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COMMENTARY
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A gloss to the Supreme Administrative Court judgement of 17 July 2018 (II GSK 844/18) – approving

Glosa do wyroku Naczelnego Sądu Administracyjnego z 17 lipca 2018 r., II GSK 844/18 – aprobująca

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Abstrakt: Wyrok, którego dotyczy glosa, prezentuje przełomowe stanowisko Naczelnego Sądu Administracyjnego, w którym sąd uznał, że decyzja Ministra Zdrowia w przedmiocie odmowy udzielenia zgody na refundację leku zawierającego medyczną marihuanę narusza prawa pacjenta w zakresie wyboru skutecznej metody leczenia, podczas gdy inne konwencjonalne metody okazały się nieskuteczne. W ocenie sądu ewentualne wątpliwości – zarówno co do wykładni przepisów dotyczących ochrony zdrowia, jak i oceny stanu faktycznego konkretnej sprawy – rozstrzygać należy na rzecz ochrony życia i zdrowia ludzkiego. Leczenie preparatami zawierającymi medyczną marihuanę wpisuje się w nurt *in dubio pro vita humana*.

Słowa kluczowe: medyczna marihuana, Naczelny Sąd Administracyjny, refundacja leków

Abstract: The sentence which the gloss refers to presents the breakthrough stance of the Supreme Administrative Court, where it is acknowledged that the decision issued by the Minister of Health, concerning the refusal to refund a medicament containing medical marijuana, infringes on the patient's rights in the sphere of selection of an effective method of treatment in the situation where conventional methods have proved inefficient. In the opinion of the Court, eventual doubts – with reference to both the interpretation of the regulations dealing with healthcare and evaluation of the factual state of the case in question – should be settled in favor of protection of life and human health. Treatment with preparations including medical marijuana writes into the current of *in dubio pro vita humana*.

Keywords: medical marijuana, Supreme Administrative Court, refunding medications

Introduction

Treatment with preparations containing medical marijuana is one of the most debatable and controversial issues which write into the broadly conceived healthcare. The right to protection of health which is proclaimed in Art. 68 of the Constitution of the Polish Republic of 2 April 1997¹ implies not only the existence of public authority commitments, but also taking a new approach towards patient's rights. One of them is the right to take advantage of treatment methods, whose effectiveness has no full justification in the paradigm of modern medical science. It is underlined in the literature on the subject that preferences of the suffering as regards the choice of treatment are not without significance in the situation where traditional methods fail.² The obligation of the public authority is not only to create a guarantee of health protection on the basis of the highest medical standards, but to supervise the recreational application of cannabis as well and to prevent drug addiction in relation to its use for medical purposes. Here, it is worth stressing that in other states, medical use of marijuana stands in an improper proportion to negative phenomena such as addictions among youth or an increased number of road accidents.³ On the other hand, in many states, medical marijuana is legal, treatment with the use of this means is refunded from the state budget, and the patient does not have to obtain any special permission (e.g. Germany). In the majority of European states, such as France, Greece, Finland, and since 2018 – Portugal, legalization of medical marijuana has resulted in the possibility of purchasing the medicament on the prescription. In turn, in Croatia, doctors can prescribe medicaments, teas and ointments which contain THC – the active component of cannabis.

One of the most liberal countries is the Czech Republic which has one of the oldest medical cannabis programs in Europe and was the second country (after the Netherlands) on the continent to authorize a domestic grow. However, till now, there has been no regulation to control the price of medical cannabis and make it more affordable for patients. Medical cannabis is not currently covered by health insurance. Study says that in the Czech Republic medical cannabis is prescribed by doctors, obtained at the regular pharmacy and not promoted.⁴

¹ Dz.U. Nr 78, poz. 483, z późn. zm. [Journal of Laws No. 78, item 483, as amended].

² K. Jahnz-Różyk, *Medycyna oparta na dowodach*, in: E. Nowakowska (ed.), *Farmakoekonomika*, Poznań 2010, p. 205.

³ M. Leyton, *Cannabis legalization: Did we make a mistake?*, "Journal of Psychiatry & Neuroscience" 2019, Vol. 44, Issue 5, p. 291-293.

⁴ B. Kilmer, *New developments in cannabis regulation*, October 2017, http://www.emcdda.europa.eu/system/files/attachments/6232/EuropeanResponsesGuide2017_BackgroundPaper-Cannabis-policy_0.pdf, accessed: 22.05.2020.

The issue of treatment with preparations containing medical marijuana writes into the current of relevant considerations run in the court-administrative jurisdiction already in an earlier period. The Supreme Administrative Court ruled that all possible doubts relating to the protection of human life and health should be settled for the benefit of the protection (*in dubio pro vita humana*). It justified the use of the principle in the scope of refunding medications in situations, among others, of a threat posed to people's life or health, yet initially this did not remain in a close relation with application of medical marijuana.⁵

In this place it is necessary to remind that in the light of the Polish law the term 'medical marijuana' denotes: "Cannabis plant matter other than fibrous and extracts, pharmaceutical tinctures, and also all other extracts from cannabis other than fibrous and resin of cannabis other than fibrous [...]," which are mentioned in Art. 33a of the Act on prevention of drug addiction of 29 July 2005.⁶ The regulations stipulate the possibility of medical use of marijuana, yet not without obtaining the permission for admission of pharmaceutical materials on the basis of cannabis to trading. Such a document, in the form of a relevant administrative decision, is issued by the President of the Office for Registering Medicinal Products, Medical Devices and Biocidal Products for the period of five years.

The key elements of the actual situation

An application was submitted with the Minister of Health by a woman-patient, requesting to have a medicament refunded upon the indication: *algodystrophy* of the lower limbs, under Art. 39 para 1 of 12 May 2011 on refunding medicaments, food products of special nutritional purposes and medical products.⁷ A demand was attached for a medical product to be purchased abroad, as it was indispensable to save the admitted woman-patient's life or health.

The Minister of Health turned to experts with the request to evaluate the justifiability of the application and the possibility of refunding the product. At the same time he requested to be informed about other methods of treatment that would be possible to apply in this case.

The experts' opinions varied, ranging from expressing the standpoint that "if according to the practice to date, the treatment with cannabinoids brings relief to the patient and the other ways do not yield expected results, then it

⁵ Sentence of the Supreme Administrative Court in Warsaw of 27 October 2017.

⁶ Dz.U. z 2019 r., poz. 852, z późn. zm. [*Journal of Laws* of 2019, item 852, as amended], (hereafter: APDA).

⁷ Dz.U. z 2020 r., poz. 357, z późn. zm. [*Journal of Laws* of 2020, item 357, as amended] (hereafter: AR).

seems purposeful to grant the request” to that “application of cannabinoids in chronic pains is not advisable due to the risk of developing an addiction, which in turn can lead to death [...]”

Eventually, the Minister of Health, upon considering the patient’s application, refused to grant his permission for refunding the medicament. In the justification of the decision, the organ pointed to the lack of meeting the criteria which are included in Art. 12, points 4-6 and 8-10 of the AR, which relate to the clinical and practical effectiveness of safety of application, ratio of health benefits to application risk. The state organ underlined – being directed by experts’ opinions – that there was no evidence which would point to the effectiveness of the product and that such a therapy should be treated as a medical experiment. Moreover, they argued that medically-acknowledged alternative methods of curing aches had not been used.

The Complainant lodged an appeal against the decision of the Minister. Relying on the medical knowledge, she pointed to the lack of effectiveness of morphine-related painkillers applied in her ailment, which she had been taking for four years until then.

The Minister of Health, upon reconsidering the matter, upheld the decision refusing to refund the medicament. In the justification, he explained that the individual woman-patient’s case had been consulted with specialists (national and provincial consultants). In the assessment of the organ, the experts’ opinions and analyses which were gathered in the case did not prove the premise of clinical effectiveness. Again, the fact was repeated that regarding the patient’s treatment, alternative methods which are accessible in Poland and considered to be basic with reference to this disease had not been made use of.

In response the Complainant filed a complaint in connection with the above-mentioned decision with the Provincial Administrative Court in Warsaw (hereafter: PAC) which – in the sentence passed on 20 December 2017⁸ – dismissed the complaint, simultaneously rejecting to grant the permission to refund the medicament containing medicinal marijuana. The PAC drew attention to the fact that the currently available publications did not point to cannabinoids as a therapeutic option in treating the patient’s ailment. The Court supported the stance of the organ that specialists’ opinions and analyses collected with reference to that case did not indicate fulfilment of the premise of clinical effectiveness. Apart from this, the Court shared the Minister’s of Health standpoint that health benefits did not outweigh the risk of application of the medicament.

Accepting the cost data and the lack of proven high effectiveness of the medicament in the patient’s medical case, as well as possible side effects, and also taking account of the fact that the financial means in the budget at the

⁸ VI SA/Wa 2114/17.

disposal of the payer did not concern financing a therapy applying only one controversial medicament, the PAC acknowledged the criterion of price competitiveness to be unfulfilled, either.

The Complainant filed a cessation appeal with the Supreme Administrative Court, requesting to have the challenged judgement annulled and the complaint recognized, or eventually to have the challenged judgement annulled in its entirety and the case transferred to the PAC in Warsaw to be recognized again.

The Ombudsman notified the Court of his participation in the proceedings and requested acceptance of the cessation appeal. He observed that the provisions binding in this respect can exclude the possibility for patients to access the therapy with medical marijuana, which can result in restricting the right of health protection guaranteed in Art. 68, para 1 of the Constitution of the Polish Republic. The Supreme Administrative Court, upon recognizing the cessation appeal on 17 July 2018, annulled the challenged judgement and annulled the challenged decision, as well as the decision of the Minister of Health, which the latter upheld and which refused the Claimant to have the medicament refunded. In this way the Supreme Administrative Court decided that the Minister's of Health decision in the said refusal to refund the drug ought not to be retained in the legal circulation and that the Complainant had the right to be treated with preparations containing medical marijuana.

Comments approving of the judgement of the Supreme Administrative Court

According to the assessment made by the adjudicating panel of the Supreme Administrative Court (hereafter: SAC), the content of the regulations in question does not allow arriving at the conclusion that the necessary condition to approve of the application for refunding and to be granted a positive decision in this respect is joint fulfilment of all the criteria mentioned in the Act (Art. 12, points 3-6, 8-11 of the AR). One needs sharing the stance of the SAC that the need for cumulative meeting the premises included in the Act does not follow from its content. They are of the equivocal character and it is for the organ to assess them and apply in the given state of things. The AR does not contain legal definitions of the notions included in it, which means that it is the relevant organ that is in position to define what the individual premises mean.

It unambiguously follows from the literal recording of the provisions that the legislator directly ordered to take them into consideration.⁹ At the same

⁹ This standpoint is presented also in the literature. Compare: J. Adamski, K. Urban, E. Warmińska, *Refundacja leków, środków spożywczych specjalnego przeznaczenia żywieniowego oraz wyrobów medycznych. Komentarz*; Lex 2014; Commentary to Art. 12, thesis 3.4.

time, a decision issued in an individual case regarding refund is aptly attributed to the nature of a discretionary one. Thus, one should agree with the SAC's judgement that in view of the discretionary character of such a decision the thesis is justified that not meeting any one of the defined criteria cannot exclude the settlement of the case that is in favor to the appealing party, since discretionary decisions are connected with the obligation to settle the case in the way that takes into consideration "social interest and righteous interest of citizens". On the other hand, all doubts with reference to the content of a legal norm ought to be settled – in compliance with Art. 7a of the Act on the Code of Administrative Proceedings of 14 June 1960¹⁰ – in favor of the party unless there are objections to doing so, resulting from opposing interests of the parties or interests of third parties, which the result of the proceedings can affect in a direct way.

The essence of the administrative approval is not application of the existing margin while interpreting notions, but the question of selecting the content of settlement. An organ of public administration by formulating the settlement should consider all legal and factual conditions and also examine all the circumstances of the given case in order to find the most appropriate settlement that reflects the objective truth and its goal.¹¹ Administrative approval consists thus in assigning to the organ the possibility of choosing an optimal solution following the juxtaposition of the factual state against the legal one.¹²

The SAC thus observed rightly that the regulation, in accordance with which the organ considering an application of refund is obliged to "take into account" relevant circumstances, means leaving to the organ a margin of decision and entitles it to issue an administrative approval.

Undoubtedly, settlements linked to an analysis of the premises contained in Art. 12 of the AR require conducting evidence proceedings.¹³ The SAC decided – sharing the Complainant's point of view – that the evidence in the case had been assessed selectively and accentuated chiefly the circumstances which justified the refusal to grant refund and omitting these fragments of experts' opinions that could speak in favor of accepting the request. The SAC agreed that in that particular case there had not been done a comprehensive assessment of the body of evidence, the reasons had not been explained for the omission when the actual state of the evidence relating to the case was established within the scope pointing to the justifiability of the refund application. Therefore, at

¹⁰ Dz.U. z 2020 r., poz. 256, z późn. zm. [*Journal of Laws* of 2020, item 256, as amended].

¹¹ Cf. The judgement of the Constitution Tribunal of 29 September 1993, file No. K 17/92.

¹² For a broader treatment of the theme see J. Zimmermann, *Aksjomaty prawa administracyjnego* Warszawa 2013, p. 203 ff.; idem, *Prawo administracyjne*, Warszawa 2018; p. 408 ff.

¹³ The importance of the evidence proceedings in this case was drawn attention to by the Supreme Administrative Court in its judgement of 10 November 2016: II GSK 972/15, LEX nr 2170654.

the same time, the principle of citizens' placing trust in state organs, which results from Art. 8 of the CAP, was undermined. This imposes on organs of public administration the obligation to conduct proceedings in a law-observing and just manner, which becomes expressed in a thorough examination of the circumstances of the case, responding to the demands of the party, as well as taking into account – in the final decision – both social interest and justifiable citizens' interest.¹⁴ Moreover, since traditional methods of treatment do not guarantee full clinical effectiveness, then satisfying this premise (100% of clinical effectiveness) is not sufficient to refuse to refund the medicament.

As far as the existence of alternative therapies is concerned, the organ should exhaustively consider whether and to what extent alternative treatment was applied in the Complainant's case and to what effect. Still, the experts' opinions were based on certain suppositions and this – in the opinion of the SAC – did not suffice to categorically acknowledge the existence of an effective method of alternative treatment. They added, and one should fully agree with the opinion, that a positive settlement of the application does not require exhausting all pharmacological possibilities. There are no premises, indeed, to unambiguously state that the patient's interest obliges to exploit pharmacological methods of treatment. This conclusion corresponds to the Constitutional Court's view which was formulated in the resolution of 17 March 2015, saying that: "In the light of valid scientific research, marijuana can be used for medical purposes [...] from the point of view of a given group of citizens taking advantage of services of the healthcare system, approval of medical use of marijuana needs considering because of its therapeutic use in certain medical conditions [...]" This thesis impacted further judicial decisions of administrative courts.

Summing-up

In the present case there occurred the necessity to weigh interests: social and a righteous one of the party. Restricting individual rights of the party must be justified by a social interest. In the said scope there were no sufficient premises to refuse to refund the medicament prepared on the basis of medical marijuana as: firstly – it was admitted for use in the light of Polish law and the patient met all the conditions to obtain the drug, and secondly – the traditional methods of treatment had proved ineffective.

The organ issuing the decision should weigh public interest and private ones, and refusing to grant a permission to refund a medication, it must prove that the public interest is so important and relevant that it requires restricting individual citizens' rights, including that to obtain treatment.

¹⁴ Cf. the judgement by SAC of 13 December 2017, file No. II GSK 917/16.

Lastly, one should approve of the SAC's conclusion that likely doubts – as regards both the interpretation of regulations dealing with healthcare and evaluation of the actual state of a concrete case – ought to be settled in favor of protection of human life and health. The fear of application of marijuana for recreational purposes was reduced on the level of legal regulations that established criteria of procuring the medicament on the basis of medical marijuana. In these circumstances depriving the patient of the possibility of being treated with preparations containing cannabis, with the simultaneous admission of this type of treatment undermines the citizens' trust in organs of public authority.

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