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"Reverse distribution chain" in public pharmacies in decisions of the Supreme Administrative Court

ABSTRACT

The purpose of this article was to demonstrate the approach of the Supreme Administrative Court to ruling in cases of the "reverse distribution chain" and its effects for the entities operating public pharmacies that participate in the "reverse distribution chain". The judgments of the Supreme Administrative Court in this area were analysed, taking into account the new legal standard prohibiting wholesale trade in medicinal products by a public pharmacy, regulations existing before the above legal standard was implemented, and the effects associated with the participation in the "reverse distribution chain". The most important conclusion of the above analysis was the fact that the Pharmaceutical Law, when regulating trade in medicinal products, defines the principles of such trade and only on the basis thereof may the activity be conducted.

KEYWORDS

reverse distribution chain, pharmacy, wholesale trade, disposal

Introduction

The "reverse distribution chain" is a term used in the media, legal doctrine, and administrative and court case law.

In the media world and healthcare market, the term "reversed distribution chain" of medicines is understood as various illegal practices undertaken with the aim of circumventing the law or acquiring medicinal products illegally and then exporting them abroad to derive significantly high profits. This procedure, especially with regard to some "unique" medicinal products available at attractive, low prices (often due to refund negotiations that result in the lowest prices in Europe), has led to significant shortages in the availability of

these medicines to patients in Poland. In the case of life-saving medicines, their lack also causes serious health risks.[1]

In the doctrine, it is assumed that reverse distribution qualifies as such when a pharmacy sells medicines to entities other than patients, i.e. other entities authorised to market the medicine.[2]

In the judicial decisions of the Supreme Administrative Court, the term "reverse supply chain" is used interchangeably with the term "reverse distribution chain", which does not change the fact that both expressions refer to the same activity of the operators of public pharmacies, who participate in the "reverse distribution chain".

The present study includes judgments of the Supreme Administrative Court with regard to the provision of Article 86(a) of the Act of 6 September 2001 Pharmaceutical Law, in force from 12 July 2015 to 6 June 2019. The purpose of this article was to present the normative context and approach adopted by the Supreme Administrative Court to ruling in cases of the "reverse distribution chain" and the effects for the entities operating public pharmacies that participate in the "reverse distribution chain".

Reverse distribution chain in normative context

The reversed distribution chain has obtained an independent regulation through the introduction of Article 86(a) into the Pharmaceutical Law. The provision was added by the Act of 19 December 2014 amending the Pharmaceutical Law and certain other laws.[3] It reads as follows: "Article 86(a). The sale of medicinal products through a public pharmacy or pharmacy shop to the pharmaceutical wholesaler, another public pharmacy or pharmacy shop shall be prohibited". The Law entered into force on 8 February 2015.

By the Act of 9 April 2015 amending the Pharmaceutical Law and certain other acts,[4] the wording of the provision has been changed and reads as follows: "Article 86(a). The disposal of medicinal products through a public pharmacy or pharmacy shop to the pharmaceutical wholesaler, another public pharmacy or pharmacy shop shall be prohibited". In this wording, the provision was in force from 12 July 2015 to 6 June 2019, when its content was seriously amended without being addressed in either the doctrine or judicial decisions of the Supreme Administrative Court. Various types of opinions appear in the media space, but they remain outside the scope of this analysis.

Wojciech L. Olszewski pointed out that the provision in Article 86(a) was introduced into the Act at the beginning of 2015 to address the problem of pharmacies that increased their sales of medicines to wholesalers who later exported them abroad. The pharmacies carrying out such activities defended themselves by claiming that there was no provision which

1 G. Mączyński, attorney-at-law at: http://aptecznerewolucje.pl/2018/11/15/odwrocony-lancuch-dystrybucji-produktow-leczniczych-jako-ogromne-ryzyko-oraz-odpowiedzialnosc-dla-aptek-i-farmaceutow/. Accessed 28.01.2020.

2 W.L. Olszewski (ed.), Article 86a, in: *Prawo farmaceutyczne*. *Komentarz*, Warszawa 2016.

3 Act of 19 December 2014 amending the Pharmaceutical Law and certain other acts, Dz.U. (Journal of Laws) of 2015, item 28.

4 Ibidem.

would explicitly prohibit such operations. Certainly, the prohibition should clearly result from the law, especially if entailing such severe sanctions as withdrawal of a pharmaceutical licence or even penal consequences. Therefore, in this context, it is impossible to question the grounds for introducing the aforesaid provision.[5]

Justyna Stefańczyk-Kaczmarzyk mentioned that the movement of goods between European Union countries was legal. It provides grounds for the principle of free movement of goods in the EU. In the case of medicinal products, the movement of goods takes place in the form of the so-called parallel import authorised by law. The economic basis for parallel import are differences between prices of medicines in individual EU countries. As a result, this phenomenon is becoming profitable despite the parallel distribution system operated by the producer. It should not result in a lack of medicines on the Polish market.[6]

On the other hand, Leszek Ogiegło stated that the Pharmaceutical Law amended in 2014 introduced a new provision, which explicitly prohibited the sale of medicines by public pharmacies and pharmacy shops to other public pharmacies or other pharmacy shops and pharmaceutical wholesalers. The existence of this restriction in the legal supply chain for medicinal products could be illustrated on the basis of the legislation in force, in particular, by showing the limits of legal distribution as set out in the established terms of reference for public pharmacies, pharmacy shops, and wholesalers. The terms of reference for entities involved in regulated business designate the limit which should not be exceeded for the entity not to be accused of illegal activity.[7]

It should be noted that in the Statement of Reasons for the draft to the Act of 9 April 2015 amending the Pharmaceutical Law and certain other acts, the legislator indicated that the need to clarify certain provisions in the Act of 6 September 2001 Pharmaceutical Law resulted from the necessity to solve the issue of uncontrolled export of medicinal products, medical devices, and foodstuffs for special nutritional purposes outside the territory of the Republic of Poland. It is necessary to introduce effective supervisory measures to be implemented by state authorities with respect to the process of distributing medicinal products, which is currently reaching a socially unacceptable level of pathology and making it impossible to ensure constant access to important medicinal products, the lack of which may cause permanent and adverse health consequences. It is necessary to provide the National Pharmaceutical Inspectorate with the competence in the monitoring, supervision and control of the distribution chain of medicinal products, foodstuffs for particular nutritional uses and medical devices. Therefore, it is assumed that the proposed regulations shall contribute to the reduction of the phenomenon of the so-called "reverse distribution" of medicinal products. The draft Act assumes that all participants in the distribution chain, i.e. the producer, wholesalers, and pharmacies, shall be obliged to regularly report on a daily basis on inventory balance and sales volume of goods.

5 W.L. Olszewski, op. cit.

6 J. Stefańczyk-Kaczmarzyk, *Art. 86(a) 86a.1.* [*Odwrócony łańcuch dystrybucji*], in: *Prawo farmaceutyczne. Komentarz*, M. Kondrat (ed.), 2nd ed., Warszawa 2016.

7 L. Ogiegło, Article 86a, in: *Prawo farmaceutyczne*, 3rd ed., Warszawa 2018.

Rafał Stankiewicz indicated that on 12 July 2015, Article 86(a) was introduced into the Act Pharmaceutical Law, pursuant to which the public pharmacy or pharmacy shop could not sell medicinal products to the pharmaceutical wholesaler or another public pharmacy or pharmacy shop. Therefore, the provision introduces an absolute ban on the sale of medicines by public pharmacies or other pharmacy shops to other public pharmacies or pharmacy shops, as well as pharmaceutical wholesalers. The aforementioned legal institution aims to prevent the creation of the so-called reverse distribution chain. At this point, it should be added that such an obligation could be inferred from the content of the previous regulations, but the implemented amendment eliminates any doubt in this regard.[8]

However, on a side note, it should be mentioned that, on the basis of the grounds for the draft Act of 4 April 2019 amending the Pharmaceutical Law and certain other acts (finally adopted on 23 April 2019), the current wording of the provision was to a large extent incomplete, as it only prohibited the sale of medicinal products by public pharmacies and pharmacy shops to other public pharmacies, pharmacy shops, and pharmaceutical wholesalers. The regulation did not cover many practical cases, such as, for example, the disposal of medicinal products by public pharmacies to nursing homes or other entrepreneurs not being patients, and the disposal of medicinal products to pharmaceutical wholesalers through herbal and public shops. In the present state of the law, the demand of the provider of medicinal products constitutes the only exception to the principle of direct supply to the public (Article 96 sec. 1 et seq. of the Pharmaceutical Law). The Pharmaceutical Law governs the above institution in a comprehensive and precise manner, without including other cases, where a pharmacy could sell medicinal products, also free of charge, to an entity other than a patient. However, pursuant to Article 65 sec. 1 of the Pharmaceutical Law, trade in medicinal products may be conducted solely in compliance with the principles described in the Act. Currently, there is no regulation in Article 86(a) of the Pharmaceutical Law that would be fully consistent with the above-mentioned rules on trade in medicinal products. This provision has been used by entrepreneurs selling medicines abroad through the aforesaid channels. The proposed wording of the provision indicates that a pharmacy or pharmacy shop may only sell medicinal products to directly supply the public, including free supply to patients – solely for the purpose of their treatment or based on the demand of entities carrying out therapeutic activities – in compliance with the principles set out in appropriate provisions of generally applicable law (in particular the Pharmaceutical Law and other regulations on official prices for medicinal products subject to refund).

In its judicial decisions, the Supreme Administrative Court mainly pointed out to the fact that the present lack of a legal norm including a direct ban on the sale of medicinal products by public pharmacies or pharmacy shops to the pharmaceutical wholesaler, other public pharmacies or pharmacy shops did not have any impact on the existence or operation of such ban. The Court inferred this prohibition from the entirety of the provisions of the Pharmaceutical Law, which govern wholesale and retail trade in medicinal products. In

8 R. Stankiewicz, *Obrót hurtowy w systemie obrotu produktów leczniczych,* in: *Instytucje rynku farmaceutycznego*, ed. R. Stankiewicz, Warszawa 2016.

its judgment of 13 August 2019, file no. II GSK 565/17,[9] the Supreme Administrative Court indicated that the ban on the sale of medicinal products by public pharmacies or pharmacy shops to the pharmaceutical wholesalers, other public pharmacies or pharmacy shops had remained in force before the implementation of Article 86(a) of the Pharmaceutical Law and resulted from the entire systematics of the Act Pharmaceutical Law, although not explicitly. The Court emphasised that the Act defined pharmacies as entities authorised to conduct retail trade only (Article 68 sec. 1 of the Pharmaceutical Law) and to supply the public (Article 87 sec. 2 point 1 of the Pharmaceutical Law). The distribution of medicines to entities other than patients generally falls within the scope of wholesale trade reserved exclusively to pharmaceutical wholesalers.[10]

In its judgment of 17 October 2018, file no. II GSK 3320/16,[11] the Supreme Administrative Court stated the following:

> The correct application, in the circumstances of the case, of Article 37ap sec.1 point 2 of the Pharmaceutical Law, as the legal basis for withdrawal of a pharmacy licence due to the ascertained loss of warranty of due execution of business in this case – contrary to the position of the complainant in the cassation proceedings – is not challenged by the amendment to the Pharmaceutical Law, introduced by the Act of 19 December 2014 amending the Pharmaceutical Law and certain other acts (Dz.U. [Journal of Laws] of 2015, item 28) and the Act amending the Pharmaceutical Law of 9 April 2015 (Dz.U. [Journal of Laws] of 2015, item 788). Pursuant to Article 103 sec. 1 point 2 of the Pharmaceutical Law, in compliance with the wording after the amendment, the voivodeship pharmaceutical inspector shall withdraw the licence to operate a public pharmacy if the pharmacy has infringed the provision of Article 86(a). Pursuant to the last provision, the disposal of medicinal products through a public pharmacy or pharmacy shop to the pharmaceutical wholesaler or another public pharmacy or pharmacy shop shall be prohibited. The Supreme Administrative Court does not find any arguments supporting the thesis that the quoted provision should be interpreted as the qualitative (normative) change with respect to the previous legal status. The above-mentioned ban on the wholesale trade in medicinal products was clearly based on the previous legislation and principles. "The sale of medicines by pharmacies/pharmacy shops to other pharmacies/pharmacy shops or pharmaceutical wholesalers was subject to sanction of withdrawal of the licence also before the entry into force of the Act amending the Pharmaceutical Law. The conditions, whose fulfilment authorised the body to issue the decision, are set out in Article 37ap of the Act, which applies to all licences regulated by the Act" (see Justyna Stefańczyk-Kaczmarzyk, *Komentarz do art. 86(a) Ustawy Prawo farmaceutyczne*, WK, 2016, Lex database). Therefore, it is justified to treat the implementation of Article 86(a) as the clarifying and editorial change. In the opinion of the adjudication panel of the Supreme Administrative Court, it may be assumed that, while under the law previously in effect – of course, depending on the factual circumstances of a particular case – it was possible to state that a pharmacy selling medicinal products to a pharmaceutical wholesaler did not entail losing the warranty of due execution of business, the implemented amendment, which introduced in Article

9 Judgment of the Supreme Administrative Court of 13 August 2019, file no. II GSK 565/17 available at the Central Database of Administrative Court Decisions, website http://orzeczenia.nsa.gov.pl/cbo/query, hereinafter referred to as "CBOSA". Accessed 12.02.21.

10 Cf. W.L. Olszewski, op. cit.

11 Judgment of the Supreme Administrative Court of 17 October 2018, ref. no. II GSK 3320/16, CBOSA.

> 86(a) the explicit ban on the sale of medicinal products by the public pharmacy or pharmacy shop to the pharmaceutical wholesaler or another public pharmacy or pharmacy shop, also provides for the consequences of breaching the provision of Article 86(a), resulting directly from the Act, in the form of an obligatory withdrawal of the licence to operate a public pharmacy by a competent authority (amended Article 103 sec. 1 point 2).

In the judgment of 5 March 2019, file no. II GSK 12/17,[12] the Supreme Administrative Court stated:

> The amendment introduced to the Pharmaceutical Law on 12 July 2015 only enhanced the existing ban on the sale of medicinal products by the public pharmacy to another pharmacy and transformed the nature of the sanction from an optional to an obligatory penalty. Pursuant to Article 103 sec. 1 point 2 of the Pharmaceutical Law, the voivodeship pharmaceutical inspector shall withdraw the licence to operate a public pharmacy if the pharmacy has infringed Article 86(a). In compliance with the last provision, the disposal of medicinal products through the public pharmacy or pharmacy shop to the pharmaceutical wholesaler, other public pharmacy or pharmacy shop shall be prohibited. The legal regulation of the Pharmaceutical law, in the wording applicable and amended in this case, provided for the disputable prohibition and authorisation of the pharmaceutical inspection authorities to withdraw the pharmacy licence in the event when it is established that the operator does not provide the warranty of due execution of business, also in the case of breach of such prohibition.

In the judgment of 15 October 2019, ref. no. II GSK 2669/17,[13] the Supreme Administrative Court stated that it shared the view expressed in the case law that the prohibition of the so-called "reverse distribution" in Article 86(a) of the Pharmaceutical Law may not be interpreted as the normative qualitative change with respect to the previous legal status. The introduction of Article 86(a) is rightly treated as the clarifying and editorial change.[14]

In the aforementioned judgments, the Supreme Administrative Court explicitly pointed out that the provision in Article 86(a) of the Pharmaceutical Law, introduced and amended in 2015, was aimed at encompassing the ban in a single provision and explaining the doubts raised so far, leading to the argumentation of the entities operating public pharmacies that the lack of the provision made it impossible to be held liable for its violation. Additionally, the Supreme Administrative Court emphasised in its rulings the fact that the provision of Article 86(a) of the Pharmaceutical Law, in the wording established in 2015, did not introduce any new solution or approach to the concept of "reverse distribution". Such wording of the introduced provision should be interpreted as the strengthening of the approach to the above-mentioned practices resulting in the infringement of not only this particular provision of the Pharmaceutical Law, but also many other regulations included therein, as discussed below.

12 Judgment of the Supreme Administrative Court of 5 March 2019, ref. no. II GSK 12/17, CBOSA.

13 Judgment of the Supreme Administrative Court of 15 October 2019, ref. no. II GSK 2669/17, CBOSA.

14 Cf. Judgment of the Supreme Administrative Court of 17 October 2018, ref. no. II GSK 3320/16 and the views included in the doctrine views referred to therein.

Prohibition of wholesale trade in medicinal products by the public pharmacy

First of all, it should be stressed that under Article 65 sec. 1 of the Pharmaceutical Law, trade in medicinal products may be conducted solely in compliance with the rules set out in the Act. As a matter of principle, retail trade in medicinal products shall be conducted in public pharmacies (Article 68 sec. 1). Article 72 sec. 1 of the aforementioned Act – stipulating that the wholesale trade in medicinal products (…) may be conducted only by entities (including pharmaceutical wholesalers) specified in this provision – excludes the possibility of such trade by pharmacies. The legislator defined "trade" in Article 72 sec. 3 as any form of supply, storage, delivery or export of medicinal products or veterinary medicinal products, with marketing authorisation for a medicinal product issued in a Member State of the European Union or the European Free Trade Association (EFTA) – a party to the European Economic Area Agreement or authorisation referred to in Article 3 sec. 2, executed for the benefit of manufacturers or importers of medicinal products which they manufacture or import, or wholesalers, or pharmacies or veterinary clinics, or other authorised persons, excluding direct supply to the public.

In its judgment of 17 October 2018, ref. no. II GSK 3320/16,[15] the Supreme Administrative Court held that the sale of medicinal products by the pharmacy to the pharmaceutical wholesaler was in the form of wholesale and such trade in medicinal products was prohibited under the Pharmaceutical Law. By virtue of article 65 sec. 1 of the Pharmaceutical Law, trade in medicinal products may be conducted solely in compliance with the rules set out in the Act.

However, already in the judgment of 22 May 2014, the Supreme Administrative Court indicated that the Pharmaceutical Law included the definition of the wholesale trade in medicinal products (Article 72 sec. 3 of the Pharmaceutical Law). The definition is closely linked to the character of the entities that receive supplies of medicinal products. The definition is explicit and clearly shows that the supplies to, *inter alia*, wholesalers and pharmacies constitutes wholesale. Article 72 sec. 1 of the Pharmaceutical Law stipulates that only wholesalers may engage in wholesale trade, whereas Article 74 sec. 1 of the Pharmaceutical Law indicates that the operation of the pharmaceutical wholesaler requires special authorisation. Nevertheless, when comparing Article 80 sec. 1 point 3 and Article 101 point 3 of the Pharmaceutical Law, it is evident that one entity may not operate the public pharmacy and pharmaceutical wholesaler at the same time, since conducting one of such businesses precludes the obtaining of the licence to operate the other business. The Court held that, on the basis of the invoked provisions, it was apparent that the wholesale trading required a special licence, which could not be obtained by the entity operating the public pharmacy. Therefore, the wholesale trading by the public pharmacies was prohibited and the prohibition did not result from Articles 86 and 87 of the Pharmaceutical Law governing the operation of pharmacies, but from the provisions on wholesale trade (Article 72 sec. 1 in connection with Article 72 sec. 3 of the Pharmaceutical Law), according to which wholesale trade could

15 Judgment of the Supreme Administrative Court of 17 October 2018, ref. no. II GSK 3320/16, CBOSA.

be conducted only by wholesalers, customs and consignment warehouses. Since these are only the wholesalers, customs and consignment warehouses that may conduct the wholesale trade, it means that other entities may not be involved in such trade. Therefore, based on this very regulation, the ban on the wholesale trade by public pharmacies should be inferred. The judgment shows that before the introduction of Article 86(a) of the Pharmaceutical Law, the Supreme Administrative Court has already taken a clear position, without any doubts as to the separation of retail trade from wholesale trade in medicinal products and the impossibility of combining these two activities. It should be mentioned that both wholesale and retail trade are carried out within an extremely sensitive area, which is the protection of human health.

The above also leads to the conclusion that the provision in Article 65 of the Pharmaceutical Law sets forth the principle that has no exceptions. The market operators involved in the marketing of medicinal products must decide to be involved in either retail or wholesale trade. Neither the legislator nor the court and administrative case law permit any derogations in this regard.

The aim of retailers in medicinal products, i.e. the operators of public pharmacies, to demonstrate the scale of their turnover or lack of health risk could not be achieved.

Consequences of the ban on disposal

Pursuant to Article 37ap sec.1 point 2 of the Pharmaceutical Law, the licensing authority shall withdraw the licence if the entrepreneur ceases to meet the conditions prescribed by law, required for the performance of business activity specified in the licence.

In its judicial decisions, the Supreme Administrative Court stated that the aforesaid provision referred to non-compliance with the laws – which proved that the entrepreneur no longer met the conditions required to conduct business as specified in the licence.

It is confirmed by, among other things, the following judgments of the Supreme Administrative Court:

- Judgment of 2 October 2019, file no. II GSK 2667/17[16] (available at CBOSA), in which the Court stated that, apart from the dispute, there was also the issue of mandatory withdrawal of the licence subject to Article 37ap of the Pharmaceutical Law; contained in Chapter 2b "General provisions on licensed business activity". Pursuant to Article 37ap sec.1 point 2, the licensing authority shall withdraw the licence if the entrepreneur ceases to meet the conditions prescribed by law, required for the performance of business activity specified in the licence.
- Judgment of 5 March 2019, file no. II GSK 1542/17,[17] in which the Court found that the withdrawal of the licence to operate the public pharmacy did not depend, according to the legislator, on the scale or seriousness of violations or the reasons therefor. On the contrary, the legislator used the imperative of this provision, expressed in the phrases "with-

16 Judgment of the Supreme Administrative Court of 2 October 2019, ref. no. II GSK 2667/17, CBOSA.

17 Judgment of the Supreme Administrative Court of 5 March 2019, ref. no. II GSK 1542/17, CBOSA.

drawal of the licence" and "the entrepreneur ceases to meet the conditions prescribed by the law", which indicated the (obligatory) competence of the pharmaceutical inspector to withdraw the licence if the conditions for carrying out pharmaceutical business had been breached. The Court pointed out that the withdrawal of the licence was based on purely objective premises, i.e. finding that the infringement had been committed. Liability for infringement of the conditions for operating a public pharmacy is objective liability (of administrative character). The legislator, probably bearing in mind higher values, such as the constitutional guarantee of the protection of human health and life as well as the social importance of the pharmacist's profession, did not decide – as was often the case – to introduce statutory conditions which, if demonstrated by the entrepreneur, would form grounds for exemptions from the "sanctions" in the form of withdrawal of the pharmaceutical licence.

Moreover, the Supreme Administrative Court emphasised that the warranty of due execution of business was one of the provisions laying down the conditions required to carry out the activity specified in the licence. Pursuant to Article 101 sec. 4 of the Pharmaceutical Law, the voivodeship pharmaceutical inspector shall refuse to grant the licence to operate a public pharmacy if the applicant does not provide the warranty of due execution of business.

In its judgment of 5 March 2019, the Supreme Administrative Court also noted that one of the premises for refusing to grant the licence to operate a public pharmacy was the loss of the warranty of due execution of business by the applicant. Therefore, the applicant who applies for the pharmaceutical licence shall not receive it if they fail to provide the warranty of due execution of business. The condition for the warranty of due execution of business must exist not only at the time of granting the licence to operate a pharmacy, but must also remain effective throughout the whole period of operation of such business activity, and the limits, within which the entrepreneur may conduct such legally regulated activity are determined by the obligations imposed under the Pharmaceutical Law. In the above-mentioned judgment, the Supreme Administrative Court stated that the Act Pharmaceutical Law, which regulates, among other things, business activity in the field of trade in medicinal products, constituted a cohesive act that should be read and interpreted as a whole, whereas an attempt to interpret a single provision without taking into account other regulations contained in that Act led to wrong conclusions. Pursuant to the provision in Article 65 sec. 1 of the Pharmaceutical Law, it is evident that the trade in medicinal products may be conducted solely in compliance with the principles stipulated therein. It means that, according to other rules, the aforementioned activity may not be carried out and any deviation from the statutory trading principles are unacceptable. The regulation contained in the Pharmaceutical Law provides for two forms of trade in medicinal products, i.e. retail trade and wholesale trade.

In addition, the Court pointed out that, subject to sec. 8 sec. 2, only pharmaceutical wholesalers, customs and consignment warehouses of medicinal products may engage in wholesale trade in medicinal products pursuant to Article 72 sec. 1 of the Pharmaceutical Law. However, by virtue of Article 68 sec. 1 of the Pharmaceutical Law, retail trade in me-

dicinal products shall be conducted in public pharmacies subject to sec. 2, Article 70 sec. 1, Article 71 sec. 1 and Article 72 sec. 3 of the Pharmaceutical Law. In both cases, it is required to obtain the appropriate licence pursuant to Article 74 sec. 1 of the Pharmaceutical Law and Article 101 of the Pharmaceutical Law, respectively. Therefore, a pharmacy may not sell medicines to other pharmacies or wholesalers, as it is only the wholesaler who is allowed to be involved in wholesale.[18]

Based on the premises specified in Article 37 sec. 1 point 2 of the Pharmaceutical Law and Article 104 point 4 of the Pharmaceutical Law, the Supreme Administrative Court clearly stated that both the public administration bodies and the Voivodeship Administrative Court did not violate the law by deciding to withdraw the licence to operate a public pharmacy, which had been granted to the entity using "reverse distribution chain" in their pharmacy. In compliance with the Pharmaceutical Law, the withdrawal of the licence is the most severe sanction for the pharmacy operator, as it deprives the operator of the possibility to run their business and consequently makes it impossible therefor to operate all public pharmacies in the country. Therefore, the Supreme Administrative Court had consistently stated in its rulings that the "reverse distribution" is an example of infringement of the requirements stipulated in the provisions of the Pharmaceutical Law.

Conclusions

The above analysis shows that the Supreme Administrative Court has consistently indicated that the provisions of the Pharmaceutical Law, which govern the regulated business activity in the field of health protection, should be read literally, as established by the legislator. When interpreting the provisions on retail trade in medicinal products, it is important to consider the purpose of the operations of the public pharmacy, which has been explicitly regulated in Article 86 sec. 1 point 1 of the Pharmaceutical Law. Once again, it is worth referring to judgment of the Supreme Administrative Court, in which it stated that the Act Pharmaceutical Law, regulating, among other things, business activity in the field of trade in medicinal products, constituted a cohesive act that should be read and interpreted as a whole, whereas an attempt to interpret a single provision without taking into account other regulations contained in that Act led to wrong conclusions.[19] In addition, the regulated business activity in the field of health protection is aimed at safeguarding such values as human health and life, hence, the control exercised over such activity should be efficient. At the same time, the Supreme Administrative Court, by shaping a uniform line of case law with respect to "reverse distribution", enhanced the form of the proper course of proceedings conducted by public administration bodies and showed how the legal norms should be construed. The "reverse distribution chain" is presented in the judicial decisions of the Supreme Administrative Court as material breach of law, going beyond the framework of the regulated business activity, i.e. trade in medicinal products.

18 Judgment of the Supreme Administrative Court of 22 May 2014, ref. no. I GSK 491/13, G. Prawna FiP 2014/150/2.

19 Judgment of the Supreme Administrative Court of 17 October 2018, ref. no. II GSK 4607/16, CBOSA.

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