal product wholesaler, a retailer of medicinal products – all these entities undoubtedly enjoy the status of an entrepreneur according to the Act of July 2, 2004 on the Freedom of Business Activity,¹¹ and by the virtue of provisions of Article 4 par. 1 of the CCPA, they are also entrepreneurs to whom provisions of the same CCPA apply. For this reason, an entrepreneur operating on the pharmaceutical market may become an addressee of a concentration decision issued on the basis of provisions of Articles 18 to 20 of the CCPA and, in case of the

¹⁰In his letter dated March 4, 2015 addressed to the Deputy Speaker of the Higher Chamber of the Polish Parliament (ref. no. DOK2-070-1/15JB), the President of OCCP rightly mentioned that, when issuing decisions on concentrations, he could not be guided by other premises which are not listed specifically by the CCPA.

¹¹ According to the provisions of Article 4 of the Act of July 2, 2004 on the Freedom of Business Activity, a status of an entrepreneur is enjoyed by a private individual, a legal person and an organisational unit which is not a legal person given legal capacity by provisions of another piece of legislature, transacting business in its own name (par. 1). Furthermore, partners in a civil law partnership, to the extent of the business they transact, are also classified to entrepreneurs.

dissatisfaction with a decision made by the President of OCCP, it has the right to appeal to the Regional Court in Warsaw (Competition and Consumer Protection Court) within one month from the date of serving the decision (Article 81 par. 1 of the CCPA). Revision of the repository of decisions of the President of OCCP is sufficient to recognise a trend showing that in proceedings related to concentration typically decisions coincident with the content of the application, i.e. decisions containing unconditional ordinary approval of the concentration notified in the application, are issued (cf. the following decisions of the President of OCCP: of March 26, 2012, file ref. no. DKK – 23/2012; of March 24, 2010, file ref. no. DKK – 29/2010; of July 3, 2008, file ref. no. DKK – 52/2008; of August 30, 2013, file ref. no. DKK – 111/2013; of 27 January 27, 2014, file ref. no. DKK – 7/2014; of September 2, 2015, file ref. no. DKK – 150/2015). Only in exceptional cases, a conditional approval of the concentration notified in the application is given (cf. decision of the President of OCCP of March 26, 2012, file ref. no. DKK-23/2012; decision of the President of OCCP of May 18, 2004, file ref. no. DOK-36/2004). This situation causes far-reaching difficulties in defining the criteria for the court control of the decisions made by the President of OCCP issued on entrepreneurs' concentration.

4. Conclusion

The shape of the legislature now in force allows us to conclude that there is a normative relation between the provisions of the Pharmaceutical Law (Article 99 par. 3 of the Pharmaceutical Law) and the provisions of the CCPA. I refer the relationship to the issue of concentration on the pharmaceutical market. The reason for narrowing down the topic of the paper to problem of the anti-competitive concentration of retail pharmacies (limited service pharmacies) according to the Pharmaceutical Law was intentional in order to highlight elements characteristic in proceedings on concentration in the pharmaceutical sector.

Summarising the above, it must be emphasized that the *lexspecialis* nature of the provisions of Article 99 par. 3 of the Pharmaceutical Law forces out the priority of its application *vis-à-vis* the general regulation implied in the CCPA and that the control of the anticompetitive concentration in the Pharmaceutical Law applies solely in the proceedings for issuing a permit to run a retail pharmacy and in the proceedings for issuing a permit to run a limited service pharmacy.

It is significant that the legislator did not decide to introduce such restrictions to the freedom of enterprise to proceedings for issuing other decisions awarding or granting the rights to start a specific type of business. An implication for introducing the provisions of Article 99 par. 3 of the Pharmaceutical Law to the legislature is a possibility to assess concentration of entrepreneurs on the pharmaceutical market in two ways, in independent proceedings. In consequence of the above, there are divergent ways of appealing from decisions related to the concentration of entrepreneurs on the pharmaceutical market as an entity may appeal from a decision issued by the Regional Pharmaceutical Inspector to the Chief Pharmaceutical Inspector and, subsequently, to the Regional Administrative Court. From a decision issued by the President of OCCP, an entity may appeal to the Regional Court in Warsaw – Competition and Consumer Protection Court (the so-called hybrid proceedings). In addition, the scope of the activity of the President of OCCP is closely related to conducting “research on the status of economy concentration and market behaviour of entrepreneurs”, unlike the Regional Pharmaceutical Inspector who, when carrying out the supervisory activities, is guided by values characteristic for the police function of the state exercised in business dealings. In spite of the above-described, noticeable differences, one should recognise the identity of objective the legislator wanted to achieve, when introducing the above-discussed provision to the Pharmaceutical Law and CCPA (protection against anti-competitive concentration).

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CONCENTRATION OF ENTREPRENEURS ON THE PHARMACEUTICAL MARKET

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Koncentracja przedsiębiorców na rynku farmaceutycznym – zagadnienia wybrane

Streszczenie

Cel: Motywem wyboru artykułu była potrzeba ustalenia podstaw prawnych koncentracji przedsiębiorców na rynku farmaceutycznym oraz zidentyfikowanie odmienności od powszechnego wzorca ukształtowanego przez przepisy ustawy z dnia 16 lutego 2007 r. o ochronie konkurencji i konsumentów. Wybór aktu prawnego (czy to ustawy o ochronie konkurencji i konsumentów, czy to ustawy – Prawo farmaceutyczne) jako właściwej podstawy rozstrzygnięcia wpływa na ukształtowanie sytuacji prawnej przedsiębiorcy na rynku farmaceutycznym zwłaszcza w zakresie wyboru określonych środków ochrony prawnej.

Metoda badawcza: Przy analizie tekstu aktów prawnych posłużono się przede wszystkim metodą językową. Poddano badaniu również cel analizowanych przepisów oraz system wartości chronionych.

Wnioski: Przepisy dotyczące antykonkurencyjnej koncentracji na rynku farmaceutycznym uregulowane w ustawie – Prawo farmaceutyczne są przepisami *lex specialis* w stosunku do rozwiązań przyjętych w ustawie o ochronie konkurencji i konsumentów (dotyczy to tylko wydania zezwolenia na prowadzenie apteki ogólnodostępnej i punktów aptecznych). Przepisy te są powiązane ze sobą treściowo. Jednocześnie różnią się przyjętymi kryteriami koncentracji (kryterium jakościowe: ustawa o ochronie konkurencji i konsumentów oraz kryterium ilościowe: ustawa – Prawo farmaceutyczne). Przepisy zawarte w ustawie o ochronie konkurencji i konsumentów mają również zastosowanie do koncentracji na rynku farmaceutycznym, ponieważ obowiązek zgłaszania zamiaru koncentracji nie jest uzależniony od branży, w której koncentracja jest przeprowadzana. Oznacza to, że Prezes UOKiK jest właściwy do badania stanu koncentracji i wydawania decyzji w sprawach koncentracji na rynku farmaceutycznym, a przedsiębiorcy służą odwołanie do Sądu Okręgowego w Warszawie.

Wartość artykułu: Zaprezentowane powyżej ujęcie tematu artykułu nie jest spotykane w literaturze, co stanowi walor artykułu. Tematyka artykułu może zainteresować przedsiębiorców prowadzących działalność gospodarczą na rynku farmaceutycznym oraz praktyków prawa.

Słowa kluczowe: koncentracja, ochrona konkurencji, produkt leczniczy, Prezes Ochrony Konkurencji i Konsumentów, apteka, rynek farmaceutyczny, sektor farmaceutyczny, wojewódzki inspektor farmaceutyczny.

JEL: K21, K23.