



Competences of the minister in charge of health related to the organisation of the provision of health services assisting procreation

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Abstract. The purpose of the publication is to answer the question whether, on the basis of the Act on Infertility Treatment, the minister in charge of health, as the central authority of government administration with the most extensive competences in the field of health, mainly realises, as assumed in the literature, normative competences, or whether he also undertakes other types of activities within the scope of the tasks set out by this Act. Its realisation, therefore, required an analysis of the competences of the minister in charge of health related to the organisation of the provision of health services in the field of medically assisted procreation, as defined by the aforementioned Act. This analysis was carried out using the dogmatic-legal method supported by scientific views. The analysis made it possible to establish, that this minister exercises two basic groups of competences: normative and competences to apply the law, which include the competences to: control, supervision, issue administrative decisions, as well as the competences to perform factual actions, including material-technical ones, and social-organizational actions. Thus, a conclusion can be drawn that it has been equipped with a whole range of forms of activity that allow the realisation of the values assumed by the legislator, among which the type of activity such as issuing normative acts taking the form of universally binding regulations plays an important role.

Keywords: minister in charge of health, competences, medically assisted procreation.

JEL Classification: K00, K10, K19, K32.

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The issue of the competence of the minister in charge of health in the area of organising the provision of health services assisting procreation, i.e. treatment of infertility with the use of medically assisted procreation procedures such as insemination with male germ cells or *in vitro* fertilisation, is regulated by a separate act concerning these particular health services (Bosek & Janiszewska, 2018, p. 34-43) - the Act of 25.06.2015 on the Infertility Treatment¹ (referred as: AIT). At the same time, for the purposes of this study, competence is understood as a complex legal construction (Ziemiński, 1969, p. 32.). Having in mind that in the competence "there is implicitly an element of obligation to realise it" (Dawidowicz, 1974, p. 57), it should be emphasised that in realising the competence, the administrative body *de facto* realises the obligations arising from two types of norms - the legal-organisational and the legal-material ones (Bojanowski, 1981, p. 85). Accordingly, this means the realisation of the duty to watch over the state of conditions justifying the taking of actions that aim at the realisation of a substantive legal norm - this duty is a constant element of the notion of competence - and the substantive duty to realise a substantive legal norm - this duty, in turn, is a variable element, because each time it results from a different substantive legal norm (Bojanowski, 1981, p. 88).

At this point, it should be noted that although the minister in charge of health is the central authority of the government administration with the most extensive competences in the field of health care - it performs the tasks assigned to its by numerous laws, together with the authorities and units subordinated to its in the statutorily defined area of activity, by legislating, applying and controlling the observance of the law (Tykwińska-Rutkowska, 2022, p. 511) - however, as noted in the literature, the basic type of activities undertaken by its within the scope of the planning, coordination, supervision and control or organisational activities imposed on him, is the issuance of normative acts (Rabiega, 2009, p. 97). The question arises, therefore, whether in fact also on the grounds of the AIT in the scope of supervisory-controlling, organisational, creative and informational-reporting tasks imposed on it, issuing normative acts is this "essential and leading" type of activity undertaken by it (Rabiega, 2009, p. 97) in order to organise the provision of services in the field of medically assisted procreation. Hence, it is a question whether it is precisely by issuing normative acts that the minister contributes to the achievement of the aim of AIT - i.e. the protection of reproductive health and the creation of conditions for the application of infertility treatment methods in a manner that protects the rights of persons affected by infertility and children born as a result of the application of medically assisted procreation procedures². Answering the above question requires an analysis of the provisions of the AIT. The research method used in the study is the dogmatic-legal method supported by the opinions of science.

On the basis of the AIT, the competences of the minister in charge of health can be divided into two main groups: normative and those to apply the law (Tykwińska-Rutkowska, 2013, p. 263). With regard to the first group - normative competences - it should be noted that, in the light of the provisions of the AIT, the minister was empowered under eleven specific authorisations to issue universally binding regulations in the form of ordinances. By these acts, he has regulated a number of issues concerning the organisation of the process of providing medically assisted procreation services, ranging from medical issues, e.g. concerning the determination of the health status of the candidate for the donor of germ cells and the health status of the recipient (Art. 35 AIT), through technical issues, e.g. concerning labelling activities to ensure the safety of germ cells and embryos and the management of the occurrence of a serious adverse event or a serious adverse reaction (Art. 42 AIT) or the keeping of records of the activities performed necessary to monitor germ cells and embryos at all stages for 90 years from the date of creation for use in human beings in a medically assisted procreation procedure (Art. 47(7) AIT), to organisational issues, relating for example to requirements for premises and equipment of medically assisted procreation centres and germ cell and embryo banks (Art. 51(1) and (2) AIT) or the conditions of export and import of germ cells and embryos

¹ Consol. text: Dz.U. 2020, item 442.

² See: Uzasadnienie do projektu ustawy o leczeniu niepłodności, Sejm VII Kadencji, Druk Sejmowy Nr 3245, p. 1.

(Art. 59 AIT). Thus, it has shaped the legal situation of all participants in the health care system - medically assisted procreation centres and germ cell and embryo banks - involved in the provision of infertility treatment by medically assisted procreation. At the same time, it should be noted that the AIT does not empower the minister in charge of health to issue orders or notices.

As for the second group of competences of the minister in charge of health - in terms of the application of the law - this body performs supervisory functions, control functions, issues individual administrative acts, also takes actions in other forms stipulated by the law, such as factual actions, in addition, it performs creative functions, as well as information and reporting functions.

Pursuant to Art. 66(1) of the AIT, the minister responsible for health shall supervise the application of the provisions of the AIT. Thus, it has been equipped with the competence to supervise, the exercise of which is contained both in the notion of observance of the law - this obligation is expressed by the rule of law principle, and in the notion of application of the law, which is understood as the implementation of the competence by the administrative entities (Dawidowicz, 1974, p. 57-64). As there is no universal definition of the notion of supervision in the law, making use of literature it should be noted that the essence of supervision is the cumulative occurrence of control and the possibility of authoritative interference, although in different types of supervision these elements may take a different form (Chelmoński, 2003, p. 456). Therefore, the content of the supervision notion should be constructed taking the will of the legislator expressed in the legal provisions on supervision as the essential point of reference (Boć & Kuta, 1984, p. 122; Boć & Miemiec, 1994, p. 140).

In the analysed case, then, it should be noted that the minister's competence to supervise coincides with the obligation to make use of it (Bojanowski, 1981, p. 85), and the purpose of this supervision is to secure compliance with the provisions of the AIT by the addressees of the norms expressed therein, i.e. to ensure the lawfulness of the actions of the entities undertaking the handling of germ cells and embryos in order to carry out a medically assisted procedure (cf. comments on the purpose of supervision: Dawidowicz, 1974, p. 57, 105; Wacinkiewicz, 2007, p. 220). In essence, then, this is not classical supervision understood as an organisational relation occurring between entities belonging to the public administration system, but control of observance of the law by entities not organisationally subordinated to the minister (see Dawidowicz's remarks on control of observance of the law: Dawidowicz, 1978, p. 22; Dawidowicz, 1970, p. 36). In the legal state under analysis, this supervision covers entities not included in the list of units subordinated or supervised by the minister in charge of health, with respect to which the minister exercises supervisory powers supported only by the norms of substantive administrative law - AIT. These include, inter alia, independent public health care institutions, as well as other therapeutic entities operating, inter alia, as entrepreneurs in various organisational and legal forms, e.g. company, to the extent to which they perform therapeutic activity and apply the provisions of AIT.

Assuming that the supervisory measures constitute "legal instruments" placed at the disposal of the minister in charge of health as a supervisory authority, or legally regulated forms of interference by this authority (cf. comments on supervisory measures: Zimmermann, 2016, p. 333; Borówka, 2018), it is questionable whether in fact Art. 67 AIT, on the basis of an open catalogue, formulates the supervisory measures understood in this way. Indeed, as follows from Art. 66(1) in conjunction with Art. 67(1) and (6) of the AIT, within the framework of the supervision on the application of the provisions of the Act, the minister, firstly, undertakes activities of a reporting and information nature - he submits an annual report to the European Commission by 30 June on the notification of serious adverse events and serious adverse reactions in the field of collection, testing, processing, storage, distribution and use of human germ cells and embryos in a medically assisted procreation procedure. In addition, it

also provides written information and reports resulting from the provisions of Directives: 2004/23/EC³, 2006/17/EC⁴ and 2006/86/EC⁵.

Secondly, as part of this supervision, the minister in charge of health exercises control. As it follows from Article 66(1) in conjunction with Art. 67(2) and (3) of the AIT, he controls the way in which data is transmitted to the registers kept under the Act and the documentation and transmission of lists of persons who have received training in the collection, processing, storage, testing and distribution of germ cells and embryos intended for use in a medically assisted procreation procedure. In addition, it is the responsibility of the Minister to inspect, *inter alia*, medically assisted procreation centres, germ cell and embryo banks and other entities indicated in the AIT, or to have them inspected by certain persons or entities pursuant to the provisions of the Act of 15.04.2011 on Medical Activity (referred as: AMA; Consol. text: Dz.U. 2023, item 991; Art. 67(5) of the AIT in conjunction with Art 68(1) and (3) of the AIT in conjunction with Art 119(1)-(2) and Art 122(1)-(5) of the AMA and the regulations issued pursuant to Art 122(6) of the AMA).

When interpreted together, Art. 67(5) in conjunction with Art. 68(1)-(3) in conjunction with Art. 71(2) of the AIT leads to the conclusion that inspection of the entities specified in the Act with respect to compliance with the requirements established by the Act may be undertaken (commissioned) by the minister on its own initiative or carried out upon a motivated written request from the competent authority of another EU Member State. This control may be either a preliminary control, e.g. in the case of entities applying for a permit to carry out procedures with germ cells and embryos as stipulated in the AIT, or a follow-up control, carried out in entities that have already obtained the relevant permit or a certain status, e.g. in a medically assisted procreation center, an infertility treatment center. The inspection initiated by the minister shall be carried out with a minimum frequency of at least once every two years or whenever a serious adverse reaction or a serious adverse event occurs (Art. 69 AIT). Although the result of the literal interpretation of Art. 69 AIT may be questionable due to the legislator's use of the conjunction 'or' - it is not clear from the current wording that it is obligatory to carry out an inspection every 2 years - the purposive interpretation reinforces the necessity of such inspections to ensure safety and attention to the quality of the procedures used (Haberko, 2016, p. 356).

Thirdly, the scope of supervision of the minister in charge of health over the application of the AIT provisions also includes the granting, refusal to grant, as well as withdrawal of permits to medically assisted procreation centres, germ cell and embryo banks. At this point, attention should be drawn to the solution adopted by the legislator, who decided to place the competence to apply the law and issue a decision with a specific heading name - permit - at the level of provisions on supervision. In the opinion of D.R. Kijowski, in the light of the law in force today, regulations providing for the issuance and refusal, as well as the limitation or withdrawal of permits, constitute an instrument of supervision of the public authority aimed at ensuring compliance with the applicable norms (Kijowski, 2000, p. 180, 197, 208-211). Thus, as a consequence of the initiation of a permit procedure, the authority - in the case under consideration, the minister in charge of health - has the opportunity to control the given intention or activity and thereby “ensure the inviolability of the goods protected by this procedure” (Kijowski, 2000, p. 180).

With regard to the granting of permits by the minister in the case of medically assisted procreation centres, the requirement to obtain a permit covers the handling of germ cells and embryos for the purpose of carrying out a medically assisted procreation procedure consisting in the collection of cells and the use of germ cells and embryos

³ Directive 2004/23/EC of the European Parliament and of the Council of 31.3.2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ UE 7.4.2004, L 102/48).

⁴ Commission Directive 2006/17/EC of 8.2.2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (OJ EU 9.2.2006, L 38/40).

⁵ Commission Directive 2006/86/EC of 24.10.2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ EU 25.10.2006, L 294/32).

in a medically assisted procreation procedure, including processing, testing, preservation and distribution. For germ cell and embryo banks, on the other hand, a permit is necessary to carry out procedures with germ cells and embryos for the purpose of medically assisted procreation involving the collection, storage and distribution of germ cells and embryos intended for use in humans in a medically assisted procreation procedure.

The granting of permission by the minister in charge of health for the above-mentioned activities is an example of the establishment of an entitlement "by way of an individual-specific administrative decision", relativised to a relative prohibition (Bojanowski, 2005, p. 49). As emphasised by E. Bojanowski, an individual subject may obtain a specific entitlement after fulfilling the conditions specified by law, which is subject to assessment and finds expression in the decision of the competent public administration body (Bojanowski, 2005, p. 49). In the case under analysis, these are the conditions normalized in Art. 48 (4) and (5) of the AIT, respectively, and their fulfilment is subject to mandatory assessment by the minister in charge of health within the framework of the control exercised and finds expression in the post-control statement (Art. 49 (2) in connection with Art. 68 (1)(3) and Art. 68(2)(1) AIT in conjunction with Art. 122(1)-(5) AMA), and in the case of requirements of a general-spatial, sanitary and installation nature, additionally in the opinion of the State Sanitary Inspection body, which takes the form of an administrative decision (Art. 48(6) AIT).

Thus, by issuing a permit, the competent public administration body determines the legal position of a specific (individually designated) legal subject in specific circumstances (Kijowski, 2000, p. 179). This position is subject to legal protection expressed in ensuring that the party is able to exercise the right granted by the permit and limiting the permissibility of its removal only to cases specified by law (Bojanowski, 2005, p. 49).

Also, in the form of an administrative decision, the minister in charge of health refuses to grant a permit and withdraws the permit issued to medically assisted procreation centres, germ cell and embryo banks. As for the refusal to grant a permit, it should be noted that due to the lack of specific grounds for refusal, it will occur when the conditions for issuing the permit - at least one of them - are not met. Therefore, by refusing to grant a permit to a medically assisted procreation centre or a germ cell and embryo bank, the authority decides that, in the factual situation of the party, certain behaviour - the handling of germ cells and embryos in the procedure or for the purpose of carrying out a medically assisted procedure - is not legally permissible (cf. comments on refusal of a permit: Kijowski, 2000, p. 179).

However, with regard to the withdrawal of the permit issued to a medically assisted procreation centre or a germ cell and embryo bank to handle germ cells and embryos in a procedure or for the purpose of carrying out a medically assisted procreation procedure, on the basis of the current legal status, it is obligatory in connection with the occurrence of the enumeratively listed prerequisites for the withdrawal of the permit in Art. 49(4) of the AIT, when all or one of them is fulfilled, and it is the minister in charge of health who is competent to overturn the decision in this manner.

Thus, it can be concluded that the provisions introduced into the AIT concerning the withdrawal of a right granted to medically assisted procreation centres and banks of germ cells and embryos are part of the group of substantive legal provisions referred to in Art. 163 of the Act of 14.6.1960 - Code of Administrative Procedure (Consolidated text: Dz.U 2023, item 775), which are "predominantly an instrument of control by the public administration body of the correctness of the execution of administrative decisions by the parties and of the exercise of the rights stemming from them" (Adamiak & Borkowski, 2022).

In the context of considerations concerning the exercise of supervision by the minister in charge of health, the analysis should also cover the provisions of Art. 66(4) AIT, which provide for the supervision of the minister over medically assisted procreation centres, reproductive cell and embryo banks and infertility treatment centres. This supervision is exercised in terms of substantive matters and, as part of this, the minister makes use of soft supervision measures consisting of informing. These are included in other provisions of the Act, in addition to Chapter 10 AIT "Tasks of the minister in charge of health, including control and supervision" - in Chapter 2 AIT "Infertility treatment centres", Chapter 6 AIT "Labelling, monitoring, storage, transport and safety and quality criteria for germ

cells and embryos" and Chapter 7 AIT "Medically assisted procreation centres and banks of germ cells and embryos". Among other provisions, these guarantee the minister the right to request certain information. For example: the submission by the infertility treatment centre of an analysis of the impact of the infertility treatment healthcare service on the health status of patients and the results of the effectiveness of infertility treatment, information and data concerning the fulfilment of the conditions necessary to obtain the status of an infertility treatment centre, etc. In addition, these provisions establish obligations in the form of orders to behave in a certain way addressed to medically assisted procreation centres and germ cell and embryo banks to submit certain information to the minister, e.g. on the number of germ cells and embryos at different stages (including collection or creation, during testing, storage, etc.), on each case of occurrence or suspected occurrence of a serious adverse event or serious adverse reaction and on the results of the investigation carried out after each case of their occurrence, and others. On this basis, it can be assumed that, even in those cases where the addressees fail to comply with the obligations imposed on them, the minister will request the information specified by law.

Furthermore, on the basis of the AIT, the minister in charge of health has been authorised to issue administrative decisions other than permits. In this legal form, the status of an infertility treatment centre is granted - as well as denied and withdrawn - to a medical entity, including a medically assisted procreation centre, which fulfils the requirements set out in the Act, after obtaining the opinion of the Infertility Treatment Council (Art. 14(1) in conjunction with Art. 15 AIT)⁶. The form of an administrative decision is also used to refuse accreditation of an entity for the organisation of training of persons in the collection, processing, storage, testing and distribution of germ cells and embryos intended for use in a medically assisted procreation procedure, as well as to revoke it (Art. 62(1) in conjunction with Art. 60(1) AIT; Art. 62(4) AIT), as well as to refuse acceptance of the training programme of an entity providing training (Art. 61(2) in conjunction with Art. 60(1) AIT). In addition, in the form of an administrative decision, the minister in charge of health shall impose administrative fines on entities that violate the orders set out in the Act to submit data to the register of medically assisted procreation centres and germ cell and embryo banks or the required information on each occurrence or suspected occurrence of a serious adverse event or serious adverse reaction (Art. 90(1) and (2) AIT).

In the light of the provisions of the AIT, the minister in charge of health, in addition to issuing individual administrative acts, also undertakes actions in other legal forms, such as factual actions related to the maintenance of registers of: donors of germ cells and embryos, medically assisted procreation centres and banks of germ cells and embryos (Art. 66(2) in conjunction with Art. 37 AIT; Art. 66(3) in conjunction with Art. 56 AIT). For both the first and the second registers, it acts as the controller of the data collected therein (Art. 37(7) and Art. 56(3) AIT). Furthermore, in the case of the donor register, it performs the factual act of making this data available to the medically assisted procreation centres (Art. 37(6) AIT). On the other hand, in the case of the register of medically assisted procreation centres, in connection with its operation, it performs factual acts of registration in the register and amendments to the register (Art. 56(6) and (7) AIT).

The category of factual acts undertaken by the Minister also includes maintaining lists of persons who have received training in the collection, processing, storage, testing and distribution of germ cells and embryos intended for use in a medically assisted procreation procedure, whose activities directly affect the quality of germ cells and embryos, as well as the safety of donors and recipients (Art. 66(10) in conjunction with Art. 60(1) AIT). Also, the maintenance of the list of infertility treatment centres, its updating and its publication on the website of the office of the minister in charge of health has the character of factual acts (Article 16 AIT). The acceptance of the training programme of persons whose activities directly affect the quality of germ cells and embryos and the safety of donors

⁶ This provision should be considered defunct due to the failure to set up the Infertility Treatment Council, whose opinion is required as part of this procedure.

and recipients, developed by an accredited body, also takes the form of a factual act of the minister in charge of health (Art. 61(2) in conjunction with Art. 60(1) AIT).

It is also in the nature of a factual action taken by the minister in charge of health to grant accreditation at the request of an interested unit that meets the requirements for organising training courses on the collection, processing, storage, testing and distribution of germ cells and embryos intended for use in a medically assisted procreation procedure, as set out in the Act and in the minister's implementing regulation⁷ (Art. 66(9) in conjunction with Art. 60(1), Art. 64 of the AIT in conjunction with § 5 and 6 of the Regulation of the Minister of Health of 20.10.2015 on training in the collection, processing, storage, testing and distribution of germ cells and embryos intended for use in a medically assisted procreation procedure⁸).

Moreover, among the factual activities which the minister in charge of health has been authorised to undertake on the basis of AIT, one should mention activities related to the analysis of the epidemiological situation in the aspect of infertility and the analysis of the availability of infertility treatment, including its effectiveness and safety, as well as cooperation with other domestic and foreign entities whose aim of activity is the development of medically assisted procreation (Art. 66 (7) and (8) AIT). The catalogue of factual activities of the minister in charge of health is also filled with such activities as the preparation of information and reports for the European Commission and the Sejm of the Republic of Poland, as specified by the provisions of the AIT (Art. 71 (1), (3) and (5) AIT).

The group of factual activities performed by the minister also includes activities aimed at the dissemination of medical standards and deontological principles in the field of medically assisted procreation (Art. 66(6) of the AIT). However, it must be emphasised that these activities constitute a different legal form of administrative action, the so-called social-organisational activities. Although the minister has limited competence to shape deontological rules (Haberko 2016, p. 348), it should be borne in mind that it may perform the tasks assigned to its in various legal forms, e.g. by issuing regulations to define organisational standards of healthcare in selected fields of medicine or in specific entities performing therapeutic activity (cf. Article 22(5) of the AMA), or by establishing specific obligations to practise the medical profession, inter alia, in accordance with the principles of professional ethics⁹, but also by undertaking social and organisational activities, which are not aimed at producing specific legal effects, but consist in initiating and organising various social actions (Jaworska-Dębska, 2021, p. 576).

Furthermore, the AIT gives creative competence to the minister in charge of health. This is because it belongs to its to appoint and dismiss members of the Infertility Treatment Council before the end of the term of office and to supplement its composition if more than 3 months remain until the end of the term of office of the council, as well as to appoint the chairman of the Infertility Treatment Council (Article 72(5), (6), (7) AIT).

The analysis made leads, therefore, to the conclusion that on the basis of the AIT, the minister in charge of health, within the scope of the supervisory, control, organisational, creative and informational and reporting tasks imposed on its, acts in various forms, thanks to which it is possible to achieve the aim of the Act, i.e. to ensure the protection of reproductive health, but also to create conditions for the application of infertility treatment methods in a manner that protects the rights of persons affected by infertility and children born as a result of medically assisted procreation procedures.

Undoubtedly, the regulations issued by the minister in charge of health by virtue of the mandates introduced in the AIT set universally applicable standards of conduct in reproductive health care. This is because they establish the necessary technical, organisational, sanitary and staffing conditions for the treatment of infertility with the use

⁷ At this point, it should be noted that the accreditation mentioned in the AIT does not constitute accreditation within the meaning of the Act of 13.4.2016 on compliance and market surveillance systems (Consol. text: Dz.U. 2023, item 1854), nor within the meaning of the Act of 6.11.2008 on accreditation in health care (Consol. text: Dz.U. 2016, item 2135).

⁸ Dz.U. 2015, item 1740.

⁹ See Art. 4 of the Act of 5.12.1996 on the Professions of Physician and Dentist (Consol. text: Dz.U. 2023, item 1516).

of medically assisted procreation procedures concerning each entity carrying out the handling of germ cells and embryos in order to carry it out, so as to ensure the safety of the patients undergoing this treatment and of the biological material used – germ cells and embryos. They can therefore be considered as this leading type of activity undertaken by the minister and an essential measure to ensure the protection of reproductive health and the creation of appropriate conditions for the use of medically assisted procreation methods.

However, the significance of other types of activities undertaken by the minister in the process of performing the tasks imposed on it under the AIT cannot be overlooked. Indeed, while exercising the competence to apply the law, i.e. to control, supervise or issue individual acts - it is worth emphasising that on the basis of the analysed regulation, the minister has accumulated in his hands the competence to issue numerous administrative decisions, which *de facto* influences his position among the group of entities performing tasks related to the organisation of the provision of health services in the field of medically assisted procreation and, in the case of permits, strengthens his statutory supervisory competence - also shapes the organisation and functioning of administrative entities in the sphere of reproductive health care. Although in these cases the activities within its competence indirectly protect reproductive health (cf. Rabięga, 2009, p. 95) and do not show a general-abstract character, they form, together with the normative competence, a full range of "forms of action most appropriate from the point of view of the realisation of the assumed values" (Cieślak, 1995, p. 75).

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