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Katarzyna Mełgieś
War Studies University, Poland
katarzyna.melgies@gmail.com
ORCID ID: https://orcid.org/0000–0003-2420–246X

Katarzyna Miaskowska-Daszkiewicz
The John Paul II Catholic University of Lublin, Poland
kamias@kul.pl
ORCID ID: https://orcid.org/0000–0002-1898–8980

Marta Sjeničić
Institute of Social Sciences, Belgrade, Serbia
marta.sjenicic@gmail.com
ORCID ID: https://orcid.org/0000–0001-7498–0169

On the Need to Change the Model of Supervision over Substances of Human Origin from the Perspective of Regulation (EU) 2024/1938: Polish and Serbian Examples

Abstract: Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC and 2004/23/EC provides a new legal framework, after almost 20 years, in which issues concerning the quality and safety of substances of human origin (SoHOs) as well as the safety of SoHO donors will be settled. One of these is the way the institutions supervising the implementation of the provisions of the Regulation are shaped. New requirements addressed to the SoHO competent authority must be met by August 2027. Hence the particular challenge facing EU Member States is adapting their own organizational solutions regarding the transplant system in a way that meets the requirements of the Regulation. Using the examples of legal and organizational solutions adopted in Poland and Serbia, the authors try to assess their performance from the perspective of the expectations of the EU legislation.

Keywords: transplants, health, SoHO, Regulation (EU) 2024/1938, public supervision

Introduction

The European Union legislation referring to substances of human origin (SoHO), based on Art. 168(4)(a) of the Treaty on the Functioning of the European Union (2012), results from a shared competence of the EU and the Member States. The authorities act in this field in line with the principle of subsidiarity. The provision gives the EU a mandate to set out measures establishing high standards of quality and safety for SoHO. Regardless of the competence invoked, Member States remain responsible for decisions of an ethical and organizational nature. Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on Standards of Quality and Safety for Substances of Human Origin Intended for Human Application and Repealing Directives 2002/98/EC and 2004/23/EC (the Regulation) provides a new legal framework, after almost 20 years, in which issues concerning the quality and safety of SoHO as well as the safety of SoHO donors will be settled. It replaces the previous framework addressing the safety of activities spanning from donation to human application: the Blood Directive 2002/98/EC and the Tissues and Cells Directive 2004/23/EC. The scope of the concept of a 'substance of human origin' in the meaning of the Regulation refers to any substance collected from the human body, whether it contains cells or not and whether those cells are living or not, including SoHO preparations resulting from the processing of such a substance (Art. 2, Point 1 of the Regulation). This means that the new legal act covers substances encompassing human-origin materials including blood, plasma, skin, corneas, embryos, sperm, breast milk and microbiota (but not solid organs), all of which play a crucial role in life-saving medical procedures (Cuende et al., 2023, p. 867). Thus it is legitimate to conclude that the Regulation performs a material defragmentation of the regulatory scope of the previous directives. Moreover, the Regulation links with the Organs Directive 2010/53/EU, in particular regarding closer collaboration between Member States' competent authorities for blood, tissues and cells and those for organs, as well as regarding vigilance requirements.

The introduction of a new legal act in the form of a regulation binding on all Member States was necessary and resulted from the fact that even though current legislation has helped ensure the safety of millions of patients undergoing blood transfusion, transplantations and medically assisted reproduction, it was found to be no longer addressing the scientific and technical state of the art and needed to be updated to take into account developments that have taken place in the sector (European Commission, 2022). Evaluation of the Blood and the Tissues and Cells directives confirmed that they have brought very good levels of overall safety and quality in these sectors. However, serious shortcomings in the legislation were identified, among others that patients are not fully protected from avoidable risks due to out-of-date technical rules. Also, Member States have divergent approaches to oversight, which hampers cross-border exchanges (European Commission, 2019); the vari-

ous national interpretations and implementations of the legislation lead to unequal protection and a lack of mutual trust between national authorities. Insufficient minimum harmonization was identified as a key reason for reduced trust between Member States, resulting in reduced cross-border exchange and sub-optimal access to SoHOs for patients. Differences between Member States reflect the lack of common provisions for the verification of effective implementation of inspection, authorization and vigilance, and inconsistency in the levels of capacities, skills and independence required of inspectors supervising establishments for blood, tissues and cells. The new Regulation repeals the two existing acts (the Blood Directive and the Tissues and Cells Directive), as a key to establishing more harmonized measures for Member States and organizations involved in the collection, testing, processing, distribution and application of SoHOs from donors to patients.

A key aspect of the Regulation was the empowerment of the European Commission (EC) to adopt implementing acts regarding patient, donor and offspring protection. One of the major objectives is to encourage innovation and the development of new therapies, while ensuring patient safety; it therefore includes specific provisions designed to encourage research and development in the field of SoHO, while maintaining high safety standards (Lex Case, 2024). In the absence of implementing acts, 'SoHO entities' (which are defined in Art. 3(33) as 'organisation[s] legally established in the Union that carr[y] out one or more of the SoHO activities') will have to apply standards established by the European Centre for Disease Prevention and Control and the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe. The aim is to ensure that technical rules applicable to SoHO activities remain updated and to avert the accumulation of obsolete rules which would stand in the way of novel SoHO-based treatments and new medical techniques (Clancy et al., 2022). For that reason the Regulation is considered the most suitable instrument, since it does not require transposition and is directly applicable. The shortcomings mentioned above were resolved in the Regulation, which also gave clear indications as to the expectations of the EU legislature regarding the so-called 'competent authority', that is the authorities which confer responsibility for SoHO supervisory activities. As the Regulation entered into force on the 7 August 2024 and applies from 7 August 2027 (Art. 87), the latter is the date by which Member States should have adapted their national laws to the assumptions of the Regulation, where this is within the scope of their competences. They are proceeding to adopt the Regulation, so considerations in this article may contribute to achieving both self-sufficiency and safety through appropriate structural modelling of supervision over the application of the Regulation's provisions.

We have selected two legal orders relevant to SoHO issues as examples for analysis. The first refers to the legal regulations in this area in Poland, as an EU Member State; the second refers to the regulations in Serbia, as a candidate country for membership of the EU. Both Poland and Serbia are faced with the need to adapt their legal

solutions to the provisions of the Regulation in order to fully harmonize their national legal systems to the *acquis communautaire*. Due to limitations in our considerations, we will focus only on the criterion of the model based on which supervision over the application and enforcement of the provisions of the Regulation should be exercised in each Member State. For the purposes of enforcement, the EC devised a supervision mechanism based on national competent authorities; chapters II and III of the Regulation are dedicated to 'competent authorities' and 'SoHO supervisory activities' respectively. The rules enable extensive coordination between the different national competent authorities and the EC (Clancy et al., 2022). Through analysis of the currently applicable legal provisions in this area in the Polish and Serbian legal systems, we assess them from the perspective of compliance with the assumptions adopted in the Regulation. The next step is to indicate the direction of solutions that should be implemented.

1. Model assumptions of the Regulation regarding the SoHO supervisory authority

Responsibility for SoHO supervisory activities has been entrusted to so-called 'competent authorities' (Art. 5(1) of the Regulation). The organizational solutions relating to the manner of shaping the SoHO competent authorities have been left to Member States and oblige them to regulate it in their internal legal systems. However, taking into account the standards set by the provisions of the Regulation in this respect, it should be stated that the EU legislation significantly limits the freedom regarding the manner of shaping this body. The Regulation's Preamble clearly and distinctly indicates the expectations related to the SoHO competent authorities as to the goal pursued, which further translates into the specific provisions of the Regulation. The purpose of establishing these bodies, as well as the function assigned to them, is to carry out supervisory activities in the SoHO area. These activities are of fundamental importance for the actual achievement of the objectives of the Regulation throughout the EU; they include both monitoring and verifying the actual compliance with and enforcement of the relevant EU requirements (Recital 35 of the Regulation).

The applicable legal regulations do not set a uniform pattern of supervision. Nevertheless, analysis of the adopted legal solutions in the Regulation (Chapter III, SoHO Supervisory Activities) leads to the view that the function of the supervising entity consists of the possibility, provided for by law, of undertaking, within a specific organizational structure, not only the checking and evaluating of the supervised entity, but also applying binding interference in its activity in order to correct it in a desired direction. The scope and methods of this interference are determined by law and designated in specific cases by appropriate legal regulations. It is a typical example of administrative supervision applied in various areas of the public domain by the legislation (Jagiel-

ski, 2018, p. 235; Ochendowski, 1999, p. 235). Supervision in public administration is a function that, in its assumptions, enables authoritative and binding influence over supervised entities. This is a more intensive action than control, which is intended to examine the existing (actual) state of affairs, compare it with the (legal) state of affairs, and in the event of any discrepancies, analyse them and formulate appropriate recommendations that will help resolve them and prevent such situations in the future. It should also be added that control is an indispensable element of supervision. These two functions are strongly related (Jagielski, 2018, p. 235; Ochendowski, 1999, p. 235).

It should be emphasized that the binding standards related to the SoHO competent authority resulting from the Regulation apply both to requirements addressed to the method of placing authorities or for modelling a competent SoHO entity in the public domain and to the scope of supervisory activities which must be carried out. Taking into account the limitations stated earlier, after further consideration we have limited ourselves to the first aspect, without an in-depth analysis of the areas covered by supervision.

The specific organizational arrangements and the designation of the SoHO competent authorities in all areas covered by this Regulation are entrusted to the Member State, as they are best placed to designate such an authority in each area. Although the number of such authorities is not prescriptively determined (Art. 5(2) of the Regulation), it is mandatory to designate a single independent national SoHO authority, which will ensure proper coordination of communications with the national SoHO authorities of other Member States and with the EC and will perform other tasks in accordance with the Regulation (Art. 8(2)). Where only one national SoHO competent authority has been designated, it shall be deemed to be the national SoHO competent authority (Art. 5(4)). An additional facilitation and streamlining factor in the organizational arrangements for supervision is the guidance that the designation of only one national SoHO authority does not prevent a Member State from allocating certain tasks to other SoHO competent authorities within that state. This could especially be the case where efficient communication with the EC or other Member States is required (Recital 36 of the Regulation) in the case of the management of SoHO rapid alerts, in order to ensure an efficient and agile communication when serious adverse reactions or events involve more than one Member State (Art. 5(4) of the Regulation). Moreover, Member States may empower a SoHO competent authority responsible for any of the SoHO supervisory activities referred to in Art. 9(1) of the Regulation to delegate them to one or more other legal bodies, so-called 'delegated bodies'. This condition is to ensure that the delegated body has the powers needed to effectively perform the SoHO supervisory activities and that it undertakes the obligations set out in Art. 10 of the Regulation.

The basic requirement addressed to Member States in terms of the way in which the SoHO competent authorities are constituted is to guarantee their impartiality, professionalism and transparency. Additionally, Art. 5(3) of the Regulation contains in-

dications regarding four basic conditions that must be met when modelling the legal premises of the structure and competences of this body to ensure effective operation. These are: (a) the autonomy to act and make decisions independently and impartially while respecting the internal administrative organizational requirements determined under national legislation; (b) the necessary powers to properly perform SoHO supervisory activities as well as to order the immediate suspension or cessation of a SoHO activity that poses an immediate risk to donors, recipients, offspring from medically assisted reproduction or the general public; (c) access to sufficient human and financial resources, operational capacity and expertise, including technical expertise, to achieve the objectives of and fulfil their obligations under the Regulation; and (d) appropriate confidentiality obligations in order to comply with Art. 75 of the Regulation. They also follow from the premise that the purpose of establishing these authorities is to act in the public interest, with adequate resources and equipment.

Regarding the requirements for modelling the structures of the SoHO competent authorities to effectively carry out supervisory activities, in order to verify the correct application of the SoHO rules, organizational guarantees that they operate independently and impartially are essential. Hence the assumption is that the supervisory function must be separate and independent from the performance of SoHO-related activities. Moreover, in order to perform their supervisory functions properly, the SoHO competent authorities should be free from political influence and interference from industry or other entities that could affect their operational impartiality. In order to achieve the intended goal of independence and impartiality, it is stated that when performing their tasks and exercising their powers, SoHO competent authorities shall act independently and impartially, in the public interest and free from any external influence, such as political influence or industry interference (Art. 6(1) of the Regulation). Moreover, SoHO competent authorities shall ensure that personnel performing SoHO supervisory activities, including inspectors and assessors, have no financial or other interest that might be considered prejudicial to their independence and, in particular, that they are not placed in a situation that may, directly or indirectly, affect the impartiality of their professional conduct. Personnel performing SoHO supervisory activities shall provide a declaration of their interests and regularly update that declaration. On that basis, SoHO competent authorities shall take the relevant measures to mitigate the risk of conflict of interests (Art. 6(2) of the Regulation).

Referring to the staff, the provisions of the Regulation (Recital 39) state that the staff performing SoHO supervisory activities should have an appropriate professional background and should be regularly trained, in accordance with their area of competence, on the obligations resulting from the Regulation, so that they can properly apply and enforce the rules falling within its scope[1].

1 See for example Art. 8(3)(f), the obligation to improve competencies, or Art. 37, competence assessment within the quality management system.

2. The SoHO supervision model adopted in Poland

The basic legal act in Poland concerning the area studied here is the Act of 1 July 2005 on the Collection, Storage and Transplantation of Cells, Tissues and Organs. The Act implemented the Tissues and Cells Directive 2004/23/EC and specifies the principles for the collection, storage and transplantation of cells, including haematopoietic cells from bone marrow, peripheral blood and umbilical cord blood, as well as the principles of procedure for the collection, storage and transplantation of tissues and organs from living donors and cadavers, including supervisory activities over them (Haberko, 2014, Art. 1).

The main authority responsible for supervisory activities connected with the application of the provisions of the Act is the Minister of Health (Art. 46 of the Act), which exercises its supervision activity directly. Regardless of the tasks performed by the Minister of Health, additional units were established and were also entrusted with supervisory tasks. Hence supervision is carried out both directly and indirectly, in a way that is divided into several units through other, subordinate ones: the 'Poltransplant' Organizational and Coordination Centre for Transplantation, the National Centre for Tissue and Cell Banking (the NCTCB) and the National Transplantation Council.

Poltransplant (Art. 38 of the Act) is a central unit organizing and coordinating transplants, which does not have legal personality, as a state budget unit subordinate to the minister responsible for health (Art. 38(2)). It participates in the performance of public authorities' tasks in the field of health protection, from the perspective of organizing and coordinating transplants (Art. 38). The NCTCB, whose basic task is to maintain a register of tissue and cell banks and to exercise supervision and substantive control over them, does not have legal personality, as it is a state budget unit subordinate to the Minister of Health (Mełgieś & Miaskowska-Daszkiewicz, 2025, p. 474; Tykwińska-Rutkowska, 2014, p. 254). Finally, the Council should be indicated as an auxiliary unit, a main advisory and consultative body to the Minister of Health. The Council was established as a term, collegial advisory and consultative body in the scope of matters entrusted under the Act (Art. 41). Taking into account the tasks assigned to it, which depend on the duties of the Minister of Health, and also its position in the public structure, it should be stated that it is an internal body supporting the Minister (Tykwińska-Rutkowska, 2013, p. 257). The Council members were appointed due to the need for the Minister to use specialist knowledge from various fields of medicine and health sciences, as well as from other sciences (Art. 41(2) of the Act); the status of its members is similar to that of consultants in healthcare (Balmas, 2015, p. 333; Budzisz, 2018, p. 703; Sikorski, 2021, p. 303).

Analysing the adopted legal solutions in this regard, the type of relationship between the Council and its members and the Minister of Health is characteristic for organizational subordination. This type of subordination can be derived in particular from the ministerial powers to appoint the Council members, including the Council's

chairperson, or the power to grant the Council statutes, specifying its detailed scope, organization and mode of operation, as well as the method of remunerating Council members described in its statutes. In addition, expenses related to the Council's activities are covered from the part of the state budget administered by the Minister of Health, and organizational and technical support for the Council is provided by the office supporting the Minister of Health.

We assume that despite the lack of appropriate guarantees in this respect, the organizational dependence between the Minister of Health and the Council should not affect the reliability of the opinions and advice provided by this body, although an appropriate standard has not been introduced in the Act. But considering the fact that the Council members come from medical professions, we should assume that they follow their obligation to comply with the basic rules and principles of the Code of Medical Ethics and the obligations arising from the provisions of the Act on the Medical Profession (Boratyńska & Konieczniak, 2019, p. 271; Rejman, 1993, p. 60). It should be noted that neither the Act nor the statute contain a mechanism to prevent members from being involved in considering matters where a conflict of interest appears, which may pose a significant threat to the impartiality and objectivity of the opinions and advice issued.

Within the Council structures, permanent or *ad hoc* working groups may be formed alongside the Council Ethics Committee. The Ethics Committee is a permanent, seven-person internal body operating within the Council, with statutory tasks. These tasks have been included in an open catalogue; those related to issuing opinions cover, among other things, opinions related to programmes concerning the collection, storage and transplantation of cells, tissues and organs; the activities of Poltransplant and the NCTCB; applications for obtaining a permit to establish a tissue and cell bank, as well as for granting permits concerning the collection of cells, tissues and organs from living donors; storing organs; and transplanting or using them in humans (Art. 41(6) of the Act). Giving opinions is a form of cooperation which, unless otherwise stipulated in legal provisions, is not binding on the addressee (Haberko, 2014, p. 323). However this is the case with giving binding opinions on applications for the transplantation of cells, tissues and organs taken from animals, as well as their use (Art. 20 of the Act; Kubiak, 2021, p. 543).

Structurally, the Minister of Health is placed above these institutions, as the central authority competent in matters concerning health (Mełgieś & Miaskowska-Daszkiewicz, 2017). As the highest authority in the structure of the healthcare system, the Minister of Health is responsible for supervisory functions that cover matters concerning the functioning of the transplantation system; its responsibility relates to both systemic and substantive supervision. The catalogue of powers granted to it is open-ended.

Within the framework of *systemic* supervision, the Minister has been authorized to obtain or request information in the form of reports on the activities of the Council, the NCTCB and Poltransplant, as well as monitoring the maintenance of registers

and lists referred to in the Act[2]. Within the framework of *substantive* law supervision, the Minister uses an authoritative regulatory instrument of administrative law – a permit – in relation to the activities specified in the Act that are undertaken and implemented by entities located outside the administrative structures[3]. The Minister is also the authority responsible for carrying out the inspections referred to in the Act, which s/he may carry out on his/her own or commission to be carried out. At the request of the EC or the competent authority of another EU Member State, s/he also provides written information on the results of the inspection referred to in Art. 35, as regards compliance with the provisions of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004.

In terms of cooperation with the EC, the Minister of Health has been entrusted with reporting duties: it submits a report every three years, in particular on the implementation of the provisions of Directive 2004/23/EC; it also submits an annual report on the notification of serious adverse events and reactions in the field of procurement, testing, processing, sterilization, storage, distribution, import and export, import activities, and transplantation or application to humans of cells and tissues; it carries out inspections at the request of Member States in the event of a serious adverse reaction or event following a transplantation and provides information on the results of such inspections (Art. 42(3) of the Act). The functioning of the transplantation system in Poland has been subject to inspection by the Supreme Audit Office, which in its report indicated numerous instances of negligence in the scope of supervision and requested the implementation of regulations, the application of which will contribute to the improvement of the organization and functioning of the transplantation system in Poland (NIK, 2022).

2 The last competencies refer to the register of objections (Art. 7), the register of living organ donors (Art. 15), the register of bone marrow and cord blood (Art. 16), the national list of persons waiting for transplantations (Art. 17), the register of transplantations (Art. 18), and the register of tissue and cell banks (Art. 40).

3 The following activities concerning cells, tissues and organs are permitted by the Minister of Health: a) establishment of a tissue and cell bank for the purpose of collecting, processing, sterilizing, storing, distributing, allowing for circulation or conducting import activities of tissues and cells intended for transplantation or use in humans; b) the conduct of activities consisting in acquiring potential donors of allogeneic bone marrow and peripheral blood haematopoietic cells, for which medical entities or foundations, referred to as 'marrow donor centres', may apply; c) the conduct by medical entities of proceedings concerning cells, tissues and organs consisting in collecting cells, tissues and organs from living donors; d) the conduct of proceedings concerning cells, tissues and organs consisting in the storage of organs in medical entities performing transplants; e) the conduct of proceedings concerning cells, tissues and organs in a medical entity consisting in transplantation or application in humans; f) the performance of activities by a laboratory consisting in testing cells, tissues and organs. For more, see Mełgieś & Miaskowska-Daszkiewicz, 2025, pp. 500–512.

3. The SoHO supervision model adopted in Serbia

Although it is not an EU Member State, the Republic of Serbia became a candidate for membership in the EU in 2012, and since 2014 has been negotiating on accession to the EU and aligning its legal framework with the *acquis communautaire*. So far, its health regulation (Chapter 28) has to a great extent been aligned with the *acquis*. When it comes to regulation of organ, tissue and cell transplantation and biomedically assisted reproduction, it has been fully aligned with the adopted EU regulation so far.

In the sphere of SoHOs, Serbia has passed several laws: the Law on Transplantation of Human Organs (THO) (Republic of Serbia, 2018/2021b), the Law on Human Cells and Tissues (HCT) (Republic of Serbia, 2018/2021a) and the Law on Biomedically Assisted Fertilization (BAF) (Republic of Serbia, 2017). When it comes to quality and safety standards, laws define the quality system, which encompasses the organizational structure, established responsibilities, and procedures, processes and means for quality management, and includes all activities that directly or indirectly contribute to quality in the field of human cells and tissues for human application (Art. 3 of the Law on HCT and the Law on BAF). The national quality standards are adopted by the Minister, on the proposal of the Republic's expert commission responsible for the fields of cells and tissues and of biomedically assisted reproduction (Art. 10 of the Law on HCT and Art. 16 of the Law on BAF), through several subsidiary laws related to human resources, equipment, premises, methods, and conditions for performing different activities of the processing of human cells and tissues and of biomedically assisted fertilization (Ministry of Health RS, 2019 a, b, c, d, e).

With the adoption of the EU Regulation, it is necessary to amend existing national regulation in the sphere of quality and safety standards, as well as of the mechanisms to ensure that quality. The Directorate for Biomedicine is the competent authority that the Regulation defines in its Art. 5. According to Art. 44 of the Law on THO, the Directorate for Biomedicine is a state administration body that supervises the implementation of the law and subsidiary laws, as well as inspection supervision of the work of health institutions that perform the tasks related to organs, tissues, cells and biomedically assisted reproduction[4]. The tasks of the Directorate for Biomedicine are: 1) proposing the Republic's Programme for Transplantation of human organs/tissues/cells, as well as monitoring the implementation of safety standards and monitoring the quality of the programme; 2) continuous monitoring of the quality of work; 3) issuing and revoking licences to carry out operations in the field of transplantation, as well as maintaining the Register of Health Institutions for the operations of taking, testing and transplanting human organs (and tissues and cells); 4) maintaining the Republic's Register of

4 Although organs are not the focus of the Regulation, the Law on THO is the relevant framework in which the Directorate and its competencies for activities related to organs, tissues, cells and biomedically assisted reproduction are thoroughly defined.

Human Organ Donors and the Register of Human Organ Recipients (including tissues and cells); 5) maintaining the Republic's waiting list by type of human organ (including tissues and cells) and monitoring the allocation of human organs (and tissues and cells) in accordance with established medical criteria; 6) maintaining the register of serious adverse events and reactions, as a system for rapid response and information exchange; 7) coordinating and improving cooperation with related international organizations in order to exchange human organs (including tissues and cells) for the purpose of transplanting; 8) planning, developing and participating in the implementation of educational promotional programmes, projects, action plans, guidelines and strategic documents in order to improve the quality and availability of human organs (including tissues and cells) for transplantation; 9) submitting reports in the field of transplantation to the EC for Health and Food Safety; 10) participating in regular meetings of competent bodies of the EC in connection with the implementation of directives in the field of human organs (including tissues and cells); 11) cooperating with related international organizations. In this sense, the Directorate already has the functions outlined in the Regulation.

The rulebook on the internal regulation and systematization of workplaces in the Ministry of Health (2024) contains a more detailed list of the activities of the Directorate, which shows that it has very large competencies. The Directorate has a sub-unit, the Group for Inspection Surveillance in the sphere of biomedicine; therefore the Directorate is also authorized for the surveillance and inspection of SoHO subjects and related activities. However, the Directorate is not a legal entity but a part of the Ministry of Health, and therefore not fully autonomous. Besides, in line with the Regulation, independent and impartial national competent authorities responsible for the supervision of SoHOs must have the necessary resources and skills to carry out SoHO surveillance activities (Lex Case, 2024), which in practice is not fully the case with the Directorate, having in mind the lack of human resources.

Conclusion

The concept of an authority competent for SoHO matters contained in the EU Regulation is based on the assumption that the Member States are entrusted with creating systemic, organizational and structural solutions adapted to local conditions, which will allow the most effective achievement of the goal set for these authorities. The purpose of such an authority, because their number depends on the decisions of the Member States and therefore their function, is to exercise supervision, covering the monitoring and verifying of the actual compliance with and enforcement of the relevant EU requirements in all areas covered by the provisions of the Regulation, by organizing appropriate supervisory activities, with clearly separated tasks for the national authority for SoHO. All these activities are undertaken in the public interest.

The assumption resulting from the adopted Regulation refers to the postulate according to which this body is to be ensured autonomy and the conditions created for it to operate independently and impartially, without political influence or interference from the industry or other entities that may affect its operational impartiality, while ensuring the transparency of its activities. In order to be able to operate effectively in the public interest, it should have the appropriate resources and equipment and provide guarantees of professionalism.

The organizational solutions concerning the functioning of the transplantation system in Poland from the perspective of the assumptions of the SoHO competent authority should be assessed as requiring changes according to the recommendations addressed to Member States in the Regulation. The current model, imposing the main supervisory functions within the scope of the implementation of tasks related to SoHO on the Minister of Health, is not based in a national body that would be guaranteed full autonomy and would be free from political influence. Therefore other structures responsible for SoHO supervisory activities subordinate to the Minister of Health are not guaranteed sufficient autonomy either. In conclusion, it should be stated that there is a lack of strong guarantees in the Polish national regulations for the implementation of the provisions of Art. 5 of the Regulation, as well as for the guarantees of impartiality specified in Art. 6. Experience to date, as reported by the Supreme Audit Office, also indicates insufficient funding, staff shortages and inefficient management of the transplantation system in Poland.

From the perspective of the Serbian legal transplantation system, when it comes to its autonomy and sufficient human resources and operational capacity, the Directorate's prerogatives are not fully in line with the Regulation. The rulebook plans 11 workplaces for the Directorate, out of which only two are in the Group for Inspection Surveillance. Practice, however, shows that even this number of employees does not exist in the Directorate, so the capacities of the Directorate are neither formally nor substantially sufficient to cover the authorities given to it (Sjeničić & Milenković, 2019, p. 508). The ongoing strengthening of the administrative capacity in the Directorate of Biomedicine is a welcome development, and the recruitment process should be swiftly completed (European Commission, 2023, p. 110).

Furthermore, the process of transplantation was stopped in 2020, due to the adopted decision of the Constitutional Court of Serbia (no. IUz-223/2018, dated 28 July 2020; Pravni Portal, 2021). The Constitutional Court decided that articles of the Law on THO and the Law on HCT, related to consent for transplantation, are not in line with the Serbian Constitution and should be taken out of force. Although new articles should have been defined and adopted within six months of the Court's final decision, this did not happen. Transplantations were initiated again when the Ministry of Health issued an instruction on the actions of transplantation teams when it comes to issues of consent (Euronews, 2022). At the moment, the Ministry of Health seems to be committed to improving the field of transplantation in Serbia – administratively, through the

necessary regulation, but above all, in terms of the number of donors and the number of transplants performed (Politika, 2024). However, enforcement of the capacities of the Directorate, as a SoHO competent authority, still seems not to be a focus.

To sum up, creating an appropriate model in which the adopted solution will be based, in order to meet the requirement of ensuring supervision over all areas covered by the Regulation, should be carried out, together with a thorough analysis of its scope. The tasks resulting from the Regulation may determine the adopted model. Only then will it be possible to appropriately transpose public tasks related to ensuring the quality and safety of SoHO into national legal systems by assigning them to previously created supervisory structures, and respectively to the body or bodies proper to SoHO. Naturally, the institutional frameworks of the two analysed countries do not necessitate fundamental restructuring, nor should the core characteristics of their respective healthcare systems be substantially altered. The primary objective should be the enhancement of SoHO bodies, particularly with respect to their institutional autonomy, as well as their human and financial capacities, and the effectiveness of their operational implementation. The matter of autonomy predominantly pertains to the domain of health legislation and would therefore require appropriate legislative amendments. Conversely, the strengthening of human and financial resources entails budgetary adjustments and a more focused commitment from health policymakers to the transplant sector within the broader healthcare system.

After the creation of an appropriate model, the adopted solution will be based on it, in order to meet the requirement to ensure supervision over all areas covered by the Regulation. Member States (and candidate countries) should thoroughly analyse the scope of the provisions contained therein and appropriately transpose public tasks related to ensuring the quality and safety of SoHO into their own legal systems by assigning them to previously created supervision structures, and respectively to the authority competent for SoHO.

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