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PROCEEDINGS CONCERNING OPINIONS ON PROJECTS OF MEDICAL EXPERIMENT

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Summary. Binding Polish legislation makes legality of conducting of medical experiments dependent on positive assessment (opinion) of expert groups, namely bioethics committees. This paper aims at answering a question, which particular arguments allow qualification of opinions on projects of medical experiments as individual authoritative acts. But, first and foremost – hypothetically assuming that we are dealing with an administrative act – the paper attempts at focusing attention on a circumstance that proceedings of bioethics committees should be undertaken and completed in accordance with elementary principles of administrative proceedings. These principles – regarding the work of committees on stating opinions on medical experiments – shall undergo a brief analysis.

Key words: bioethics committee, administrative act (administrative) decision, opinion, administrative proceedings

INTRODUCTION

Undoubtedly, a medical experiment on a human being depends on a consent of a participant [Paszkowska 2014, 81ff]. However, equally significant is the fact that Polish regulations make legality of conducting of medical experiments dependent on positive opinion of expert groups, such as bioethics committees.

According to Art. 29 of the Act on doctors and dentists professions,[1] medical experiments can only be conducted following a positive opinion of an independent bioethics committee, composed of experts of high moral authority and specific qualifications. A committee states an opinion by way of a resolution including ethical criteria as well as the purpose and feasibility of a project.

Literally speaking, the aforementioned regulation gives the impression that a positive condition for conducting a medical experiment is a committee expressing its "view" or a "statement." The problem with these "views" or "statements" is that they bind experimenters applying for opinion as for their rights to which they are (presumably) entitled. In other words the "views" and "statements" decide on the experimenters' right or obligations. Such "decision-making" (i.e. on ri-

[1] Act of 5 December 1996 on doctors and dentists professions, Journal of Laws of 2020, item 514 as amended [henceforth cited as: d.d.p.].

ghts or obligations) is nothing else but issuing of an administrative, as act referred to in the Polish Code of administrative proceedings.[2]

A question worth asking here is which particular arguments allow qualifycation of opinions on projects of medical experiments as individual authoritative acts. But, first and foremost – assuming that we are dealing with an administrative case – elementary principles of conducting administrative proceedings leading to giving final opinion, as referred to in Art. 29 d.d.p., should be considered.

1. OPINION ON A PROJECT OF MEDICAL EXPERIMENT AS UNILATERAL AUTHORITATIVE ADMINISTRATIVE ACT

Beginning slightly on the fringe of the main considerations, it is worth putting attention to the fact that commonly binding Polish regulations do not provide any legal definition of a medical experiment, instead, they only divide the experiments into the therapeutic and research ones, determine general conditions of experiment admissibility and lay down a procedure regarding consents to be obtained as a *sine qua non* for an experiment to be conducted (Art. 21, sect. 1 d.d.p.). However, even a brief analysis of literature in that matter allows determination of the following "circumstances" to be encompassed by the definition of a medical experiment, either the therapeutic or the research one: implementation of new or only partially tried diagnostic, therapeutic or preventive methods, since the existing ones are no longer effective or insufficiently effective; broadening horizons of medical knowledge; direct health benefits; implementation of new preventive methods; expansion of empirical knowledge; collecting information on processes and phenomena occurring in a human body; medicine development without reference to benefits of a particular patient [Bosek and Gałązka 2018, 45–85; Zielińska 2004, 39–51; Wnukiewicz–Kozłowska 2004; Czarkowski 2008; Kania 2009; Kubiak 2015; Kujawa 2011; Nesterowicz 2004; Niżnik–Mucha 2009; Nowak 2005; Idem 2013; Tymiński 2010].

Assuming therefore, that since a medical experiment is to be conducted in the foregoing circumstances, consisting in the exercise of rights and entitlements (sometimes obligations) of the experimenters (researchers), guaranteed by constitutional freedom of scientific research, the process of decision-making on exercising these rights and entitlements by an experimenter should itself be considered as issuing of an administrative act.

To confirm the foregoing (i.e. to indicate that the opinion of a committee enabling an experiment to be conducted, stated by way of a resolution, may be qualified as an administrative act, referred to in c.a.p., resolving an individual case, and not as opinion-giving statement of non-administrative nature), it is worth noticing that an "administrative case" is inseparably linked to proceedings before

[2] Act of 14 June 1960, the Code of Administrative Proceedings, Journal of Laws of 2020, item 256 as amended [henceforth cited as: c.a.p.].

public administration authorities on matters within their competence and resolved by way of administrative decisions (Art. 1, point 1 c.a.p.). Hence, in huge simplification, when dealing with an "authority" (i.e. an entity within the competence of which lies the power of decision-making on rights and entitlements or obligations of other persons), an "individual case" (concerning a particular natural or legal person, as well as an organisation unit not having the status of a legal person) or an "administrative decision" (understood as an authoritative, unilateral decision on rights/entitlements or obligations), each of them are the elements determining existence of an administrative case.

It should be pointed out that taken into consideration judicature of the Supreme Administrative Court[3] leads to the conclusion that each and every case, in which a public administration authority precisely decides on rights/entitlements or obligations, is resolved by way of an administrative decision. The foregoing has to do with a "situation where three conditions require fulfillment. First of all, a public administration authority applies a substantive provision based on commonly binding law. Secondly, such a provision does not directly form a substantive relation, in a way authoritative specification remains unrequired. Third of all, the provision identifies no form of administrative action but a decision as the only in this case to be applied relevantly"[4] [Adamiak 2005, 17–18].

Moreover, the SAC refers to presumption of judicial proceeding of all administrative cases, where a unit (such as researcher or a group of researchers acting as an organisation unit) has its claims and demands grounded on the substantive legal basis. For instance, the SAC ruled in its judgement of February 23, 2005 that "the principle of presumption of resolving cases by way of an administrative decision was followed several times in judicature, which emphasized the unit's right to have its claims – based on substantive law – examined and resolved under a certain procedure. Examination of claims and demands beyond judicial proceedings by any public administration authority is incompatible with constitutional rules and principles."[5]

Similar conclusions can be drawn from the judicature of voivodeship administrative courts.[6] The VAC in Gdańsk points out that "the substantive provisions provide a decision-making form of examining and resolving a certain case, not only in a direct way, but also indirectly, by using verbal attributes indicating competences of authorities to resolve cases (e.g. allows, assigns, states, orders, determines, grants, refuses, etc.).

It is also assumed that when a certain act is not literally worded a decision, but embraces all its characteristic features enabling recognition of a certain administrative action as an administrative decision (i.e. designates a competent authority issuing an act, indicates an addressee of this act, includes decision on the sub-

[3] Henceforth cited as: SAC.
[4] Order of the SAC of 4 December 2018, II GSK 1702/18, ONSA.
[5] Judgement of the SAC of 23 February 2005, OSK 1185/04, Lex no. 165713.
[6] Henceforth cited as: VAC.

stance of a case, and signature of a person representing the authority), is indeed such a decision. It should also be noted that, in favour of adopting a decisive form of settling an administrative matter, wherever the provisions authorize an administrative body to resolve such a matter, but do not specify the form of its settlement, there is an argument to guarantee the fullest possible protection of a party's interests, since a decision – as an administrative act in a procedural form – is issued in a legally regulated procedure, with a set of guarantees and assurance of verifying the matter resolved."[7]

Furthermore, the VAC in Szczecin, referring to judicature of the Constitutional Tribunal, indicates that "there cannot emerge a situation where the statutory regulations define the competence of a public administration authority to deal with a specific category of administrative matters, and these matters could not only be resolved due to the lack of directly defined form of the settlement by a legislator", and, therefore, it should be assumed that every matter/case in which a public administration body makes authoritatively specifies the rights or obligations of an entity is resolved by way of an administrative decision.[8]

Referring to the foregoing "guidelines" of the courts regarding medical experiments, it should be noted that they can only be carried out when an appointed entity operating in the public sphere (bioethics committee) issues a positive opinion (authoritative concretisation) on a request (demand, claim) submitted by a physician (researcher), based on commonly binding law (*inter alia* the d.d.p.). Therefore, there should be no doubt that we are dealing with the aforementioned elements of an administrative case.

Noteworthy is also the indisputable statement of the SAC that "norms of substantive law regulate the content and form of execution of public administration. It is therefore the substantive law provisions that should determine the form of resolving of a given administrative matter. Analysing the current legislation, it is easily noticeable that the legislator, by means of various legislative techniques, determines the forms of the authoritative concretisation of the norms of substantive law; for instance, it states directly that resolving of an administrative matter takes the form of an administrative decision or does not determine the form of its resolving, but only generally indicates that the provisions of the Code of Administrative Proceedings apply to a given category of cases, or, finally, does not standardise these issues at all, leaving the emerging doubts to be settled by the judicature and doctrine."[9]

Therefore, it is impossible not to pay attention to the case law specifically referring to the issue of medical experiments.

In its judgement of April 18, 2007, the SAC concluded that opinions stated by bioethics committees are autonomous acts resolving administrative cases, containing consents or stating lack of consent to conduct a medical experiment. Ac-

[7] Judgement of the VAC in Gdańsk of 11 July 2019, II SA/Gd 338/19, ONSA.
[8] Judgement of the VAC in Szczecin of 27 June 2019, II SA/Sz 128/19, ONSA.
[9] Order of the SAC of 27 June 2019, II GSK 429/19, ONSA.

cording to this court, the committee's statement is an expression of knowledge and experience aimed at resolving the case, and thus it is subject to appeal to the administrative court.

At the same time, it is hardly possible to disagree with the argumentation (from the same judgment) that "the statutory regulation of the issue of establishing bioethics committees, both of first and second instance, and entrusting bioethics committees with the task of adjudicating on issues whether a medical experiment requested by a physician (a project of medical experiment) can receive a positive opinion, or whether it does not meet the conditions for its approval, and as a result, the decision on the admissibility of a medical experiment (since a positive opinion of the bioethics committee is a necessary condition for conducting the experiment), which belongs to the forms of practising the medical profession (Art. 2, sect. 3 d.d.p.), puts the committee within the sphere of public administration, and its opinion constitutes an autonomous act resolving an administrative matter initiated by the request of a doctor and considered according to the procedure defined by the legislator."[10]

Also, the VAC in Warsaw did not deny acting of bioethics committees as administrative bodies. In justification to its judgement of April 28, 2009, the court worded that "a resolution adopted by a bioethics committee includes signatures of the members participating in its adoption. In principle, decisions issued by collective bodies should be signed by all its members taking part in the decision-making process,"[11] by which it clearly confirmed the public-law nature of the committee.

Similarly, some representatives of the doctrine attempt to prove that a committee's opinion is an expression of administrative authority, characteristic of public administration bodies. For example, P. Brzezicki claims that the committee "through its resolutions and opinions enters the gates of constitutionally guaranteed freedom of scientific research with the ability to limit this freedom or even exclude it," and therefore "it is indisputable that these entities (i.e. committees – author's note), within the scope of their authority, should be treated as a part of the executive power being a structure performing functions in the field of public administration" [Brzezicki 2012, 9ff].

B. Świątkowski as well recognises bioethics committees as entities characteristic of administrative power. In his opinion (although he does not directly refer to medical experiments, but to proceedings concerning the authorisation to conduct clinical trials of a medicinal product), bioethics committees are public administration bodies, and their opinions are, in fact, administrative decisions [Świątkowski 2013, 72–73].

A slightly different opinion on the status of bioethics committees and their role in authorisation of a medical experiment to be conducted, comes from L. Ogie-

[10] Order of the SAC of 18 April 2007, II OSK 1112/06, ONSA.
[11] Judgement of the VAC in Warsaw of 28 April 2009, VII SA/Wa 420/09.

gło. He argues that "there is no reason to treat an opinion (of a bioethics committee – author's note) as a legal administrative decision," although, he sets out that "undoubtedly a more precise determination of the legal nature of opinions stated by bioethics committees (as well as the bioethics committee itself) belongs to the *de lege ferenda* postulates" [Ogiegło 2014, 267].

To clear the matter out, it is worth noticing that when it comes to committee' opinions on clinical trials of a medicinal product (often classified as medical experiments) we are dealing with exceptional circumstances. In such experiments, the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (formerly a Minister of Health) is the decision-making body in the case of permission to start studies, while an opinion of a bioethics committee is only an integral part of the documentation attached to the application.

The VAC in Warsaw spoke on the issue concerning this type of experiment, pointing out that "the resolutions adopted by both the bioethics committees and the Bioethics Appeals Committee have the nature of an opinion on conducting clinical trials," since "only the content of the Bioethics Appeals Committee's opinion, included in the resolution after considering the appeal against the resolution of the Bioethics Committee, is the basis for issuing an administrative decision of the Minister of Health (the minister issued decisions in the previous legal status – author's note), which constitutes an authoritative act as to the substance of the matter initiated by the motion of a person who has a legal interest in issuing this decision. In the case under consideration, such a decision was made by the Minister of Health on [...]."[12] Logically speaking, since clinical trials of a medicinal product involve a special procedure (including a decision-making authority specified by law), which has not been established for other types of medical experiments, the aforementioned court's statement cannot be attributed to committees' resolutions other than those on clinical trials of a medicinal product.

In my opinion, it is necessary to approach the status of bioethics committees and their opinions on medical experiments in such a way as to make it relevant to jurisdictional practice. Since the tendency to assume that the bioethics committee acts as an administrative authority in the subject under consideration is more evident in the case law of administrative courts, it should be assumed that the opinions referred to in Art. 29 d.d.p. are, in fact, administrative decisions. The most important argument justifying the above is also the fact, that it will allow for independent judicial review of acts, which may limit the constitutional freedom of scientific research and, what is important, the courts are given the possibility to confront the interest of the participant of the experiment with the public interest, taking the necessity to protect the "patient's good" into account.

[12] Judgement of the VAC in Warsaw of 25 June 2014, VII SAB/Wa 15/14, ONSA.

2. THE KEY ELEMENTS OF ADMINISTRATIVE PROCEEDINGS LEADING TO AN OPINION ON A PROJECT OF A MEDICAL EXPERIMENT

Assuming (as the aforementioned courts and part of the doctrine do) that an opinion of a bioethics committee on a project of a medical experiment (not regulated by other provisions, such as experiments concerning research on medicinal products), expressed by way of a resolution, constitutes an authoritative administrative act (decision), referred to in the c.a.p., it is worthwhile to briefly draw attention to the basic procedural principles aimed at protecting the rights of a party to administrative proceedings, which – in my view – should be applied in matters of issuing an opinion on a medical experiment. These principles are intended not only to ensure the formal correctness of the proceedings leading to the issuance of an opinion, but also to protect the rights of the applicant and participants of the experiment.

Of course, it is impossible – by means of the paper – to describe all possible procedural problems resulting from the application of the c.a.p. regulations in proceedings leading to the issuance of an opinion, therefore – just to indicate, since even in such a form it is not very common to come across publications that link administrative proceedings with the issues of (broadly understood) medical law – I shall draw attention to fundamental – in my view – aspects in that area.

First of all, a bioethics committee should take into account the principle of legality, which states that administrative authorities act only on the basis of and within the scope of commonly binding law. As P. Przybysz worded (referring to the SAC judicature): "Public administration bodies are not subject to the principle that they may take any action that is not legally prohibited. Thus, an action of an administrative authority will be qualified unlawful both when it has been unlawfully taken and when there was no legal basis for the action" [Przybysz 2019]. The committee should not, therefore, justify its refusal (i.e. a negative opinion) on the basis of reasons arising out of internal sources of law (ministerial orders, by-laws or statutes of scientific departments or research centres, guidelines, etc.). Nor can the authority justify its refusal on non-legal grounds (not governed by law) or take any action which is not based on commonly biding law (e.g. request submission of documents which are not governed by law).

The principle of furnishing information specified in Art. 9 c.a.p. should also apply in proceedings before the committee. This provision stipulates that public administration authorities shall duly and fully inform the parties on factual and legal aspects which may influence the establishment of the parties' rights and duties being the object of the proceedings. The authorities shall safeguard the parties and other persons participating in the proceedings, so that neither the parties nor the persons suffer any damage due to their ignorance of law and to this end the authorities shall furnish the parties and persons with necessary explanations and guidelines.

It is worth paying attention to the postulates of A. Wróbel, who links the principle of furnishing information to the following responsibilities of the authority: "to request a party to take an unambiguous stand on the nature and scope of the demand, if it is drafted in an awkward and incomprehensible manner; a request for collecting and submitting by a party all the necessary evidence should obligatorily and clearly indicate the circumstance to which the evidence shall relate; to provide all information relevant to the handling of the administrative matter concerned [...]; to inform the party of the obligation to notify the authority of the change of address and the consequences of its failure to do so; to inform the parties of the infringement of their rights by the authority and to indicate to them the way leading to removal of infringement conditions incompatible with their interests; to precisely determine the subject matter of the request/demand; to inform the applicant of the time limit for requesting/demanding the effective remedy of the infringement" [Wróbel 2019]. The committee must therefore keep the experimenter widely informed – even before issuing its opinion – not only of the law in force but also of other circumstances affecting the content of the decision, including the provisions of the administrative proceedings, the possible infringement of which could affect the content of the opinion. The bioethics committee should also consider whether the experimenter is able to provide adequate information and intends to inform the participants of the experiment about all aspects of the experiment that could affect their life or health. If the experimenter fails to provide relevant information, the committee then should bear responsibility to inform other participants of the experiment.

Clearly, the process before a bioethics committee should respect and apply the principle set out in Art. 10 c.a.p., i.e. the principle of hearing the parties (active participation). The provision reads that public administration authorities shall ensure that the parties may actively participate in every stage of the proceedings, and prior to issuing a decision the authorities shall give the parties an opportunity to present their position as to collected evidence and materials and submitted demands. The doctrine compliments the foregoing and states that "active participation" also means the right to be notified of and to participate actively in evidentiary proceedings (this includes in particular: asking questions to witnesses, experts and other parties, submitting explanations, demands, proposals and allegations), to express their views on the evidence gathered, and to have access to all the case file [Knysiak–Sudyka 2019].

This means that before the committee adopts a resolution, it must consider whether it grounds it solely on the documentation submitted by the applicant or whether it has gathered other evidence (documents, opinions, etc.) and – in that case – give the future experimenter access to the entire file and then to comment on the evidence gathered. This principle will not only protect the applicant, but shall potentially lead to a thorough explanation of the case, and thus may reveal possible irregularities and attempts to act *a contrario* to medical ethics. The prin-

ciple shall also protect the experimenter from unreliable and arbitrary collection of evidence by the committee.

Proper proceedings before bioethics committees should also be characteristic of reliably applied provisions on formal correctness of the application/request. Provisions of Art. 63, para. 2 c.a.p. provide that the application should include at least an indication of a person whom it comes from, their address and request/demand, as well as satisfy other requirements set out in specific provisions. It is worth noticing – echoing J. Wegner – that "in the case of natural persons (e.g. when dealing with an experimenter or a group of experimenters – author's note), the provision obliges to provide the address of residence or place of work to which correspondence is to be directed in the proceedings. It should be considered that the failure to provide the address of residence or place of work makes it impossible to serve documents in a manner specified in para. 1 and para. 2 of Art. 42, para. 3 c.a.p. The address appears to be the most important formal element of an application, since the absence of it prevents the letter from being proceeded; the absence of the address, because of impossibility of contacting the applicant, shall be irreparable" [Wegner 2019].

However, a "special" provision referred to in Art. 63, para. 2 c.a.p. is para. 4, sect. 2 of the regulation on detailed rules for the creation, financing and functioning of bioethics committees,[13] which provides the application should include designation of a person or other entity intending to conduct a medical experiment, and in the case of a multi-centre experiment – also the names of all centres in the country where the experiment is to be conducted; the title of the project, its detailed description and justification as to the advisability and feasibility of the project; name, surname, address and professional and scientific qualifications of the person in charge of the medical experiment; information on insurance conditions for persons intending to participate in the medical experiment; data on expected medical and cognitive benefits and other benefits for people who have undergone a medical experiment.

Apart from the above elements, the following should be attached to the application (para. 4, sect. 3 of the Regulation): a project of a medical experiment; information intended for persons subjected to the medical experiment, containing details on aims and principles of conducting the medical experiment, expected therapeutic and other benefits for these persons and the risk connected with undergoing the experiment; a specimen form of consent of a patient subjected to the medical experiment; a specimen declaration of acceptance of insurance conditions; a specimen declaration submitted by the person subjected to the medical experiment, in which he/she agrees to the processing of data related to his/her participation in the experiment by the person or another entity conducting the medical experiment.

[13] Regulation of the Minister of Health and Welfare of 11 May 1999 on detailed rules for the creation, financing and functioning of bioethics committees, Journal of Laws No 47, item 480 as amended [henceforth cited as: Regulation].

Such a detailed scope of the application undoubtedly impacts the protection of interest of the participants in the experiment, and the "protection" is further strengthened by the disposition of Art. 64, sect. 2 c.a.p., according to which, if the application does not meet other requirements set out in the provisions of law (including the d.d.p. and the Regulation – author's note), the applicant should be required to remove the deficiencies within a specified period of time, not shorter than seven days, and informed that failure to remove these deficiencies will leave the application without consideration. What is important here is that it would be illegal to consider an application for an experiment, despite its incompleteness (e.g. omitting any of the aforementioned elements specified in the Regulation and the c.a.p.).

The foregoing regulations influence application of the principle of objective truth, defined in Art. 7 c.a.p., according to which the authority, *ex officio* or at the request of the parties, undertakes all steps necessary to clarify the factual status of the case in detail and to settle it. The court judicature interpret this principle toward recognition that "a public administration body conducting administrative proceedings is obliged to assess individual evidence in connection with other evidence collected in the case and cannot replace this assessment of evidence with a general reference to the technical assessment made in the case. It should be noted that the authority is not exempt from the obligation to make a thorough assessment of a given evidence also in terms of its suitability for resolving the case and, if such a doubt exists, to carry out further evidence in this procedure which will allow the doubts to be allayed."[14] However, at the same time – echoing A. Plucińska–Filipowicz – "it is not only the authority that is the sole entity taking care to ensure that evidence is selected in such a manner that the case is thoroughly clarified, but also the parties have, or should have, their share in this respect. Special provisions often require a party (requesting initiation of the proceedings) to provide relevant evidence attached to the request" [Plucińska–Filipowicz 2011]. Therefore, in the case of an application for a positive opinion on a medical experiment, the experimenter cannot be passive and count on investigation of the committee itself, avoiding participation in the evidentiary procedure and refusing to submit explanations and evidence.

The assumption that a resolution of a bioethics committee constitutes a decision in an individual case should lead to the conclusion that the provisions of the c.a.p. concerning the issuance of decisions, particularly with regard to formal correctness, apply.

In accordance with Art. 107, para. 1 c.a.p., the decision should contain: the particulars of the public administration authority; the date of issue; the particulars of the party or parties; the legal basis; the determination; factual and legal reasons; the instruction on the right and manner of appeal against the decision and waiver of the right to appeal and effects thereof; the signature including the forename,

[14] Judgement of the SAC of 28 October 2015, OSK 438/14, ONSA.

surname and official position of the employee of the authority who is entitled to issue the decision and – if the decision has been issued in the form of an electronic document – a qualified electronic signature; and, in case of a decision with respect to which an action may be brought in a common court, and an opposition or complaint in an administrative court – an instruction on the right to bring an action, opposition or complaint and the related fees, if they are expressed in fixed terms, or on the fee calculated on a pro rata basis, as well as on the party's right to apply for an exemption from such fees or for being granted the right to legal aid.

Equally important issue follows from para. 2 of that provision, i.e. specific provisions may also set out additional components to be included in the decision.

The *lex specialis* provisions in this respect are those contained in the Regulation (on detailed rules for the creation, financing and functioning of bioethics committees), however, it follows from the content of para. 6, sect. 4 of the Regulation that a bioethics committee may express a statement supplementing the project of medical experiment under review with additional conditions allowing it to be conducted. The "supplementation" of the project is nothing but setting of additional conditions for its implementation, so they can be included as "additional" components of the decision of the committee referred to in Art. 107, para. 2 c.a.p.

Highly significant for the formal correctness of the opinion remains the order resulting from para. 6, sect. 5–7 of the Regulation for the committee to "resolve" (expressed its statement) by secret ballot, with more than half of the committee's members voting, including the chairman or deputy chairman and at least two members of the committee who are not doctors, and only vote for or against the opinion. It should also be noted that the resolution is signed by the members participating in its adoption. Thus, if the resolution does not contain signatures of all members of the committee participating in the voting (including those who voted "against"), it should be considered that it has not been adopted and does not function in legal affairs. Similarly, the adoption of the resolution cannot be considered, if some committee members taking part in the voting abstained from it.

At the same time, it is evident that some general principles of administrative proceedings are limited in cases before bioethics committees. Such limitations are experienced, for example, by the principle of the speed of proceedings, adopted in administrative proceedings, which implies that matters should be dealt with immediately, and sometimes within a month or two months (in particularly complex matters). It follows from para. 6, sect. 8 of the Regulation that the committee expresses its opinion no later than within 3 months of receiving complete documentation of the experiment. This limitation appears to be justified. The extended term of the investigation procedure may lead to a reliable explanation of the case and a thorough examination of all aspects of the planned experiment. Similarly, it is appropriate to extend (beyond the standard month specified in the c.a.p.) the time limit for the Bioethics Appeals Committee to 2 months (see para. 8, sect. 3 of the Regulation).

In my view, the principle of resolving doubts in favour of a party (applicant, experimenter) should also be restricted. The specific nature of a medical experiment requires the protection of essential values (health and life) as the priority and overriding priority over "the development of medicine" and "the achievements of civilisation." It is therefore justified – in proceedings concerning stating of an opinion – to apply the exception specified in Art. 7a, para. 2, point 1 c.a.p., that this principle does not apply if an important public interest requires it. The public interest (although also individual) is primarily the protection of human life and health.

CONCLUSION

To briefly sum up the foregoing considerations, it can be concluded that there are reasonable grounds for assuming that the opinion on a project of a medical experiment, referred to in Art. 29 d.d.p., is an individual authoritative act. The bioethics committee acts as an entity with competence in the public sphere, making authoritative concretization of the request/demand submitted by a doctor (researcher) in the application, entering the scope of constitutionally guaranteed freedom of scientific research, being able to limit or even exclude this freedom, as well as deciding on the basis of sources of commonly binding administrative law.

It is therefore worth postulating, that the proceedings before the committee should be conducted with application of the aforementioned principles characteristic of administrative procedure. In my opinion, bioethics committees should assume that specific provisions do not limit the obligation to comply with the principle of legality. It is necessary to ensure that the experimenter is actively involved in evidence proceedings. The committee should take care of both the formal correctness of the application, consistent not only with the provisions of the Regulation but also those of the c.a.p., as well as the correct formulation and justification of the decision (opinion) itself. On the other hand, it is worth postulating limitation of the committee's full responsibility for gathering evidence (implementing the principle of objective truth), because it is the applicant (researcher) who has knowledge of all the planned aspects of the experiment. Similarly, it is justified – because of the necessary protection of human life and health – to limit the strict application of the principle of resolving doubts in favour of the party (experimenter).

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POSTĘPOWANIE W SPRAWIE OPINII O PROJEKCIE EKSPERYMENTU MEDYCZNEGO

Streszczenie. Obowiązujące w Polsce przepisy uzależniają legalność przeprowadzenia eksperymentu medycznego od pozytywnej oceny (opinii) specjalnie powołanych podmiotów eksperckich, jakimi są komisje bioetyczne. Niniejszy artykuł ma na celu odpowiedź na pytanie, jakie argumenty pozwalają na uznanie, iż opinia o projekcie eksperymentu medycznego to rozstrzygający sprawę administracyjną indywidualny akt władczy? Przede wszystkim jednak – stawiając hipotezę, że mamy do czynienia z aktem administracyjnym – artykuł jest próbą zwrócenia uwagi na okoliczność, iż postępowanie komisji bioetycznych powinno być realizowane zgodnie z podstawowymi zasadami prowadzenia postępowania administracyjnego. Zasady te – w odniesieniu do prac komisji nad wydaniem opinii o eksperymencie medycznym – poddane są krótkiej analizie.

Słowa kluczowe: komisja bioetyczna, akt administracyjny, decyzja, opinia, postępowanie administracyjne

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