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The 13 July 2023 Amendment to the Pharmaceutical Law Act²

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Abstract

The article deals with the latest amendment to the Pharmaceutical Law Act, dated 13 July 2023, which is related to anti-concentration restrictions on the issuance of licenses to run generally accessible pharmacies. On 4 October 2023, the President of the Republic of Poland, pursuant to Article 191 section 1 item 1 of the Constitution of the Republic of Poland, filed a motion to examine the constitutionality of this amendment. In the motion, the President argued that the amendment introduces a new ban on pharmacy market concentration (Article 99 section 3aa of the Pharmaceutical Law), which was introduced in violation of the principle of protection of acquired rights and without adequate *vacatio legis*. In light of the President's motion, the subject of this article is an analysis of the provisions of the amendment with regard to the changes involving the addition of sections 3aa and 3ab under Article 99 and sections 2a-2d under Article 103 of the Pharmaceutical Law in order to determine their legal nature, comply with the principle of protection of acquired rights, and to decide whether the adopted *vacatio legis* period is appropriate.

Keywords: conditions for running a pharmacy, license, revocation of license, anti-concentration requirements, validity of anti-concentration requirements.

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Introduction

The provisions of Article 99 of the Act of 6 September 2001 – Pharmaceutical Law, uniform text in the Journal of Laws of the Republic of Poland of 2024, item 686 (“the PL”) govern issues related to granting licenses to operate generally accessible pharmacies. The provision of Article 99 section 3 of the PL specifies when a license is not issued to the requesting entity³. This provision has been supplemented in recent years by sections 3a and 3aa. The provisions of section 3a were added by way of the Act on Amending the Pharmaceutical Law Act (“the amendment of 7 April 2017,” also known as the “Pharmacy for Pharmacist” Act), which came into force on 25 June 2017. The provision of section 3aa, in turn, was added to Article 99 by way of the Act of 13 July 2023 on Amending the Act on Export Insurance Guaranteed by the State Treasury and Certain Other Acts (“the amendment of 13 July 2023”)⁴.

On 4 October 2023, the President of the Republic of Poland, pursuant to Article 191 section 1 item 1 of the Constitution of the Republic of Poland, filed a motion to examine the constitutionality of the 13 July 2023 Act Amending the Act on Export Insurance Guaranteed by the State Treasury and Certain Other Acts⁵ (hereinafter “the President’s motion”). The President deemed the act to be non-compliant with the law in force as follows: 1) Article 2 and Article 12 were considered non-compliant with Article 118 section 1 and 3 and Article 119 section 2 of the Constitution; 2) Article 12, in the part comprising Article 99 section 3aa of the PL and Article 20 in connection with Article 99 section 3aa, Article 103 sections 2a-2d, Article 127 cd, and Article 127d section 2 of the PL were considered non-compliant with the principles of trust in the state and the laws made by it, protection of acquired rights

³ The provisions of Article 99 section 3 items 2-3 of the PL in their current wording were adopted by way of the Act on Amending the Pharmaceutical Law Act, the Act on the Professions of Physician and Dentist, and the Act – Implementing Provisions – Pharmaceutical Law, the Act on Medical Devices, and the Act on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products of 20 April 2004, and have been in force since 1 May 2004, Journal of Laws of the Republic of Poland no. 92, item 882.

⁴ Journal of Laws of the Republic of Poland of 2017, item 1015.

⁵ Journal of Laws of the Republic of Poland of 2023, item 1859.

and ongoing business, and appropriate *vacatio legis* derived from Article 2 of the Constitution⁶.

In light of the President's motion, the subject of this article will be an analysis of the provisions of the 13 July 2023 amendment with regard to the changes involving the addition of sections 3aa and 3ab under Article 99 and sections 2a-2d under Article 103 of the PL in order to determine their legal nature, to find if they comply with the principle of protection of acquired rights, and to decide whether the *vacatio legis* period adopted for this amendment is appropriate.

New provisions of Article 99 section 3aa and 3ab of the PL and Article 103 sections 2a-2d of the PL

The purpose of adopting the provisions of Article 99 section 3a of the PL was to prevent concentration of entities operating generally accessible pharmacies. The rationale for this amendment implies that in their current form, the regulations do not guarantee the proper implementation of the goals and principles of pharmacies⁷ that have the status of a public healthcare institution.⁸ Similarly, according to the judicial decisions issued⁹ and the views of legal scholars, academics, and commentators,¹⁰ the purpose of these regulations is to prevent the phenomenon of concentration in the pharmacy market¹¹. In the course of parliamentary work on the 7 April 2017 amendment, it was pointed out that due to the purpose of the introduction of Article 99 section 3a of the PL, it is necessary for it to be complied with throughout the period of operation of pharmacies¹². Consequently, it is possible

⁶ <https://www.prezydent.pl/prawo/wnioski-do-tk/wniosek-prezydenta-do-trybunalu-konstytucyjnego,75762> (access: 11.06.2024).

⁷ See: statement of reasons for a deputies' bill on amending the Pharmaceutical Law Act, Sejm paper no. 1127 of December 2016.

⁸ See: D. Kaczan, *Świadczenie usług farmaceutycznych w aptekach jako udzielanie świadczeń zdrowotnych*, "Ruch Prawniczy, Ekonomiczny i Socjologiczny" 2019, 4, p. 154 and the literature cited therein; K. Melgieś, *Prawne determinanty funkcjonowania aptek ogólnodostępnych a bezpieczeństwo pacjenta*, "Rocznik Nauk Prawnych" 2021, 31(2), p. 46 and the literature cited therein.

⁹ See: Supreme Administrative Court's judgement of 26 June 2008, ref. II GSK 201/08, ONSAiWSA 2009/5/93, and Provincial Administrative Court in Warsaw's judgement of 23 July 2015, ref. VI SA/Wa 399/15, Lex no. 1819873.

¹⁰ See more: L. Ogiegło, *Prawo farmaceutyczne. Komentarz*, Warsaw 2018, Legalis, thesis 4 to Article 99; M. Krekora, M. Świerczyński, E. Traple, *Prawo farmaceutyczne. Zagadnienia regulacyjne i cywilnoprawne*, Warsaw 2008, p. 368 et seq.; M. Kondrat (ed.), *Prawo farmaceutyczne. Komentarz*, Warsaw 2009, p. 936 et seq.

¹¹ M. Szydło, *Opinia prawna o projekcie ustawy o zmianie ustawy – Prawo farmaceutyczne (sejm paper no. 1126)*, Sejm Bureau of Research of the Chancellery of the Sejm, 9 January 2017 r., pp. 6–7.

¹² See more: ibidem; P. Kościelny, *Opinia prawna dotycząca poselskiego projektu ustawy o zmianie ustawy – Prawo farmaceutyczne (Sejm paper no. 1126)* of 23 March 2017.

– and necessary – to monitor if an entity holding said license does not violate the provisions of Article 99 section 3a of the PL after the license is issued. The explanations offered by representatives of government bodies, especially of the Ministry of Health, also implied that compliance with the requirements of Article 99 section 3a of the PL can also be verified after a license is issued.¹³ The Chief Pharmaceutical Inspector expressed a similar view¹⁴. Legal scholars, academics, and commentators also argued that the authority that grant licenses should monitor the licensee entity's compliance with the statutory requirements for conducting activity subject to licensing, both before and during its conduct¹⁵. However, there occurred also different standpoints¹⁶.

A similar stand was taken by the drafters in the course of their work on Article 99 section 3aa of the PL, which was adopted by means of the 13 July 2023 amendment. The drafters pointed to the practice of circumventing the provisions of Article 99 section 3a of the PL by converting pharmacies into companies, buying out shares in them, and thus avoiding the licensing proceedings in which concentration restrictions are examined¹⁷. The provision of Article 99 section 3aa of the PL does not impose new rules. It aims to enforce the ones that have existed for a long time¹⁸.

Thus, it is apparent from both the rationale for the introduction of Article 99 section 3a of the PL and Article 99 section 3aa of the PL that the intention of the legislature was to adopt provisions that will enable the verification of compliance with anti-concentration requirements not only during the issuance of the license, but also after its issuance, i.e. during its validity. Authentic interpretation, on the other hand, as offered by the entity who created the text to be interpreted, takes

¹³ See: response of Undersecretary of State in the Ministry of Health Rafał Niżnikowski to interpellation no. 7885/2004 on anti-concentration provisions of the Pharmaceutical Law in the context of purchases made and planned to be made by Polska Grupa Farmaceutyczna, <http://orka2.sejm.gov.pl/IZ4.nsf/main/600ABF81> (accessed: 11.06.2024).

¹⁴ See: letter PORZ.520.10.2017.MP.1. of 3 October 2017, <http://www.nia.org.pl/wp-content/uploads/2018/03/Za%C5%82%C4%85cznikNr2GIFjedenprocent.pdf> (accessed: 11.06.2024).

¹⁵ See: L. Ogiegło, op. cit, thesis 8 to article 37ap. See also: C. Kosikowski, *Ustawa o swobodzie działalności gospodarczej. Komentarz*, 7th edition, Warsaw 2017, Lex/el., a commentary to Article 75, thesis 3.

¹⁶ Cf. letter from the SME Ombudsman of 7 August 2019 to the Association of Pharmacists Employers of Polish Pharmacies, ref. RMSP-365/2019/WIP, pp. 2-3. In the views of legal scholars, academics, and commentators, see: D. Pudzianowska, A. Rabeiga-Przyłęcka, *Cofanie zezwoleń na prowadzenie aptek ogólnodostępnych z powodu przekroczenia ograniczeń antykoncentracyjnych – analiza problemu w świetle orzecznictwa*, "Przegląd Prawa Handlowego" 2021, 11, p. 23; M. Jabłoński, S. Jarosz-Żukowska, *Działalność gospodarcza na rynku aptecznym i jej ograniczenia. Uwarunkowania konstytucyjne*, Warsaw 2022, p. 345 et seq.

¹⁷ <https://www.sejm.gov.pl/Sejm9.nsf/biuletyn.xsp?skrn=FPB-445> (accessed: 11.06.2024).

¹⁸ <https://www.senat.gov.pl/prace/komisje-senackie/przebieg,10281,1.html> (accessed: 11.06.2024).

precedence, according to the principle of *cuius est condere, eius est interpretari* (*eius est interpretari leges, cuius est condere*), i.e., he who establishes the law, interprets it¹⁹.

According to the President's motion (p. 22), "a new and further prohibition of concentration in the pharmacy market was introduced" by means of section 3aa added to Article 99. It was pointed out that this prohibition is "a normative innovation that can be considered a significant change for the functioning of the pharmacy market in Poland" (p. 26 of the President's motion). It is difficult to agree with the arguments in the President's motion, in particular with that implying that a new and further prohibition on concentration in the pharmacy market has been introduced. The content of Article 99 section 3aa item 2 letters a-d of the PL is virtually the same as that of the existing Article 99 section 3a items 1-4 of the PL. These provisions differ only in their opening sentences. Article 99 section 3a of the PL refers to issuing a license, and Article 99 section 3aa of the PL refers to a change of control. It can be argued that the prohibition in Article 99 section 3aa of the PL is derived from the regulation underlying Article 99 section 3a of the PL. The provision of section 3a was added to Article 99 section 3 of the PL by means of the amendment of 7 April 2017, which came into effect on 25 June 2017, meaning that the provisions it introduced have been in effect for seven years. Thus, it is difficult to consider Article 99 section 3aa of the PL as a normative innovation. The amendment came as a result of a different interpretation of the anti-concentration provisions. In their early days of being in force, Provincial Administrative Courts issued a number of rulings and judgements where it was argued that the requirement to comply with the limit on the number of pharmacies operated (Article 99 section 3.2 of the PL) is one of the basic conditions not only for obtaining a license, but also for running a pharmacy in general²⁰. Later on, the decisions of the Supreme Administrative Court appeared to promote a different standpoint, according to which anti-concentration requirements should be applied when issuing a license – and should no longer apply when operating a generally accessible pharmacy²¹. However,

¹⁹ L. Morawski, *Wstęp do prawoznawstwa*, Toruń 2009; M. Koszowski, *Dwadzieścia osiem wykładów ze wstępu do prawoznawstwa*, Warsaw 2019.

²⁰ Provincial Administrative Court in Warsaw's judgement of 23 July 2015, VI SA 399/15, Lex no. 1819873. See also: Provincial Administrative Court in Warsaw's ruling of 19 January 2018, ref. VI SA/Wa 2905/15, LEX no. 2139047; Provincial Administrative Court in Warsaw's judgement of 26 April 2017, ref. VI SA/Wa 2906/15; Provincial Administrative Court in Warsaw's judgement of 29 November 2017, ref. VI SA/Wa 128/16, Legalis no. 1630750; Provincial Administrative Court in Warsaw's judgement of 2 August 2022, ref. V SA/Wa 4749/21, bip.warszawa.wsa.gov.pl (accessed: 11.06.2024) Provincial Administrative Court in Warsaw's judgement of 24 May 2017, ref. VI SA/Wa 2581/1, www.orzeczenia-nsa.pl (accessed: 11.06.2024); Provincial Administrative Court in Warsaw's judgement of 28 December 2017, ref. VI SA/Wa 2690/15, Legalis no. 1731226.

²¹ Cf.: Supreme Administrative Court judgements of 4 February 2020: ref. II GSK 3026/17, ref. II GSK 3027/17, ref. II GSK 3135/17, www.orzeczenia-nsa.pl (accessed: 11.06.2024).

even during this period, the rulings of PACs offered different views – that is, ones in line with the previous line of judicial decisions²².

The 13 July 2023 amendment also added sections paragraphs 2a-2d after section 2 in Article 103 of the PL. These added sections define the procedure and legal consequences for an entity if control is changed in violation of the prohibition specified in Article 99 section 3aa of the PL. In particular, the provision of Article 103 section 2a of the PL stipulates that the provincial pharmaceutical inspector shall revoke the license to operate a generally accessible pharmacy granted to an entity over which control has been taken in violation of the prohibition referred to in Article 99 section 3aa. The matter that needs to be determined, therefore, is the legal nature of the amendment involving the addition of Article 99 section 3aa of the PL and Article 103 section 2a of the PL. The Supreme Administrative Court's decisions, which define such changes as "clarifying and editorial," can surely be helpful in this context²³. The SAC dealt with changes that also involved Article 103 of the PL. The provision of Article 103 section 1 item 2 of the PL introduced the sanction of revoking a license for violation of Article 86a of the PL, meaning a provision providing for the prohibition of so-called "reverse distribution of drugs." It was added by way of the Act of 19 December 2014 Amending the Pharmaceutical Law and Certain Other Acts, and came into force on 8 February 2015²⁴. The provision of Article 103 section 1 item 2 of the PL, in turn, according to which the revocation of a license in light of violation of Article 86a of the PL, was introduced by the Act of 9 April 2015 Amending the Pharmaceutical Law and Certain Other Acts, which came into force on 12 July 2015²⁵. This did not mean, however, that at an earlier time, i.e. before 12 July 2015, when Article 103 section 1 item 2 of the PL entered into force, the so-called "reverse distribution of drugs," prohibited under Article 86a of the PL, which in turn became effective on 8 February 2015, was permissible and did not result in mandatory revocation of the license granted. On the contrary – according to the decisions issued by the Supreme Administrative Court, such a prohibition did exist under the previous regulations of the PL. In the event of a violation in question, the provision of Article 37ap section 1 item 2 of the PL was applied.²⁶

²² See: Supreme Administrative Court's judgements of 11 August 2020, ref. II GSK 4336/17 and ref. II GSK 3573/17.

²³ Cf.: Supreme Administrative Court's judgement of 2 October 2019, ref. II GSK 2667/17, Legalis no. 2263484.

²⁴ Journal of Laws of the Republic of Poland of 2015, item 28.

²⁵ Journal of Laws of the Republic of Poland of 2015, item 788.

²⁶ See: Supreme Administrative Court's judgement of 17 October 2018, ref. II GSK 3320/16, Legalis no. 1864803. See: M. Kondrat, *Prawo farmaceutyczne. Komentarz*, Warsaw 2016, a remark to Article 86a. Similarly, Supreme Administrative Court's judgements of: 17 May 2023, ref. II GSK 367/20, <http://www.>

The changes involving the addition of sections 3aa and 3ab under Article 99 and sections 2a-2d under Article 103 of the PL, which also have a clarifying and editorial purpose, should be viewed in a similar light. Therefore, it is not possible to agree with the claim included in the President's motion (p. 26), according to which Article 99 section 3aa of the PL imposes a prohibition on concentration in the pharmacy market for legal or factual acts that occurred after the date of issuance of a license to operate a generally accessible pharmacy, and that, at the same time, in the previous legal state, did not result in the revocation, expiration of or refusal to transfer the license.

Protection of acquired rights

Pursuant to Article 12 of the 13 July 2023 amendment, the provisions of Article 99 sections 3aa and 3ab of the PL apply to a change of control that occurred after the date of entry into force of the amendment, i.e. they are effective for the future. The provision of Article 12 clearly stresses the *ex nunc* effect. These provisions apply to a change of control which, in accordance with the Act of 16 February 2007 on Competition and Consumer Protection (the CCPA)²⁷, occurred after the entry into force of the 13 July 2023 amendment. The adopted solution reflects the drafter's pursuit of goals related to the specific nature of the pharmacy market. The Constitutional Tribunal's (CT) judicial decisions related to the limits of the discretion of the ordinary legislator indicate that the legislator has the authority to design the content of the law in accordance with the chosen direction of state policy. The legislator has the right to pursue their own goals through appropriate legal measures. The limits of this discretion – or freedom – are set by constitutional norms²⁸.

The President's motion points to the need to respect the principle of protecting acquired rights (pp. 16-17). It appears from the Constitutional Tribunal's decisions that the principle of protection of acquired rights provides protection of subjective rights – both public and private – acquired through concrete decisions granting benefits, as well as rights acquired *in abstracto* (in accordance with the law prior to the request for their granting), as well as fully formed expectatives, i.e. those that meet all the essential statutory prerequisites for the acquisition of rights under

orzeczenia-nsa.pl (accessed: 11.06.2024); 15 October 2019, II GSK 2669/17, <http://www.orzeczenia-nsa.pl> (accessed: 11.06.2024); 17 October 2018, ref. II GSK 3250/16, <http://www.orzeczenia-nsa.pl> (accessed: 11.06.2024); 17 October 2017, ref. II GSK 3645/15, <http://www.orzeczenia-nsa.pl> (accessed: 11.06.2024).

²⁷ Uniform text in the Journal of Laws of the Republic of Poland no. 50, item 331.

²⁸ See: CT ruling of 20 November 1996, ref. K 27/95, OTK ZU no. 6/1996, item 50; CT judgement of 9 June 2003, ref. SK 12/03, OTK ZU no. 6/A/2003, item 51.

a given act²⁹. The principle of protection of acquired rights is not absolute³⁰, and only arbitrary and disproportionate restriction of such rights is prohibited. These rights can be depleted “in special circumstances” not only due to constitutional values, but also economic and social reasons³¹, particularly due to the need to reform the legal system³². The protection granted is not tantamount to prohibiting the legislator from changing the provisions that define the legal situation of an individual to the extent that the situation is not expressed in the subjective rights of that individual³³. The constitutional principle of protection of acquired rights does not preclude the enactment of regulations that limit or abolish subjective rights or the enactment of regulations that are less favourable³⁴. In determining the permissibility of exceptions to the principle of protection of acquired rights, it is necessary to consider the extent to which an individual’s expectation of protection of acquired rights is justified, since the principle of protection of acquired rights protects only justified and rational expectations³⁵.

It is important to bear in mind that the source of the acquisition of the right to operate a pharmacy is a constitutive decision to grant (or transfer) a license to operate a pharmacy (Article 99 section 1, Article 104a section 1 item 1 of the PL)³⁶. Thus, until a given entity receives such a decision, it is impossible to state with complete certainty that the entity has acquired such a right or that the expectative of such a right has been created. In the practice of applying Article 99 section 3a of the PL, an entity could acquire the right to operate a pharmacy indirectly, i.e. by buying out the ownership rights in the company that holds a license to operate a pharmacy

²⁹ See: CT ruling of 11 February 1992, ref. K 14/91, OTK 1992, part I, item 7 and CT judgements of: 23 November 1998, ref. SK 7/98, OTK ZU 1998, no. 7, item 114; 22 June 1999, ref. K 5/99, OTK ZU 1999, no. 5, item 100; 30 March 2005, ref. K 19/02, OTK ZU-A 2005, no. 3, item 28; 25 July 2006, ref. P 24/05, OTK ZU 2006, no. 7A, item 87; 18 September 2006, ref. SK 15/05, OTK ZU 2006, no. 8/A, item 106, and 8 December 2011, ref. P 31/10, OTK-A 2011 no. 10, item 114.

³⁰ See: CT judgement of 22 June 1999, K 5/99, OTK 1999, part II, item 31; CT judgement of 25 June 2002, ref. K 45/01, <https://www.saos.org.pl/judgments/206153> (accessed: 11.06.2024); CT judgement of 16 January 2007, ref. U 5/06, OTK ZU 2007, no. 1/A, item 3; CT judgement of 8 January 2009, ref. P 6/07, OTK ZU 2009, no. 1/A, item 2; CT judgement of 10 February 2015, ref. P 10/11, <https://www.saos.org.pl/judgments/206708> (accessed: 11.06.2024).

³¹ See: Compiled by the Office of the Constitutional Tribunal: *Proces prawotwórczy w świetle orzecznictwa Trybunału Konstytucyjnego. Wypowiedzi Trybunału Konstytucyjnego dotyczące zagadnień związanych z procesem legislacyjnym*, Warsaw 2015, p. 40.

³² See: CT judgement of 22 June 1999, ref. K 3/99, OTK ZU 1999, no. 5; CT judgement of 13 March 2000, ref. K 1/99, OTK ZU 2000, no. 2, item 59. See also: CT judgement of 28 April 1999, ref. K 3/99, OTK ZU 1999, no. 4, item 73.

³³ See: Compiled by the Office of the Constitutional Tribunal: *Proces prawotwórczy...*, p. 39.

³⁴ CT judgement of 29 May 2012, ref. SK 17/09, Legalis no. 478578.

³⁵ See: CT judgement of 4 January 2000, ref. K 18/99, OTK ZU 2000, no. 1, item 1.

³⁶ See: J. Stefańczyk-Kaczmarzyk, [in:] M. Kondrat, *Prawo farmaceutyczne. Komentarz*, Warsaw 2016, a remark to Article 99 item 99.1.

(shares, stocks, all rights and obligations). This was possible even if the entity did not meet the requirements for obtaining a license to operate a pharmacy, i.e. this action could be considered *praeter legem*, or even *contra legem*, in which the source of the right to operate a pharmacy was a legal act and not the said administrative act.

It is therefore difficult to consider the right thus generated as protected in the sense described above. The scope of application of the principle of protection of acquired rights does not cover legal situations that do not have the nature of subjective rights or of expectatives of these rights³⁷. Thus, the scope of application of this principle includes only cases in which a given legal regulation is the source of subjective rights or of expectatives of such rights³⁸. The situation in question did not involve any of these situations. In addition, the regulations introduced do not deprive anyone of previously acquired rights because according to Article 12 of the 13 July 2023 amendment, the provisions of Article 99 sections 3aa and 3ab of the act amended in Article 2 of the 13 July 2023 amendment apply to a change of control that occurred after the date of entry into force of the amendment. A situation where an entity has performed certain actions that may lead to a specific effect in the future, let alone a situation where an entity is not even aware that there may be certain legal consequences for the entity in connection with the performance of legal or factual actions, can hardly be considered a subjective right or, even more so, an expectative of a right.

Change of control

The President's motion also pointed out that the principle of protecting "ongoing business" may be violated³⁹. In the motion there is an argument that the concept of "change" of control is not specific, which destabilises the legal situation of pharmacy operators. Therefore, the prohibition may affect the obligation relationships that pharmacy owners establish among themselves or with other business partners. In addition, the determination of whether an entity is controlled is not limited to an analysis of data from records, which calls for a more extensive, in-depth analysis. Finally, the change of control may be a consequence of circumstances over which the pharmacy operator had no control (pp. 28-31 of the motion).

The President's motion seems to be aimed at demonstrating that, due to vagueness, there is an incompatibility of Article 4 section 4 of the CCPA – which contains

³⁷ See: CT judgement of 22 June 1999, ref. K 3/99, OTK ZU 1999, no. 5.

³⁸ See: CT judgement of 8 January 2009, ref. P 6/07, OTK ZU 2009, no. 1/A, item 2.

³⁹ See: CT ruling of 2 March 1993, ref. K 9/92, OTK 1993, no. 1, item 6; CT judgement of 25 November 1997, ref. K 26/97, OTK ZU 1997, no. 5–6.

the definition of change of control – with Article 2 of the Constitution. The definition of change of control provided in this provision is based on the concept of control contained in Article 3(2) of Council Regulation (EC) no. 139/2004 of 20 January 2004 on the control of concentrations between undertakings (EC Merger Regulation)⁴⁰. It has been used for a long time in antitrust and pharmaceutical law. Article 3(1) of Regulation 139/2004 also includes a definition of concentration, which is based on the definition of control. Change of control, which is a legal event, means obtaining the power to exercise decisive influence over another entrepreneur, and stems from both legal and factual circumstances. According to the judicial decisions of the Court of Justice of the EU (CJEU), the state of control emerges as a result of not only certain legal circumstances, which include e.g. the conclusion of an agreement, but also of certain factual circumstances, in particular: reporting of data to the (dominant) entrepreneur, including sales data⁴¹, issuing instructions to the dependent entrepreneur⁴², exchange of information between entrepreneurs⁴³, coordination of activities between entrepreneurs⁴⁴. The judicial decisions of Polish courts, in turn, suggest the state of control is not the result of concluding a single agreement, but of several interrelated agreements⁴⁵.

The President's motion refers to hypothetical market situations, but conditional, time-bound agreements or recurring obligations do not occur among pharmacy operation licensees in market practice – especially with such content that would result in a state of “change of control.” Thus, in practice, there is a very low likelihood of entrepreneurs who have entered into said agreement becoming dependent entrepreneurs – subsidiaries – after the 13 July 2023 amendment comes into force⁴⁶. Another issue worth bearing in mind is that the fulfilment of a conditional, recurring or time-bound obligation would result in change of control that would take

⁴⁰ OJ L 24.

⁴¹ CJEU judgement of 25 March 2021, C-152/19 P, item 86, ECLI:EU:C:2021:238.

⁴² *Ibidem*, items 95 and 96.

⁴³ European Commission Communication, *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (Text with EEA relevance; 2011/C 11/01)*, items 58-59.

⁴⁴ *Ibidem*, item 60.

⁴⁵ Provincial Administrative Court in Warsaw's judgement of 9 February 2024, ref. V SA/Wa 1456/23, warszawa.wsa.gov.pl (accessed: 11.06.2024).

⁴⁶ Cf.: Supreme Administrative Court's ruling of 17 October 2022, ref. II GSK 1756/21, ref. II GSK 1971/21, ref. II GSK 2505/21, www.orzeczenia-nsa.pl (accessed: 11.06.2024), as well as the Provincial Administrative Court in Warsaw's judgements of: 9 February 2024, ref. V SA/Wa 1456/23, warszawa.wsa.gov.pl (accessed: 11.06.2024); 20 February 2024, ref. V SA/Wa 861/23, warszawa.wsa.gov.pl (accessed: 11.06.2024); 21 February 2024, ref. V SA/Wa 919/23, warszawa.wsa.gov.pl (accessed: 11.06.2024); 22 February 2024, ref. V SA/Wa 915/23, warszawa.wsa.gov.pl (accessed: 11.06.2024).

place after the granting of a license, which would mean circumventing the provisions of the law (*ius cogens*) by means of a legal action.

The threats referred to in the President's motion, related to the establishment of the prohibition in Article 99 section 3aa of the PL, are also valid for those entities that apply for the granting or transfer of a license. The concept of control has been present in the PL since its enactment, by virtue of the provisions of Article 99 section 3 items 2 and 3, which define the restrictions on pharmacies by invoking the CCPA. The entities affected by these restrictions are also groups of companies (or 'capital groups') (Article 4 section 14 of the CCPA), which consist of e.g. dominant entrepreneurs, i.e. entities that take control over other entities. They should also demonstrate that they are not controlled entities (due to the anti-concentration requirement). Such circumstances give rise to a state of legal uncertainty. An entity applies for the granting (transfer) of a license and can never be certain whether the existing legal and factual relations in which it operates do not cause a situation where it is denied the right to operate a pharmacy. However, this cannot justify the conclusion that the references to the concept of "change of control" in Article 99 section 3 items 2 and 3 and Article 99 section 3a items 2 and 3 of the PL are not legitimate.

Length of *vacatio legis*

The President's motion points out that the *vacatio legis* granted is too short to comply with the regulations enforced. According to Article 20 of the 13 July 2023 amendment, it enters into force 14 days after the date of its promulgation⁴⁷, which is the standard duration of *vacatio legis*⁴⁸. The amendment was promulgated on 13 September 2023, so its provisions entered into force on 28 September 2023. And almost 2.5 months passed between the date of the amendment adding Articles 2 and 12 to the 13 July 2024 amendment and the date of the act becoming effective.

The primary function of *vacatio legis* is to let the entities to be affected by legal norms familiarise themselves with the new regulations⁴⁹ and to adapt to the changing legal circumstances⁵⁰. This aims mainly at eliminating situations where regulations

⁴⁷ Except for: 1) Article 3, Article 13, Article 14, Article 16, and Article 19, which shall enter into force on 1 January 2024; 2) Articles 7 and 17, which shall enter into force on the day following the date of promulgation.

⁴⁸ See: Article 4 section 1 of the Act on Promulgation of Normative Acts and Some Other Legal Acts, uniform text in the Journal of Laws of the Republic of Poland of 2019, item 1461.

⁴⁹ See: CT judgement of 2 December 2014, ref. P 29/13, OTK ZU 2014, no. 11/A, item 116.

⁵⁰ See: CT judgement of 27 June 2006, ref. K 16/05, OTK ZU 2006, series A, no. 6, item 68; CT judgement of 19 March 2001, ref. K 32/00, OTK ZU 2001, no. 3, item 50; CT judgement of 23 March 2006, ref. K 4/06, OTK-A 2006, no. 3, item 32.

introduced or amended take those affected by them by surprise⁵¹. Legal scholars, academics, and commentators argue that in determining the length of the *vacatio legis* period, it is necessary to take into account: the objectives that the enacted legislation is intended to achieve; the factual circumstances that determine the proper functioning of the enacted legislation; the need not to surprise those affected by the legislation; the harmonious functioning of the system into which the new legislation is incorporated⁵². The judicial decisions of the CT follow a similar line of thought⁵³. However, it is emphasised that *vacatio legis* is a variable category, and the determination of the adequacy of *vacatio legis* always depends on the content and nature of the legislation coming into force and its political and socio-economic context⁵⁴.

In considering the length of the *vacatio legis* period in the 13 July 2023 amendment, it is important to remember that the amendment concerns changes to regulations that have already been in place for 7 years, and, in fact, since 2001 – if the provision of Article 99 section 3 items 2 and 3 of the PL are taken into account. It has already been shown that the content of Article 99 section 3aa item 2 letters a-d of the PL is virtually the same as that of Article 99 section 3a items 1-4 of the PL – in force for several years now. These provisions differ only in their opening sentences. Therefore, it would be wrong to claim that new, previously unknown regulations were created for the entities affected by these regulations, since during the initial period of several years after the entry into force of Article 99 section 3a, both the Provincial Pharmaceutical Inspectors and the Chief Pharmaceutical Inspector, as well as the administrative courts interpreted the existing regulations in a way that the provision in question applies not only during the issuance of licenses, but also after the issuance of a license in connection with Article 37ap section 1 item 2 of the PL. The business of operating a community pharmacy is a professional and regulated activity, subject to licensing. In addition to basic pharmacy knowledge, it is also necessary to be familiar with the regulations in force under the Pharmaceutical Law Act. The holder of a pharmacy license “is responsible for ensuring that the pharmacy operates in accordance with applicable regulations.”⁵⁵ The

⁵¹ See: CT judgement of 28 October 2009, ref. Kp 3/09, OTK ZU 2009, no. 9/A, item 138.

⁵² See: S. Wronkowska, M. Zieliński, *Komentarz do zasad techniki prawodawczej*, Warsaw 2004, p. 111; L. Morawski, *Wstęp do prawoznawstwa*, Toruń 2002, p. 75; S. Wronkowska, *Podstawowe pojęcie prawa i prawoznawstwa*, Poznań 2005, p. 53; eadem, *Publikacja aktów normatywnych – przyczynek do dyskusji o państwie prawnym*, [in:] G. Skąpska (ed.), *Prawo w zmieniającym się społeczeństwie*, Toruń 2000, p. 343.

⁵³ See: CT judgement of 20 January 2010, ref. Kp 6/09, OTK ZU 2010, no. 1/A, item 3; CT judgement of 8 May 2012, ref. K 7/10, OTK-A. 2012, no. 5, item 48; CT judgement of 15 July 2013, ref. K 7/12, OTK ZU 2013, no. 6A, item 76; CT judgement of 31 July 2015, ref. K 41/12, OTK ZU 2015, no. 7A, item 102.

⁵⁴ See: CT judgement of 22 September 2005, ref. Kp 1/05, OTK ZU 2005, no. 8/A, item 93.

⁵⁵ See: p. 7 of the rationale for the amendment of 7 April 2017.

vacatio legis period provided for in the 13 July 2023 amendment should therefore be considered adequate.

Conclusion

The changes introduced by means of the 13 July 2023 amendment, involving the addition of sections 3aa and 3ab under Article 99 and sections 2a-2d under Article 103, are clarifying and editorial changes.

The constitutional principle of protection of acquired rights does not preclude the enactment of regulations that limit or abolish subjective rights or the enactment of regulations that are less favourable. The scope of application of the principle of protection of acquired rights does not cover legal situations that do not have the nature of subjective rights or of expectatives of these rights. The main source of the acquisition of the right to operate a pharmacy is a constitutive decision to grant (or transfer) a license to operate a pharmacy (Article 99 section 1 Article 104a section 1 item 1 of the PL), which makes it possible to determine clearly if such a right exists. The regulations enacted by way of the 13 July 2023 amendment do not deprive anyone of previously acquired rights because according to Article 12 of the amendment in question, the provisions of Article 99 sections 3aa and 3ab of the PL apply to a change of control that occurred after the date of entry into force of the amendment.

The concept of change of control has been used for a long time in the provisions of the CCPA and the PL. The definition of change of control derives from EU regulations and has a well-established meaning in CJEU decisions. Therefore, it seems impossible to agree with the claim that there occurs some vagueness that gives rise to the incompatibility of Article 4 section 4 of the CCPA – which defines the concept of change of control – with Article 2 of the Constitution. The fulfilment of a conditional, recurring or time-bound obligation, which would result in change of control that would take place after the granting of a license, would mean circumventing the provisions of the law (*ius cogens*) by means of a legal action.

The adopted *vacatio legis* period for the provisions of the 13 July 2023 amendment should be considered appropriate due to the fact that it applies to changes in the scope of regulations that have already existed in the pharmaceutical law for several years and are aimed at entities engaged in professional activities based in particular on familiarity with the law in force.

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