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Iustitias vestras iudicabo – European Commision's action against Poland over the prohibition of pharmacy advertising

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Abstract. In July 2023 the European Commission has announced bringing an action to the Court of Justice of the European Union against Poland. The action concerns on the functioning of the prohibition of pharmacy advertising in Polish law, which leads to the question - whether and how such prohibition may violate European law. The objective of this research paper is to give, in particular for a foreign reader, a general overview of the prohibition of pharmacy advertising institution, as well as the proceedings conducted by the European Commission under Art. 258 of the Treaty on the Functioning of the European Union against Poland. The other objective of this paper is to conclude whether there are existing any alternatives to resolve dispute between the Commission and Poland, without a necessity for bringing an action to the Court and also what are the possible consequences of not using them. The author of the paper shares his remarks on one of the allegations presented in the European Commission's press release.

Keywords: freedom of establishment, freedom to provide services, electronic commerce, prohibition of pharmacy advertising.

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INTRODUCTION AND SHORT HISTORICAL BACKGROUND OF THE PROHIBITION

In July 2023 the European Commission has announced bringing an action to the Court of Justice of the European Union against Poland (European Commission, 2023). The action concerns on the functioning of the prohibition of pharmacy advertising in Polish law, which leads to the question - whether and how such prohibition may violate European law. However, it is impossible to assess that without understanding how the prohibition is functioning in Polish law and how it affects the market. The objective of this research paper is to give, in particular for a foreign reader, a general overview of the prohibition of pharmacy advertising institution, as well as the proceedings conducted by the European Commission under Art. 258 of the Treaty on the Functioning of the European Union (2007, hereinafter as "TFEU") against Poland. The other objective of this paper is to conclude

whether there are existing any alternatives to resolve dispute between the Commission and Poland, without a necessity for bringing an action to the Court and also what are the possible consequences of not using them. The author of the paper shares his remarks on one of the allegations presented in the European Commission's press release. Because of the ongoing proceedings, the author was only able to use publicly available press releases, Polish and foreign scientific literature and the current Court of Justice's case law.

An amendment to the Ustawa Prawo farmaceutyczne (2001) (hereinafter as "Pharmaceutical Law Act"), which entered into force on 1 January 2012, has been controversial from the outset (e.g., Kozik & Pietyga, 2014). It was not just because of the new wording of Art. 94a of the Pharmaceutical Law Act, which constitutes a limitation on the advertising activities of pharmacies. Doubts could have been raised by the procedure in which the amendment was carried out. Art. 94a has been amended by a provision of a completely different act - Act on medicine, foodstuffs intended for particular nutritional uses and medical devices reimbursement (Ustawa o refundacji, 2011, art. 60 point 7). Such a procedure may be seen as questionable from the point of view of conformity with the principles of legislative technique that were in force at that time. Although, Rozporządzenie Prezesa Rady Ministrów (2002, Para. 83 point 2) indicated that it is acceptable to amend a provision of an act with an amending provision provided for in another act. However, under the provision of Para. 3 (3) of the Regulation, an act could not amend the provisions regulating matters which do not fall within or relate to its subject matter or personal scope. Dończyk & Stupak (2020, p. 20-21) and also Wiszniewska (2019, p. 3) indicate many different from the accepted standards circumstances in the handling of amendments - for example: failure to conduct public consultations, failure to conduct inter-ministerial consultations, amending the provision of Art. 94a of the Pharmaceutical Law Act at the final stage of legislative works. According to the information available on the official website of the Constitutional Tribunal, the mentioned provision has been the subject of three constitutional complaints, however no substantive judgment has been made on the constitutionality of the provision (proceedings with reference numbers SK 23/15, SK 32/15 and SK 11/16 were discontinued[1]). The literature suggests that the declared *ratio legis* of the amended provision – significantly, it was externalized only after the law was passed – was concern for the protection of public health, specifically, counteracting excessive consumption of medicines as a result of certain advertising activities - the same source highlights that it was raised in the public discourse that the real reason for the change could be the stimulation of the pharmaceutical retail market by reducing competition in favour of smaller operators (Olszewski, 2016, p. 960). Wiszniewska (2019, p. 3-4) indicates similar official motivation of the amendment as Olszewski (2016) complementing it with the goal of preventing self-medication[2]. Furthermore, she suggests that the new wording of the provision was proposed by the Naczelna Izba Aptekarska [The Supreme Pharmaceutical Chamber], and the Chamber's reasoning was accepted uncritically by participants of the legislative process (2019, p. 4).

NATIONAL LAW AND ITS INTERPRETATION

The current wording of the provision of Art. 94a Para. 1 of the Pharmaceutical Law Act (2001) constitutes a highly restrictive ban on advertising by pharmacies and pharmaceutical points as well as their activities. It only clarifies that the information about location and working hours of the pharmacy or pharmaceutical point does not constitute advertisement. Moreover, the following provision of Art. 94a Para. 1a of the Act states that in the case of non-pharmacy outlets only the advertisement of their activities relating to medicinal products or medical devices is prohibited. According to the Pharmaceutical Law Act retail trade in medicinal products in the territory of Poland is

[1] Information retrieved from: Internetowy Portal Orzeczeń Trybunału Konstytucyjnego [The Internet Portal of Constitutional Tribunal Decisions] – search record for the subject of review: "Ustawa z dnia 6.09.2001 r. Prawo farmaceutyczne" - https://ipo.trybunal.gov.pl/ipo/SzukajSprawy?cid=1.

[2] Wiszniewska is reffering to the content of the parliamentary questions: Interpelacja poselska Nr 25899 (2014, April 7), Interpelacja poselska Nr 21536 (2013, October 31), Interpelacja poselska Nr 22456 (2013, December 12).

conducted generally by retail pharmacies (Ustawa prawo farmaceutyczne, 2001, Art. 68 Para. 1). Other entities authorized to retail medicinal products are the pharmaceutical points (Ustawa prawo farmaceutyczne, 2001, Art. 70 Para. 1) and the non-pharmacy outlets which are allowed to retail OTC medicines indicated in the list included to the minister of health's regulation with exclusion of the veterinary medicinal products (Ustawa prawo farmaceutyczne, 2001, Art. 71 Para. 1 i 3). As Świerczyński (2020, p. 522) indicates, the categories of pharmaceutical points and general pharmacies are distinguished mainly by the smaller range of medicinal products that can be offered and smaller range of services that can be provided, no possibility of medications compounding, as well as mandatory for pharmaceutical points, which was established after the provision entered into force, location in rural areas where (within a village) there is no general pharmacy. As it was stated in the aforementioned provision of the Act, non-pharmacy outlets are herbal-medical shops, specialist medical supply shops and public accessible stores (e.g., grocery stores, petrol stations, etc.). Importantly, as Olszewski (2016, p. 975) points out, the prohibition of pharmacy and pharmaceutical points advertising is targeted not only at the owners of the aforementioned entities, but at all entities advertising pharmacies and pharmaceutical points or their activities. The prohibition of advertising also extends to the so-called "online pharmacies" that conduct mail-order sales. In this context as a prohibited form of pharmacy advertising on the Internet are mentioned for example: Google AdWords advertisements, online forms of loyalty programs or discount coupons, as well as other activities aimed at promoting the pharmacy itself (Dończyk & Stupak, 2020, p. 53-57; Śmigulska-Wojciechowska, 2020, p. 22).

The legal position of the owners of pharmacies or pharmaceutical points and the owners of non-pharmacy outlets is therefore different which has not escaped the attention of the legal literature (see Wiśniewska, 2018, p. 426). The inadmissibility of advertising the activities of a pharmacy or pharmaceutical point in the meaning of Article 94a Para. 1 of the Act covers the entire activity of the pharmacy – not only that related to medicinal products, which is reflected in the judicial decisions (e.g. Wyrok Wojewódzkiego Sądu Administracyjnego w Warszawie [Judgment of the Voivodeship Administrative Court in Warsaw], 2014). As was mentioned previously, in the case of non-pharmacy outlets the prohibition of advertising covers only the advertisement of their activities relating to medicinal products or medical devices. Unequal treatment of these entities on the basis of Art. 94a of the Act seems to be unjustified. After all, the main purpose of the amendment to the provision was to counteract excessive consumption of medicines. In the meantime, both non-pharmacy outlets and pharmacies or pharmaceutical points can:

- distribute OTC medicines – although non-pharmacy outlets in limited scope (Ustawa Prawo farmaceutyczne, 2001, Art. 68 Para. 1 and 3, Art. 70 Para. 1 and Art. 71 Para. 1 and 3);
- conduct sales of non-medicinal products such as e.g.: hygiene products, dietary supplements, baby care and sick care products (for pharmacies the legal base for distribution products listed in Art. 72 Para. 5 of the Pharmaceutical Law Act is Art. 86 Para. 8 of the Act) (Ustawa Prawo farmaceutyczne, 2001).

Furthermore, it should be taken into account that, in accordance with Art. 86 Para. 1 (Ustawa Prawo farmaceutyczne, 2001) general pharmacies are "public health facilities" and pharmaceutical services within the meaning of the Act on profession of pharmacist (Ustawa o zawodzie farmaceuty, 2020, Art. 4 Para. 3) can be provided at them. For example, such services are:

- compounding of medicinal products combined with assessment of their quality, including sustainability;
- conducting pharmaceutical interview (this is an activity mainly targeted at selecting appropriate medicinal product and providing advice on usage of a product or recommending medical consultation – see Ustawa o zawodzie farmaceuty, 2020, Art. 3 point 8);
- providing pharmaceutical advice (in order to ensure correct usage of medicinal products, medical devices or foodstuffs intended for particular nutritional uses);
- performing blood pressure measurements.

Pharmaceutical care is provided in pharmacies (Ustawa prawo farmaceutyczne, 2001, art. 86 Para. 2). It is healthcare benefit provided by pharmacist in cooperation with at least patient and medical practitioner who treats

him, where pharmacist monitors the progress of the pharmacotherapy through e.g.: conducting pharmaceutical consultations, performing Medicines Use Reviews, issuing prescriptions to ensure continuity of medical treatment in scope of continuing medical practitioner order (Ustawa o zawodzie farmaceuty, 2020, art. 4 Para. 2). General pharmacies are also allowed to sell medicinal products or compounded medications for human use, which will be used on animals, on the basis of veterinarian's prescription (Ustawa prawo farmaceutyczne, 2001, art. 86 Para. 5).

Considering the analysis given above, it should be concluded that the pharmacies scope of activities is much broader than distribution of OTC medicines or even distribution of prescription medicines, which should not be qualified as significant part of the problem that the amendment of Art. 94a of the Pharmaceutical Law Act was intended to prevent. Prescription medicines are, in a certain sense, regulated – prescriptions can be filed only by particular entities which are responsible for this activity in various forms. Meanwhile, the provision of Art. 94a, amended to fight against excessive consumption of medicines, prohibits advertisement of pharmacies and pharmaceutical points while ignoring the fact that OTC medicines are legally available in for example supermarkets, which are allowed to advertise their activity if the advertisement is not related to medicinal products or medical devices. Furthermore, it should be noted that certain categories of goods distributed by non-pharmacy outlets may be also distributed by pharmacies and pharmaceutical points, but without opportunity to advertising such activity legally. Such goods are for example, hygiene products or baby care products. As a result, proportionality and advisability of introduced regulation may raise serious doubts.

According to Art. 94a Para. 2-4 of the Pharmaceutical Law Act (Ustawa Prawo farmaceutyczne, 2001) the Wojewódzki Inspektor Farmaceutyczny [the Voivodeship Pharmaceutical Inspector] supervises compliance with the prohibition of advertising worded in Para. 1 and 1a. The Inspector is authorized to issue an immediately enforceable administrative decision ordering cessation of advertising that violates the provision. Art. 129b of the Act states that the Inspector imposes an administrative monetary penalty in the amount up to 50 000 PLN on the one who infringes the prohibition of advertising. There is also a legal norm expressed by Art. 103 Para. 2 point 5 of the Act which allows the Inspector to issue a discretionary administrative decision on withdrawal pharmacy license. Therefore, the penalties for infringement of the prohibition of advertising can be very severe, especially for the owners of the pharmacies and pharmaceutical points who violates the provision of Art. 94a.

The Pharmaceutical Law Act (Ustawa Prawo farmaceutyczne, 2001) does not define the term "pharmacy advertising" in any other way than this indicated by the wording of the provision of Art. 94a. In the literature available to the author, it is often mentioned that administrative courts have established – although, as Olszewski (2016, p. 960) highlights, after some time - uniform ruling practice in this matter and the term of pharmacy advertising is interpreted as broadly as possible (e.g. Wiśniewska, 2018, p. 427; Dończyk & Stupak, 2020, p. 21). The view that uniform ruling practice is established in this matter is not shared by Wiszniewska (2019, p.3). The relatively frequently referred (e.g., by Dończyk & Stupak, 2020, p. 21; Stefańczyk-Kaczmarczyk, 2016, p. 1117-1118) ruling in this context is the Wyrok Wojewódzkiego Sądu Administracyjnego w Warszawie [Judgment of the Voivodeship Administrative Court in Warsaw] (2008), where the court took a position that "The pharmacy advertisement might be each action addressed to general public, towards the increasing sales of medicinal products and medical devices offered therein. It will be also, (…), the list mentioning by name reimbursed medicines, even if it does not contain price comparison, but is preceded by low price and high discounts slogans, as it was in this case.". Another frequently referred ruling (e.g., by Olszewski, 2016, p. 962; Stefańczyk-Kaczmarczyk, p. 1117) is the Wyrok Sądu Najwyższego [Judgment of the Supreme Court] (2007), where the court uses definition of advertisement understood as any presentation or statement in any form within the scope of commercial, business, craft activity or exercising a liberal profession in order to support sales of goods or provision of services. The Judgment also suggests that the advertisement includes all forms of communication which can be taken by the recipients as incentive to purchase. In a slightly newer ruling (Wyrok Naczelnego Sądu Administracyjnego [Judgment of the Supreme Administrative Court], 2022) the Supreme Administrative Court refers to its own case law and concludes that the advertisement is every action aimed at encouraging potential clients to purchase specific goods or to use specific services regardless

of the form, method and measures used. Despite the formal exception to the prohibition that allows inform about location and working hours of the pharmacy or pharmaceutical point, there have been cases where both the public administration authority and the court stated that the banners with information about the name and the location of the pharmacy (direction and distance from the banner) are a form of advertising. In the court's opinion, the banners were too big and attracted too much attention from the potential patient. Quoting from the Wyrok Wojewódzkiego Sądu Administracyjnego w Warszawie [Judgment of the Voivodeship Administrative Court in Warsaw] (2020) - "(…) in the Court's opinion the advertising banners did not constitute only an information about the location of the pharmacy. Considering the form of expression (huge banners visible from the distance) and not only their content, as well as additional elements in the form of directional arrows, it had to be considered that the banners were in fact an advertisement of specific pharmacy owned by the Complainant.". It can be observed that the Polish administrative courts are relatively consistent on application of a broad interpretation of the prohibition of pharmacy advertising.

THE PROCEEDINGS BEFORE THE EUROPEAN COMMISSION AND DECISION ON REFER POLAND TO THE COURT OF JUSTICE

Recently, the European Commission in the press release (European Comission, 2023) informed about referring Poland to the Court of Justice of the European Union (hereinafter as "the CJEU"). This is the culmination of two proceedings conducted so far in this case before the Commission – infringement procedure under Art. 258 TFEU (infringement number INFR(2018)4028 - ended by bringing an action before the CJEU) and EU-Pilot procedure 7216/14/MARK, which, according to Wiszniewska (2019, p. 10) and which seems to be confirmed by the press release of the Konfederacja Lewiatan[3] (2023), was initiated in October 2013. The main allegations of the Konfederacja Lewiatan (which was the applicant) in the EU-Pilot proceedings were based on the thesis, that Poland through adopting and maintaining in force Art. 94a of the Pharmaceutical Law Act infringes (Wiszniewska, 2019, p. 11):

the principle of the primacy of European Union law and art. 4(3) of the Treaty on European Union;

- Art. 34 TFEU;
- Art. 49 TFEU;
- Title VIII of the directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use;

Art. 3 Para. 3 of the Treaty on European Union and the Protocol (No 27) on the internal market and competition, Art. 4 Para. 3 of the Treaty on European Union, Art. 101 TFEU.

Wiszniewska (2019, p. 13), which refers to the content of the letter of the Polish Minister of Foreign Affairs, indicates that the EU-Pilot procedure has been closed on 11 April 2018, and the European Commision did not accept the explanations of the Minister of Justice concerning raised allegations. As the Minister of Health's answer to the Parliamentary Question No. 9544 (Odpowiedź Ministra Zdrowia na zapytanie nr 9544, 2019) mentions, after the end of the EU-Pilot procedure in 2018, works on the amendment of the provision of Art. 94a of the Pharmaceutical Law Act (2001) was underway. However, the works only involved excluding from the prohibition of pharmacy advertising the display of information on the honoring of the Karta Dużej Rodziny[4] as well as the information about the Card itself provided in relevant Act. These drafts were contained in the bill on profession of

[3] Also confirmed by Piskorski, M. (2022, May 20). Zakaz reklamy aptek stoi na drodze rozwoju usług i opieki farmaceutycznej. Available at: https://lewiatan.org/zakaz-reklamy-aptek-stoi-na-drodze-rozwoju-uslug-i-opieki-farmaceutycznej/ (visited: 28 August 2023).

[4] Karta Dużej Rodziny [The Large Family Card] is a measure that identifies a member of a large family and certifies his right to entitlements under the card. In Poland, it is regulated by the Ustawa o Karcie Dużej Rodziny [The Large Family Card Act] (2014, December 5). t.j. Dz. U. z 2021 r. poz. 1744.

pharmacist (bill of the Ustawa o zawodzie farmaceuty, 2020) and were to have been introduced by this bill, which ultimately did not happen. Obviously, such a narrow approach to the problem identified by the Commission would not solve it anyway.

The Commission's press release (European Commision, 2023) states that, the European Commission issued a letter of formal notice to Poland in January 2019 followed by a reasoned opinion in July 2020, which, according to the press release, has not had the effects expected by the Commission and resulted in referral procedure to the CJEU. The allegations, at least those mentioned in the press release which is so far one of the few publicly available sources of information on the ongoing proceedings, have been significantly reduced in comparison to those contained in the Konfederacja Lewiatan's complaint to the European Commission. The allegations include infringement of Art. 49 and 56 TFEU and violation of unspecified provisions of the Directive on electronic commerce[5].

The functioning of Art. 94a of the Pharamaceutical Law Act (Ustawa Prawo farmaceutyczne, 2001) and the practice of its application in the Polish legal system seems to raise serious doubts about its conformity with the previously mentioned acts of European Union law. The Polish administrative courts do not seem to notice it. Suffice it to say that, until August 2023 probably no Polish court has made a reference for a preliminary ruling in this matter, despite ongoing proceedings before the Commision. By making a few remarks on this ground, the author would like to emphasize that it is necessary to take into consideration the broader context of European Union law when considering a possible violation of Art. 56 TFEU. First of all, the prohibition of advertising affects not only the pharmacies themselves, but it also affects providers of advertising services, which was mentioned above. This is particularly important in the age of information society and widespread offering and provision services via the Internet. Therefore, the potential victims of the prohibition may be not only those entities, which operates on the domestic pharmaceutical retail market, but also other operators from other Member States, such as: advertising agencies, non-Polish online pharmacies that conduct mail-order sales or pharmacies operating in a border areas. Even if we naively assume that there are no pharmacies connected with other European Union Member State on Polish pharmaceutical retail market, this is acceptable to rely upon Art. 56 TFEU against own state of establishment which is confirmed by the Courts of Justice settled case law. However, it is necessary to provide services in another Member State – even if the service provider remains in own Member State while providing service (Moens & Trone, 2010, p. 102). Therefore, a Polish online pharmacy that conduct mail-order retail to the other Member States, which could not advertise in those Member State because of Polish advertising prohibition, can rely on Art. 56 TFEU before both national courts and the CJEU. Furthermore, as Moens & Trone (2010, p. 103-104) mentions - "*Apart from prohibiting discrimination on the basis of nationality, the Court has held that Art 56 TFEU requires the "abolition of any restriction . . . which is liable to prohibit, impede or render less advantageous the activities of a provider of services established in another Member State where he lawfully provides similar services". See Société Civile Immobilière Parodi v Banque H Albert de Bary et Cie (C-222/95) [1997] ECR I-3899 at [18]; [1998] 1 CMLR 115 (…)*". This view also can be considered as confirmed by the CJEU settled case law – for example by judgment in Case C-405/98 (2001), which is mentioned in the further part of the cited text. The Judgment in this case was based on a situation similar to the Polish prohibition of pharmacy advertising (it concerned restrictions on advertising alcoholic beverages introduced in Sweden). Because of that, it should be analyzed in detail, in particularly the view of the Court expressed in point 42 of the Judgment, where the Court conditioned the legality of a prohibition on the advertising of alcoholic beverages on the impossibility of ensuring the protection of public health by measures having less effect on intra-Community trade. Probably it is not difficult to imagine other, less market-damaging state actions that can be taken to counteract self-medication or abuse of OTC medicines.

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[5] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market.

Very important in this regard is also the doubtful quality of the justification for the prohibition of pharmacy and pharmaceutical points advertising[6]. It seems illogical, especially if we note that, the Polish legislator simultaneously allows, under certain limitations, the advertisement of OTC medicines (Dończyk & Stupak, 2020, p. 34). Moreover, the competent authorities in Poland have the possibility to decide on the admission of each OTC medicine to the retail in non-pharmacy outlets or even on including each medicinal product to each category of medicinal product (see Ustawa prawo farmaceutyczne, 2001, Art. 23 Para. 3 and Art. 71 Para. 3). The limitations on the advertising of medicinal products themselves (regulated at both national and EU level) partly fulfil the same role that the provision of Article 94a was intended to. Those limitations, among others of their functions, counteract the negative impact of advertising activities of the pharmacies on excessive consumption of medicines (see Case C-530/20, 2022, point 55). Equally important is the fact that the European Union law *per se* does not provide any restrictions, which would apply only to the pharmacy and pharmaceutical points advertising (see Dończyk & Stupak, 2020, p. 36-38). The ineffectiveness of achieving the objective that Art. 94a was intended to achieve is, in a sense, acknowledged by the Polish legislator. The explanatory memorandum to the bill on proffesion of pharmacist (Druk Sejmowy nr 238, 2020, p. 93), which was issued 8 years after the amendment of Art. 94a of the Pharmaceutical Law Act, indicates that there is a problem with the non-functioning pharmaceutical care, which results in... increasing risk of self-medication with OTC medicines. This may show that the problems identified as a justification for the functioning of the amended Art. 94a of the Pharmaceutical Law Act (2001) have not been eliminated by 2020. It is not known how the absolute prohibition of pharmacy advertising affected this situation. All these facts may result in narrowing the possibilities of defense for the Polish party in the dispute before the CJEU, because in order to be acceptable, the national measures limiting the freedom to provide services should be proportional, be justified by an overriding reason relating to the public interest and respect the control exercised over the service provider in the state of establishment (Skrzydło-Tefelska, 2012, p. 953).

Even before the preliminary ruling in criminal proceedings against Luc Vanderborght (Case C-339/15, 2017) it was noted that, it could be substantial for the case of the Polish prohibition of pharmacy advertising (see Wiszniewska, 2019, p. 11). The Court ruled that national legislation which imposes a general and absolute prohibition of any advertising relating to the provision of oral and dental care services is in conflict with the Directive on electronic commerce and Art. 56 TFEU. The Court's view on the application of Directive on electronic commerce expressed in point 39 and 40 of the Judgement is significant[7] - "*(…) advertising relating to the provision of oral and dental care services by means of a website created by a member of a regulated profession constitutes a commercial communication which is part of an information society service or which constitutes such a service for the purposes of Article 8 of Directive 2000/31. Therefore, it must be held that that provision, (…), means that Member States must ensure that those commercial communications are, as a rule, authorised.*".

Even after a brief analysis of the facts ofc a case on the basis of publicly available information, it is possible to describe the situation of Poland in a dispute with European Commission as at least uncertain. An unfavorable decision of the CJEU may have serious consequences. The procedure under Art. 258 TFEU, as the wording of the provision implies, is aimed at enforcing the proper fulfilling of the treaty obligations by the Member State. The Court's case law specifies that this procedure is intended to declare an act or omission of a Member State which infringes European Union law in an objective manner (Sikora, 2015, p. 236). As Półtorak (2012, p. 266) indicates, once the procedure has been initiated the Commission establishes an informal contact with the Member State - after that the Commission issues a letter of formal notice to the Member State concerned by the procedure in order to determine the subject matter of the proceedings and to enable the Member State to defend itself as well as to express

[6] As it was mentioned at the beginning of the paper, the available literature indicates counteracting excessive consumption of OTC medicines and preventing self-medication as the main objectives of the regulation.
[7] See also point 44 and 46 of the Judgement.

their opinion. It is also an opportunity to the cessation of an act or omission which infringes European Union law. If explanations or actions undertaken by the Member State are insufficient in the Commission's opinion, the Commission issues a reasoned opinion and sets a time limit for the removal of infringements. Failure to comply with the time limit entitles the Commission to bring an action before the CJEU even if the Member State will cease infringing behavior. The Court in this case will consider the factual and legal background at the time of expiration of the time limit (Sikora, 2015, p. 239). If the infringement action was lodged and the Court declared that the Member State has failed to fulfill the treaty obligation, then in accordance with Art. 260 Para. 1 TFEU the Member State has the obligation to take the necessary measures to comply with the judgment of the Court. Moreover, the judgment of the Court has a direct effect on the national law and immediately binds all the legislative, executive and judicial authorities (Sikora, 2015, p. 242). According to Art. 260 Para. 2 TFEU, if the Member State has not taken the necessary measures to comply with the judgment of the Court, the Commision may bring the case before the Court and ask to impose a lump sum or penalty. From the perspective of Polish law, the judgment of the CJEU can lead to the serious consequences in the context of administrative procedure, which is particularly important for the administrative proceedings conducted due to violation of the Art. 94a of the Pharmaceutical Law Act. Pursuant to Art. 145aa of the Code of Administrative Procedure (Ustawa Kodeks postępowania administracyjnego, 1960) the judgment of the CJEU, which affects the wording of the administrative decision, is a ground for the reopening of the administrative proceedings. The same effect is provided by an act that regulates the administrative court proceedings[8]. Furthermore, the Polish civil law allows to seek compensation for any damage caused by an unlawful action or omission of the public authority, including for damages caused by legislative action or by administrative decision.

In searching for possible alternatives to the settlement of a dispute by the CJEU, attention should be paid to the EU-Pilot procedure. Bruggeman & Verschueren (2019, p. 180) states that this procedure preceded the formal infringement proceedings against a Member State. The European Commission in 2010 emphasized that it is a procedure orientated towards cooperation between the Commission and Member States, aimed to assist citizens and businesses, who consider themselves to be affected by the infringement, on the application of European Union law quickly and effectively - in practice the Commission contacts the authorities of the Member States to request information or seek solutions to problems and the correction of infringements (European Commision, 2010). However, the nature of the EU-Pilot procedure has evolved over the time and the Commision started to launch infringement procedures without relying on the EU Pilot procedure "*(…) unless recourse to EU Pilot is seen as useful in a given case.*" (Communication from the Commission, 2017). Therefore, this procedure supports dialogue or negotiations between the Commission and Member State. There should be no doubt that the opportunity to avoid referral to the CJEU and to reach a consensual solution for ending the dispute existed even before the formal opening of the infringement procedures under Art. 258 TFEU, especially considering that the EU-Pilot procedure on the Polish prohibition of pharmacy advertising have been opened in 2013.

SUMMARY AND RECOMMENDATIONS

Due to the information about bringing the action to the CJEU, it can be concluded that attempts to resolve the dispute out-of-court were unsuccessful. That has happened despite the fact that, in theory, the procedural norms applicable in such situations offer many opportunities to settle the dispute without the necessity of bringing an action to the Court. The possibility of putting an end to the dispute by cooperating with the Commision under EU-Pilot procedure has not been taken. It is certainly unfavorable and may be a sign of ineffectiveness of the Polish

[8] See: Ustawa Prawo o postępowaniu przed sądami administracyjnymi [The Law of the Administrative Courts Procedure Act] (2002, August 30). t.j. Dz. U. z 2023 r. poz. 1634. Art. 272 Para. 2a.

diplomacy in relations with the European Commision. As the literature indicates, the Commission has a large discretion in deciding whether to bring such an action to the CJEU and the decision in this matter can be also determined by the "policy perspective" (see Hellwig, 2019, p. 157-158 and Sikora, 2015, p. 239). Despite the strong arguments for the existence of infringements, the Polish authorities did not cease potentially infringing behaviors also when the Commision issued a letter of formal notice or a reasoned opinion. It should be noted that litigation before the Court involves the risk of a significant increase in costs. According to Art. 138 of the Rules of Procedure of the Court of Justice, the unsuccessful party might be ordered to pay all the litigation costs. Additionally, as was mentioned, when the Member State does not comply with the judgment of the Court, it may impose a lump sum or penalty payment on it. The consequences under the national law can also be severe. Obviously, currently it is unknown what has caused the Polish government to adopt such strategy in the dispute with the European Commision. However, the political situation might be one of the factors that probably could have influence on this situation. The topic of the tensions between current Polish government and certain European Union institutions is still alive in the public discourse[9]. Regardless of the political views represented, the examples such as the case of Turów mine or the case of dispute over the Białowieża Forest, where Poland also did not use the possibilities of settling the dispute without the CJEU judgement, illustrates that perhaps the better way is to concentrate on out-of-court dispute resolution methods provided for example by the treaties or on diplomatic efforts. Will Poland benefit from these experiences? As usual, everything depends on the government. The upcoming parliamentary elections and ongoing campaign can play a decisive role.

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