Legal and Administrative Intricacies of the Romanian Healthcare Policies in the Field of the Human Organs Transplants[*]

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Abstract: Objectives: The article elaborates on the intricacies brought on the Romanian Law by the adoption, on 7 July 2010, of Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation, raising for the Romanian legal system the question of rapidly adapting its regulations and procedures to the newly introduced European standards, as well as the question of harmonizing its essential legislation by transposing Directive 2010/45/EU provisions into national law. **Prior Work:** Liability of Public Administration for damages caused by unsafe transplant procedures represents one of the major themes, in the recent specialized literature. The problematic of informed consent to organ donations, as well as that of organ traceability represents an interesting, though insufficiently explored and exploited issue, in contemporary Romanian Law. **Approach:** The author applies, as research method, the analysis of jurisprudence, doctrinal writing and legal provisions in force referring to the problematic of the human organs transplant and donations. The paper also discusses the text of Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation. **Results:** The "opting-in – opting out" dichotomy is discussed, as common standard for informed consent in the field of organ donations. The author also formulates *de lege ferenda* proposals. **Implications:** The paper interests legal practitioners confronted with the problematic of human organs donations, law students, as well as jurists specialized in Consumer Law and Administrative Law, since the problematic of organ transplantation also reverberates on the protection of the consumers of medical services. **Value:** The analysis insists on the degree of compliance of national law to the EU's regulations when removing disparities on donor's consent procedure or on standards of safety related to the transport of human organs. The paper is also enriched by a presentation of the new European standards on the National Register of living donors and on the National Data bases on serious adverse events.

Keywords: administrative law; healthcare policies; organ transplants; organ donations; EU's Law

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1. Introductory Comments

Reforming the Romanian healthcare system has never been proven to be an easy task, especially in terms of pertinent legislation, medical mobility or financial sustainability and the episodic attempts, such as the adoption of Law 95/2006 on reformative measures in the field of public health, later modified, merely represented modest steps for the Romanian Public Administration. On the other side of the coin, the relative urgency of the healthcare reform, after EU's enlargement in 2007 by accepting Romania and Bulgaria, is currently doubled by the provocation launched for the two new Member-states in terms of approximation of legislation in the field of consumers of medical services' rights, under the frame of the European Union's law. Recently, the urgency of political decision and legislative innovation became more salient by the adoption, on 7 July 2010, of Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation[1], raising for the Romanian legal system the question of rapidly adapting its regulation and procedures to the newly introduced European standards.

At the EU's level, adopting Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation indubitably marks an important progress toward uniform high standards of security in the mentioned area, while representing a provocation for the Member States to modernize and harmonize national criteria of safety in the field of organ transplants. The new European regulation brings a series of major changes referring to the collecting of organs procedure, donor's informed consent and transport of human organs. For instance, the reporting system and management concerning serious adverse events and reactions associated to the human organs transplant are reformed, as to ensure common standards, applicable in all Member States, along with a uniform procedure of organ traceability. Essential in the economy of human organs transplants becomes the "characterization of donor's" procedure, seen as a preparatory stage, before transplantation, in which trained medical personnel collects relevant data on the donor, respecting the two informational settings offered in Annex A and B of the Directive discussed, containing sets of essential minimum data, collected for each donation and of complementary data to be collected in addition, based on the decision of the

[1] Directive 2010/45/EU has been published in the Official Journal of the European Union L 207/14 from 6 August 2010.

medical team, taking into account the availability of such information and the particular circumstances of the case.

Offering human organs for transplantation keeps its non profit character under the regulation of article 13 of Directive 2010/45/EU, banning national legal provisions which are indulgent to offers of organs purchase and imposing to all Member States the adoption of regulations forbidding the sell of organs; the only licit variant remains that of non payable offers, through the judicial means of living or deceased donations. An annual report, publicly accessible, on competent national authorities' activities related to the testing, characterization, procurement, preservation, transport and transplantation of organs intended for transplantation into the human body becomes compulsory, under the terms of article 18 of the Directive, as observed in the lines below.

The time factor may also constitute a source of worries, as the Romanian legislator is expected to transpose Directive 2010/45/EU before 27 August 2013 and report to the European Commission and every three years thereafter, on the activities undertaken in relation to the provisions of the Directive in discussion and on the experience gained in implementing it, which leaves Romanian Administrative authorities a two years period for complying to the European requirements, by adopting an adequate set of legal measures on organs donations and supervising their transposition into practice.

Romania's compliance to the new European regulations may be expected to represent a significant progress, in comparison to the ambiguous legislation in force, namely Law 95/2006 on reformative measures in the field of public health (later modified) and the introduction by the Public Administration of resort of the new European standards of quality and safety for the human organs transplant procedures is more than salutary, though it does not constitute an easy task.

Administrative measures to be taken will imply: (a) creating a specialized Administrative body, uncharged with the accurate, rapid and verifiable reporting (to the European organisms inclusively) of serious adverse events and reactions related to human organs transplants; (b) creating national and local Administrative organs in charge of the management of serious adverse events and reactions in accordance with Directive 2010/45/EU provisions; (c) elaboration of new legislation on packaging and labeling of organs in accordance with the new European standards, as the actual Romanian legislation in force lacks explicit imperative provisions on standards regarding human organs packaging and

labeling; (d) elaboration of legal rules and specific Administrative procedures for the authorization of transplantation centers; (e) the establishment of conditions of procurement and systems of traceability of organs intended for transplantation into the human body etc.

The article therefore analyses the implications of the most recent European regulations in the field of Administrative procedures related to human organs transplant – Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation – on national medical and legal procedures related to numerous aspects such as donation, testing, characterization, procurement, preservation, transport and transplantation of organs intended for transplantation into the human body, obviously excluding the cases when such organs are used exclusively for research purposes. Directive 2010/45/EU provisions are also expected to have an important impact on Romanian legal texts, as removing disparities on donor's consent procedure or on standards of safety related to the transport of human organs, for example, become necessary. This paper also attempts to offer an overview of the essential aspects thought to characterize the new European framework for quality and safety in the field of transplantation of human organs, as set by Directive 2010/45/EU, referring to the Administrative procedures of verification of donor's identity; the verification of donor's / donor's family's consent; the verification of the completion of the organ and donor's characterization; the procurement, preservation, packaging and labeling of organs in accordance with the new European standards set by Directive 2010/45/EU provisions; the transportation of organs in accordance with the harmonized European rules; ensuring traceability of human organs, guaranteeing compliance with the European Union's and national provisions on the protection of personal data and confidentiality; the accurate, rapid and verifiable reporting of serious adverse events and reactions; the management of serious adverse events and reactions in accordance with Directive 2010/45/EU provisions.

Also, it should be observed that the new EU's legislation is meant to ensure that organs comply with recognized standards of quality and safety, despite the initial discrepancies in national regulations and that the later will be finally harmonized, as to reassure consumers of medical services that human organs "procured in another Member State carry the same basic quality and safety guarantees as those

obtained in their own country"[1]. The necessity of establishing common quality and safety standards for the procurement, transport and use of organs at the European Union's level, in the context in which these common standards would facilitate exchanges of organs to the benefit of an enormous group of European patients in need of this type of therapy each year, justified the recent developments of the European Law, as synthesized in Directive 2010/45/EU provisions. It should be added that Directive 2010/45/EU, although having as its first objective the safety and quality of organs, indirectly contributes to combating organ trafficking through the establishment of competent authorities, the authorization of transplantation centers, the establishment of conditions of procurement and systems of traceability, as unacceptable practices in organ donation and transplantation – including trafficking in organs, sometimes linked to trafficking in persons for the purpose of the removal of organs – also constitute a serious violation of EU citizens' fundamental rights and, in particular, of human dignity and physical integrity.

2. Theoretical Background

Liability of Public Administration for damages caused by unsafe transplant procedures represents one of the major themes, in the recent specialized literature[2]. For instance, one stream of research found that no difference of treatment, when establishing the existence of the culpability, is to be made between private clinics and public hospitals, as both are compelled to respect safety standards associated to medical services (Mangu, 2010) (Turcu, 2010, p. 237). A second body of literature, which focused on general paradigms of responsibility related to contracts concluded by consumers of medical services, found that risks of unsafe products and procedures are, in practice, frequently associated with the use of human organs in transplantation and that use of uniform, well organized national and international transplantation systems can significantly reduce the associated risks of transplanted organs for recipients[3]. A third group of studies investigated the effects of exoneration clauses over public hospitals' liability, arguing that the gravity of

[1] As underlined in the sixth paragraph of Directive 2010/45/EU Preamble.
[2] See, for further details (Astărăstoae, 2010, p. 23; Borzan & Mocean, 2002, pp. 89-112; Fauvarque-Cosson, 2007, pp. 956-960; Guettier, 1996, pp. 226-227; Turner, 2011, p. 23; 1-7)
[3] For a fully analysis of the issue (Simion, 2011, *passim).* For other European experiences in the field, see for instance (Grytten & Sørensen, 2009, pp. 11–27)

damages is not to be superposed on the concept of medical fault (Waline, 2010, p. 184)[1].

While previous research has attempted to determine whether the concept of medical fault should play a role in determining public hospitals' liability for damages caused in the field of organs transplant or whether a objective type of liability should be imposed, independent of the victim's success in proving a medical fault, but dependent on the clinic's failure to prove its lack of negligence, the extent to which such criteria are to be used in determining public hospitals' responsibility for traceability of negative reactions and events related to human organs transplant remains unknown. This is an important gap in the literature because, realistically, these criteria do not operate in isolation. Indeed, a prominent theory of civil liability, le Tourneau's (2000) social policies theory (le Tourneau & Cadiet, 2000)[2], states that establishing a national compensation fund destined to cover financial losses of medical *malpraxis* victims in the public health system, including the field of organs transplants, becomes vital in the XXI century society, extracting victims from the insurmountable situation when the responsible public hospital does not dispose of financial resources as to cover damages caused and established by a legal sentence. Unfortunately, Romanian literature lack debates on the establishment of such national compensation fund, as well as on the sources to be used for contributions (for instance, a percentage of the monthly contribution to medical and social insurance funds).

The lack of specialized literature allocated to the theme of Administrative procedures of consent to organ donation and traceability of transplants, on the other side of the coin, is explained by the fact that the change of the European standards of quality and safety is very recent, as the adoption of Directive 2010/45/EU operated on 7 July 2010. Nevertheless, Romania, as well as the other Member States is expected to designate, until 2013, one or more competent authorities of the Public Administration in the area concerned with Directive 2010/45/EU provisions (probably subordinated to the Health Department)[3]. Secondly, after its designation, the competent national authority is called to establish and keep

[1] For further details see (Tapinos, 2008, p. 311) as well as, for Romanian literature (Popa, 2003, pp. 59-63; Frunză, 2009, pp. 3-23).
[2] For an interesting insight, see (Shah, Brieger & Peters, 2011, pp. 275-287).
[3] To this respect, Member States are allowed to delegate (or may allow a competent authority to delegate) part or all of the tasks assigned to it under Directive 2010/45/EU to another body which is seen to be suitable under national provisions to assist the competent authority in carrying out its functions.

updated a framework for quality and safety in accordance with article 4 of Directive 2010/45/EU. In addition, organ procurement organizations and transplantations centers will have to be controlled or audited on a regular basis, to ascertain compliance with the requirements of the Directive.

Donor's consent to the transplant procedure, in the field of living donations, as well as in the perimeter of deceased donations, also raises the question of the legal right to retract his / her prior consent on the basis of the information received on the consequences and the risks of the medical procedure involved, as donor's consent needs to be based on a free, informed and unequivocal manifestation of will. A general theory of the consent retract in the Romanian Consumer Law is generally absent, both the judicial doctrine and the juridical practice being not familiarized with the problematic of the mentioned judicial concept, thus the necessity of harmonizing national regulations with the new European legal provisions becomes urgent, as the text of Law 95/2006 on reformative measures in the field of public health, later modified, does not include a specific procedure for donor's withdrawal of prior consent. The sole internal approach of the theme consisted in salutary analyses, unfortunately punctual and incomplete, based on the investigation of classical species of withdrawal rights. Similarly, the rare references made to the subject of the patients' right to retract their assent on the bases of the insufficiency of information delivered kept unsolved legal problems as the progressive formation of consent to a medical act. In the field of Romanian law, analyzes of the consumers legal right of consent withdrawal are sporadic, the major characteristics of retract rights reserved by convention remaining unexplored and unexploited.

3. Practical Difficulties Associated to the Harmonization of the Organ Procurement Procedures

One of the most salient tasks of the Romanian authorities in the next two years is to grant, suspend or withdraw, as appropriate, the authorizations of procurement organizations or transplantation centers or prohibit procurement organizations or transplantation centers from carrying out their activities, where control measures demonstrate that such organizations or centers are not complying with the requirements of the Directive; on the other versant, a reporting system and management procedure for serious adverse events and reactions is expected to be put in place at the Romanian healthcare system's level, as provided for in article 11, paragraph (1) and (2) of the Directive. Widening especially the traditional

Romanian point of view, the Heath Department is expected to issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted; it is well known that, at the moment, no uniform guides and procedures are used, on the Romanian territory, for legal organ procurement and pre and post transplantation storage of information.

Finally, protection of collected personal data regarding donors and recipients constitutes another important feature of the harmonized system proposed in the text of Directive 2010/45/EU, Romanian authorities being also called to ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with EU's provisions on the protection of personal data, in particular Directive 95/46/EC; in addition, competent authorities are called to participate, whenever possible, in the European network of competent authorities referred to in article 19, to coordinate at national level input to the activities of that network and to supervise organ exchange with other Member States and with third countries as provided for in article 20, paragraph (1) of the Directive.

Focusing on the records and reports concerning procurement organizations and transplantation centers, it should be noted that article 18 of the mentioned directive imposes Member States to ensure that the competent authority: (1) registries the activities of transplantation centers and procurement organizations, the numbers of living and deceased donors and the types and quantities of organs procured and transplanted included and that the activity of data registration respects the EU's and national provisions on the protection of personal data and those concerning the statistical confidentiality; (2) an *annual report* on the activity of the national competent authority in the field of organ transplantation is elaborated and made publicly accessible; (3) an updated record of procurement organizations and transplantation centers is established and maintained at a national level. In this context, all Member States are compelled to provide information on the record of procurement organizations and transplantation centers, upon the request of the European Commission or of another Member State, as to ensure the accessibility of this information at the EU's level. The public character of this annual report is also to be noticed, all European consumers of medical services being the potential

beneficiaries of the centralized informational system described in the Directive 2010/45/EU text.

None of these administrative bodies exist, at the moment, in the autochthon healthcare system; both reporting and recording procedures are expected to become available in the next two years, by the effort of the Health Department. Exchange of information at the EU's level, on all the relevant aspect associated to the human organs transplants is not to be neglected and according to the Directive provisions, the European Commission will organize a network of the national competent authorities concerning the exchange of information on their experience acquired as regarding the implementation of the Directive; consequently, in certain cases, experts on organ transplantation, data protection supervisory authorities or representatives from European organ exchange organizations, as well as other relevant parties will have the capacity of associating with the mentioned network (article 19 of Directive 2010/45/EU on standards of quality and safety of human organs intended for transplantation).

Reports concerning the application of the Directive by each Member State are regulated by article 22, imposing that Member States report to the European Commission before 27 August 2013 and every three years thereafter on the activities undertaken concerning the application of Directive provisions and on the experience gained by the national authorities in implementing the common European standards of quality and safety. In addition, before 27 August 2014 and every three years thereafter, the European Commission will transmit to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, a report on the implementation of the Directive. As to the penalties applicable to non compliance to the new European standards of quality and safety of human organs intended for transplantation, it is the Member States mission to establish specific rules on penalties applicable to infringements of the national provisions adopted while transposing the Directive into internal law and thus to take all measures necessary to ensure that the prescribed penalties are thoroughly implemented. Directive's authors mentioned, however, in article 23, that the penalties provided for must be "effective, proportionate and dissuasive".

4. Procedures of Consent to Organ Donations: Opting-in *versus* Opting-out Systems

Removing obsolete procedures in the field of consent to organ donation represents one of the most important tasks of Romanian Public Administration in the next two years. Inspiration for the new model of consent may be found in several models of consent to donation that coexist in the Union, including *opting-in systems*, in which consent to organ donation has to be explicitly obtained (a) and *opting-out systems*, in which donation can take place unless there is evidence of any objection to donation (b). Certain Member States have even developed specific registries systems, in which citizens interested in consenting to an organ donation record their prior assent; such official records constitute, in our opinion, one of the zones where the import of legislation is necessary. On one hand, is should be noted that Directive 2010/45/EU is not intended to prejudice the broad diversity of the systems of consent already in place in the Member States, but to ensure that harmonized forms of informed consent become available at the EU's level. On the other hand, however, it should be recalled the interminable hesitancies that have been accompanied Romanian legislator's attempts, in 2006, when adopting Law 95/2006 on reformative measures in the field of public health (later modified), of reforming medical procedures of consent. In fact, there is no uniform procedure or harmonized forms to be respected by the Romanian public hospitals regarding patient's assent to organ donations and transplants, each hospital usually using its own types of document and thus the discrepancies between medical practices being frequent (Simion, 2011, p. 311; Turcu, 2010, p. 216).

It is largely known that the consent to a medical procedure involving transplant of a human organ may be emitted also by the donor's family, in cases mentioned by national regulations, usually implying donor's impossibility, at the time of the medical act, to express his / her will regarding the transplant procedure; in certain national legislations, however, the validity of donor's family consent is conditioned by the inexistence of donor's living refuse of the transplant, expressed while being alive. However, an attentive analyze of Law no. 95/2006 on reformative measures in the field of public health provisions shows that the Romanian legislator avoided the establishment of a univocal setting in the field of donor's consent, the opting-in system coexisting with the opting-out system, as the patient is allowed to either express his or her refusal to donate while alive, either to expressly consent to an organ donation, regulating that donation can take place unless there is evidence of any objection to donation, priory expressed by the potential donor.

Import of European recognized principles guiding practices in organ donation and transplantation becomes urgent, including the certification or the confirmation of death in accordance with national provisions before the procurement of organs from deceased persons and the allocation of organs based on transparent, non-discriminatory and scientific criteria. Therefore, it is Health Department's task to elaborate in the next two years uniform national forms for the certification or the confirmation of death (a), in the case of donors, a transparent (probably electronic) data basis of allocation of organs and recipients' identity (b), along with harmonized forms of donor's and recipient's consent to an organ transplant[1] (c).

As mentioned above, the *organ characterization* also falls under the sphere of incidence of Directive 2010/45/EU, referring to the collection of all the "relevant information on the characteristics of the organ, needed to evaluate its suitability, in order to undertake a proper risk assessment, to minimize the risks for the recipient and optimize organ allocation" (article 3). While the *procurement of human organs* describes the process by which the donated organs become available for the potential recipients, the activity of *organs preservation* means "*the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation*". Finally, by *procurement organization* it should be understood "*a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, that is authorized to do so by the competent authority under the regulatory framework in the Member State concerned*", as regulated by article 3 of Directive 2010/45/EU.

The transplantation of organs process, as defined by the cited article 3, refers to a the medical procedure intended to restore certain functions of the human body by transferring an organ from a donor to a recipient; from the angle of the applicability of Directive 2010/45/EU into national law, traceability of human organs destined to be transplanted is also important, as referring to the ability to locate and identify

[1]As indicated in article 2, Directive 2010/45/EU is applicable to donation, testing, characterization, procurement, preservation, transport and transplantation of organs intended for transplantation into the human body, excluding in principle the cases when such organs are used exclusively for research purposes. In this context, the "human organ" is legally defined as "a differentiated part of the human body, formed by different tissues, that maintains its structure, vascular capacity and capacity to develop physiological functions with a significant level of autonomy"; on the other hand, a part of an organ is also considered to be an organ, to the purpose of the application of Directive 2010/45/EU provisions, "if its function is to be used for the same purpose as the entire organ in the human body", maintaining the requirements of structure and vascular capacity (article 3 of Directive 2010/45/EU).

the organ at each stage in the chain from donation to transplantation or to organ disposal, in cases in which the transplant is canceled on subjective or objective criteria, including the ability to identify the organ donor, as well as the procurement organization, respectively to identify the recipient(s) at the transplantation centre(s) and, finally, to locate and identify all relevant data, constituting non-personal information and concerning products and materials which came into contact with that human organ intended for transplantation. In this context, is should be underlined the vital intervention of the transplantation centers, defined as healthcare establishments, teams or units of a hospital or any other bodies which undertake the transplantation of organs and are authorized to this respect by the national competent authority in each Member State, under a specific regulatory framework, developed into national law in order to establish standards for the transplantation centers' functioning.

A few considerations are reserved for the Romanian authorities' option for the consecration of both living and deceased donations. The latter is practiced along with the former in most European medical systems, as living donation coexists with deceased donation in almost all Member States, the judicial difference being extracted from the formal declaration of will; in the first case, the donor accepts that the transplant take place during his/her life, while in the second case, the consent becomes effective after donor's death. As mentioned in Directive 2010/45/EU preamble, the evolution of living donation over the years permit extracting the conclusion that good results can be obtained even where there is no genetic relationship between donor and recipient, grace to recent developments of medical science; however, risk of disease transmission could jeopardize the success of the transplant procedure.

Therefore, living donors should be subject to an adequately elaborated procedure of evaluation, meant to determine their suitability for donation and also to minimize the risk of disease transmission to the organ recipients, a field in which the necessity on uniform European standards of safety becomes evident[1]. Regarding

[1] In addition, living donors face risks linked both to testing to ascertain their suitability as a donor and to the procedure to obtain the organ. In this field, medical, surgical, social, financial or psychological complications may arise, while the level of risk depends, in particular, on the type of organ to be donated, as well as on the type of medical procedure involved. Therefore, living donations need to be performed in accordance with uniform European standards, which are applicable in each Member State, in a manner that minimizes the physical, psychological and social risk to the individual donor and to the recipient, while the public's trust in the healthcare community is maintained. See (Frunză, 2009, pp. 12-14; Rousset, 2009, p. 315).

donor's consent, it should be underlined that the potential living donor has to be able to take an independent decision on the basis of all the relevant information concerning the organ procurement, as well as the consequences and dangers of the medical procedures attached and the associated risks, while properly and priory informed on the purpose and nature of the donation. Legal questions related to the organization of health care services providing transplant services and doctor patient relationship while discussing potential organ donations are addressed by numerous provisions of Directive 2010/45/EU, which are meant to guarantee respect of common principles governing donation of human organs and to ensure the highest possible standard of protection for the living donors, both in the judicial and the medical area. It should also be noted that some Member States are signatories to the Convention on Human Rights and Biomedicine of the Council of Europe, and its additional protocol on Transplantation of Organs and Tissues of Human Origin, the provisions of which become incident also in the field of human organs transplant, when appropriate. Therefore, a proper evaluation of potential donors, a complete and thorough information on the essential data concerning the transplant and an adequate follow-up of transplant successes, in the process of organ traceability, are internationally recognized measures aimed at protecting the living donors, as well as the organ recipients, measures also contributing to quality and safety of organs insurance, in the absence of which complications may be medical, surgical, social, financial or psychological.

Another aspect relies to the efforts to be made as to increase deceased organ donation, which as opposed to living donation, represents no risk to the donor, concerning medical complications or death arising from the transplant procedure. In this context, it is important to stretch the necessity of legal procedures of consent to organ donation in the case of decedent's family members, as in practice the rate of family refusals to consent to organ donation remains high. Posterior to patient's death, it is the difficulty of dealing with a great emotional distress and suffering that makes families' decision-making concerning organ donations much more difficult that for a living donor, as families tend to concentrate their attention on aspects such as the circumstances in which the diagnosis of death is made and on the protection of the decedent's bodily integrity. Thus Member States efforts have to be focused on educational programs towards families' consenting to deceased organ donation, underlining their importance in the process of life-saving for otherwise incurable patients.

The salient negative aspect, on the other hand, is the lack of regulation in the field of patients' rights of withdrawal of life-sustaining treatment, a problem commonly associated to the transplant of human organs and unfortunately kept outside the incidence of Directive 2010/45/EU, whose authors chose not to elaborate on procedures related to the mentioned withdrawal. Patients whose existence is severely limited and dependent on some form of life-sustaining treatment, such as a ventilator or feeding tube raise the question of knowing if having these treatments withdrawn is or not to be seen as a question of a legal right of retract, permitting them to avoid a persistent vegetative state and allowing human organs to be procured for transplant purposes.

The major legal problem associated to withdrawal of life-sustaining treatment, unfortunately unsolved by Directive 2010/45/EU, nor by Romanian legal provisions, is the lack of clear and convincing standards to be used by courts in order to determine the adequacy of an individual's expressed will not to be maintained by life-supporting measures, while consenting to an organ transplant. As to the free character of donor's will, is has been reaffirmed that patient's right to self-determination remains crucial in the context of informed consent. The concept of patient's right to the preservation of his/her bodily integrity lies under the national regulations, being not described in the Directive 2010/45/EU text; however, due to its firm constitutional foundation, the mentioned right is usually guaranteed by the means of national regulations.

Similarly, the recipient's consent has to present the same free character as the donor's, the potential recipient having the right to refuse invasive treatment or have withdrawn various life-saving or life-sustaining therapies, as part of patient's right to self-determination. Generally, legal discourse has given considerable difference to a patient's right to refuse treatment, including an organ transfer, whether the potential recipient of the human organ was competent and legally able to make his or her whishes known (a) or mentally incompetent or speaking through a surrogate (b), in which case no valid consent was expressed. Patient's legal competency usually raises no difficulty, as the patient is able to assert his or her rights individually; however, is has been held that a patient's decision to have vital support withdrawn or to reject organs transplant, even when resulting into death,

does not constitute proof of legal incompetence and therefore represents an unequivocal manifestation of will[1].

5. Adapting Healthcare Policies to the New European Standards

As observed above, Romanian healthcare authorities are called to adapt medical procedures of organ transplantation to the new European quality and safety standards before 2013. Article 15 of Directive 2010/45/EU reminds Member States that they are compelled to adopt appropriate measures meant to ensure the highest possible protection of living donors in the process of organ procurement and transplant, while guaranteeing the quality and safety of organs intended for transplantation; in particular, selection of living donors has to be performed on the basis of donors' health and medical history, while the competent healthcare professionals are suitably qualified and trained, with respect to the European standards of quality in the field of organ transplantation. Taken as a whole, the mentioned assessments may provide for the exclusion of persons whose donation could present unacceptable health risks for the organ recipients. In addition, Member States will organize a national register or record of the living donors, which is kept in accordance with the European Union's and national provisions on the protection of the personal data and statistical confidentiality. Therefore, as a EU member, Romania shall pursuit the establishing of a follow-up of living donors system and shall organize a system meant to identify, report and manage any event potentially relating to the quality and safety of the donated organ, also focused on the recipient's safety, while registering all serious adverse reactions that may result from the donation for the living donor, as well as for the organ recipient. These standards present patients with more effective access to high-quality medical care concerning the transplantation steps and is, therefore, an important legal tool in strengthening patients' rights.

[1]In the terminology coined by (Turcu, 2010, p. 288) the donor has the right to be adequately informed on the entire medical and judicial consequences of his / her will, the accent being put, while discussing the judicial content of the duty of information, on the purpose and nature of the donation, its consequences and its risks, as essential pillars of donor's will.

5.1. National Register of Living Donors

Creating a national record system of the living donors is of crucial importance to the development of Romanian uniform system of organs traceability. When transposing in the national law Directive 2010/45/EU provisions, Member States are called to ensure that all procured organs and the donors thereof are characterized or are subjected to a "characterization procedure" before transplantation, implying the collection of the relevant information set out in the Annex of the Directive. These informative documents contain a set of minimum data which has to be collected for each organ donation, prior to the transplant procedure, while information specified in Part B of the Annex contains a set of complementary data to be additionally collected upon the decision of the medical team, adapted to the availability of such information on the organ donor and recipient and to the particularities of the transplant case. The use of the risk-utility balance as a criterion is expressly favored in the text of article 7 of Directive 2010/45/EU, establishing that, if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the annex are available. The "donor characterization" procedure, as set by article 7 of the Directive, implies the collection of relevant information on the characteristics of the organ donor, needed to evaluate his/her suitability for organ donation, in order to undertake a proper risk assessment and minimize the risks for the recipient, as well as optimize organ allocation. As usually noted, at the moment the Romanian medical system does not use a standardized donor characterization procedure, the implementing of the new European standards thus representing an absolute novelty for the autochthon Public healthcare system.

5.2. National Data Bases on Serious Adverse Events

One of the most important branches of the Public healthcare authorities' duty becomes the establishing of national data bases on serious adverse events, referring to the registration of all undesired and unexpected occurrences associated with any stage of the transplantation chain, from donation to effective transplant, that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs hospitalization or morbidity, while ensuring that patients have the legal means of

making complaints and are guaranteed remedies and judicial compensation in hypotheses of harm caused by the treatment received associated to a transplant procedure.

The serious adverse reactions, on the other hand, are defined as unintended responses, including a communicable disease, in the living donor's health state or in the recipient's, that might be associated with any stage of the transplant chain, from organ donation or procurement to transplantation, response that is fatal, life-threatening or disabling, even incapacitating for the recipient or for the living donor; in this category are also included medical responses to an organ transplant that result in or prolong patient's hospitalization or morbidity, upon the case; relevant data on these negative responses are also meant to be centralized at an European level, in order to avoid future dysfunctions concerning the transplant procedures; the mentioned aspect therefore constitutes one of the biggest positive steps attributed to the adoption of Directive 2010/45/EU at the EU's level. Though Romania does not dispose, at the moment, of national records on undesired and unexpected occurrences associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs hospitalization or morbidity, it is expected that such data bases are created, as to collect relevant information on the unintended responses, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs donor's or recipient's hospitalization or has the potential of causing morbidity. These data are meant to be registered at a national and European level, in order to avoid future incidents or adverse medical responses and to provide consumers of medical services with high, uniform standards of safety. As mentioned above, the regular storage of such data is that of a 30 years period, imposed by the new European standards.

Harmonizing the creation of national data bases on serious adverse events associated to organ transplants and the development of a common approach at the European Union's level as to evaluating post-transplant results are to be welcomed, especially from the angle of the necessity of recording medical events in the state of recipients' health, at regular intervals following transplantation. Such recording procedures may also help identify the extent to which re-transplantation becomes necessary for certain recipients, as well as examining post-transplant outcomes,

while focusing on national data bases of serious adverse events resulting from different categories of organ donation.

5.3. The Principle of Benevolent Offering of Human Organs

The benevolent character of organ offering represent no novelty of the commented European act, its roots being found in the immoral character of transactions over the human body, usually kept in most of the Member States' legislations; though not newly proclaimed, the express reiteration of the organs sell prohibition is meant to eradicate all potential discrepancies between national legal provisions, some incomplete ore evasive, as to ensure a harmonized point of view at the EU's level, on the immoral and illicit character of transactions over human organs intended for transplantation. Directive 2010/45/EU imposes Member States, in article 13, the duty to ensure that donations of organs from deceased and living donors are "voluntary and unpaid". Paragraph 2 of the cited article mentions, however, donors' right of compensation for expenses objectively related to the transplant procedure, establishing that "the principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation; Member States shall define the conditions under which such compensation may be granted, while avoiding there being any financial incentives or benefit for a potential donor"[1]. Basically, what the Directive imposes in the area concerned is that all Member States ensure that the procurement of organs is carried out on a non-profit basis, perpetuating a legal state already existent in most of EU's members, where the organs donations are already seen, at the level of relevant legislation, as excluding validity of offers to sell or purchase the human organs involved.

The aspect of altruistically oriented behavior is essential in the field of human organs transplant, while, in the terms of Directive 2010/45/EU, the violation of these principles might be associated with risks that are normally unacceptable in the process of organ transplant. For instance, where organ donation is not voluntary, but imposed or is oriented towards financial gain, it is the quality of the process of donation that is put under question, while diminishing or evanishing recipient's warranties of safety. Therefore, in hypotheses in which the donor's

[1]Advertising for human organs also remains prohibited, as regulated by paragraph 3 of article 13 ("Member States shall prohibit advertising the need for or availability of organs where such advertising is with a view to offering or seeking financial gain or comparable advantage").

main scope lies not in benevolent purposes such as improving the quality of recipient's life or saving the life of another person, the organ offer has the potential of endangering recipient's health, no warranties attached to the sincere character of donor's declarations on his or her medical record. The Preamble of Directive 2010/45/EU recalls that, even in the cases in which the process of organ transplantation is developed in compliance with the appropriate quality standards, donor's declarations or clinical history might not be sufficiently accurate in terms of health conditions or diseases potentially transmissible from donor to recipient, as long as these data are obtained from either a potential living donor or, for instance, from the relatives of a potential deceased donor who are pursuing financial gain or, in certain hypotheses, are subjected to some kind of coercion interfering with their decision on the organ donation. Therefore, the deliberately maintained silence over negative medical history could give rise to numerous safety problems for potential recipients, since the medical team would have a limited capability for performing an appropriate risk assessment[1].

As it has been observed, the promotion of altruism in organ donation at the EU's level and the prohibition on financial gain associated to human organs donation are connected to broader bioethical principles and human rights, in the attempt of preserving human dignity and of avoiding the so-called instrumentalisation of human bodies, reminding the rule according to which no part of the human body may not be the subject of commercial transactions.

Another feature worth noting is that at this point, Romania, as a Member State, is also called to provide efficient legal remedies, while adopting and implementing operating procedures for: (a) the verification of donor's identity; (b) the verification of details of the donor's or the donor's family's consent, authorization or absence of any objection, in accordance with the other national rules that apply in the field of donation and procurement of human organs; (c) the verification of the completion of the organ and donor characterization in accordance with article 7 and the annex of Directive 2010/45/EU; (d) the procurement, preservation, packaging and labeling of organs in accordance with articles 5, 6 and 8 of Directive

[1] In this context, The Charter of Fundamental Rights of the European Union should be recalled, notably the principle set out in article 3, paragraph (2), letter (c) thereof. The mentioned principle of non onerous organs procurement is also enshrined in article 21 of the Convention on Human Rights and Biomedicine of the Council of Europe, which many Member States have ratified and it is also reflected in the World Health Organization Guiding Principles on Human Cell, Tissue and Organ Transplantation, whereby the human body and its parts may not be the subject of commercial transactions.

2010/45/EU; (e) the transportation of organs in accordance with article 8 of Directive 2010/45/EU; (f) ensuring traceability of human organs, in accordance with article 10 of Directive 2010/45/EU, guaranteeing compliance with the European Union's and national provisions on the protection of personal data and confidentiality; (g) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with article 11(1) of Directive 2010/45/EU; (h) the management of serious adverse events and reactions in accordance with Article 11(2) of Directive 2010/45/EU. In addition, as recorded in article 5 of the mentioned Directive, the harmonized framework for quality and safety is meant to ensure that the healthcare personnel involved at all stages of the transplant chain, from donation to transplantation or organ disposal, are suitably trained and adequately competent, including the development of specific training programs for this medical personnel.

6. Setting Uniform Standards for Confidentiality of Personal Data

This part of the paper is concentrated on the necessity of elaboration, at a national level, of uniform security standards when processing of personal data of organ donors and recipients both by public hospitals and private clinics[1]. The text of article 16 of Directive 2010/45/EU is dedicated to the question of confidentiality and protection of personal data in the field of human organs transplants, Member States being called to ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with European Union's provisions on the protection of personal data[2].

With respect to Directive 95/46/EC provisions on the protection of personal data, Romanian Public authorities are thus subjected to the duty of taking all necessary measures to ensure that the data processed relating to organ transplants are kept

[1] In order to meet the quality and safety requirements laid down in the Directive discussed, the medical team is requested to obtain all necessary information from living donors, purpose in which the medical team is subjected to a specific duty to inform the potential donors, providing them with the needed information, as to understand the consequences and the risks of donation. In the case of deceased donation, as mentioned above, the medical team, where possible and appropriate, is requested to obtain such information from relatives of the deceased donor; in accordance to article 7 of the Directive, the medical team shall also endeavor to make all parties from whom information is requested aware of the importance of the swift transmission of that information.

[2] Such as Directive 95/46/EC and, in particular, article 8, paragraph (3), articles 16 and 17, as well as article 28, paragraph (2) thereof.

confidential and secure as provided by articles 16 and 17 of Directive 95/46/EC and that any unauthorized accessing of data or systems that makes identification of donor or recipients possible is penalized in accordance with article 23 of Directive 2010/45/EU. Thus any use of systems or data that makes the identification of donors or recipients possible oriented towards tracing donors or recipients, in cases other than those permitted by article 8, paragraph (2) and (3) of Directive 95/46/EC, research pursuing medical purposes included, are penalized in accordance with article 23 of Directive 2010/45/EU. Another important feature is that the processing of data concerning health is usually prohibited, a rule which has to be reshaped as to fit under the specific requests of the organs transplants procedure; article 8 of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data prohibits in principle the processing of data concerning health, while laying down limited exemptions. Directive 95/46/EC also requires the controller to implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access and against all other unlawful forms of processing. In the context of human organs transplantation, Member States are therefore called to ensure that strict confidentiality rules and security measures are in place for the protection of donors' and recipients' personal data, in accordance with Directive 95/46/EC[1].

7. Intricacies of the Traceability of Organs

As opposed to the actual state of progress, the traceability of organs transplant cases, at all stages of the chain, becomes vital under the terms of Directive 2010/45/EU, as to permit competent authorities to access relevant data on organ and donor characterization during a minimal period of 30 years since the human organs procurement through a valid donation[2]. Most importantly, Member States

[1] As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family, except in cases in which the national legislation in force, under specific conditions, might allow such information to be made available to donors or donors' families and organ recipients. It should be noted that the Romanian legislation in force does not establish particular cases of donors or donors' families and organ recipients' right to have access to personal data concerning health; however, this state of affairs is expected to change, at the moment of Directive 2010/45/EU transposition into national law. See, for further details (Simion, 2011, pp. 219-220).

[2] In accordance to article 10 of the mentioned European act, Member States have the duty to ensure that "all organs procured, allocated and transplanted on their territory can be traced from the donor to

have to make sure in the future, on one hand, that the competent authority or other bodies involved in the chain from donation to transplantation or disposal keep the data needed to ensure traceability at all stages of the chain, from donation to transplantation or disposal and the information on organ and donor characterization, as specified in the annex, in accordance with the framework for quality and safety set by the Directive discussed and, on the other hand, that data required for full traceability is kept for a minimum of 30 years after donation[1]. In our opinion, founding a traceability of organs system will represent one of the most difficult tasks for the Romanian Health Department, as at the moment there is no tradition of using electronic data bases for the registration of living donors, potential recipients or severe reactions associated to human organ transplants.

From the transport of human organs perspective, safety of transport is at the core of the medical procedure itself, as poor standards of transportation may irremediably endanger the quality of transported organs. Therefore, as requested by article 8 of Directive 2010/45/EU, Romanian authorities of resort are called to ensure that the organizations, bodies or companies involved in the transportation of organs have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time and that the labels of the shipping containers used for transporting organs contain information on the organ procurement organization and the establishment where the organ procurement took place, their addresses and telephone numbers included. Another set of data contained by the mentioned labels concern the identification of the transplantation centre of destination, its address and telephone number included. Finally, a statement that the package contains an human organ intended for transplantation, specifying the type of organ, accompanied by the expression "Handle with care" must be attached to the shipping containers used for transporting organs. Nevertheless, the containers will be accompanied by a list of recommended transport conditions and of instructions for keeping the container at an appropriate temperature and position. Also, in accordance to the new European standards, the organs transported have to be accompanied by a report on the organ and donor characterization, as underlined in the section above.

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the recipient", in order to ensure safety for the health of donors and recipients. Additionally, Member States are called to ensure the implementation of a donor and recipient identification system, able to identify every donation and the associated organs and recipients; to this respect, the Member States must ensure that confidentiality and data security measures comply with European Union's and national provisions, as referred to in article 16 of Directive 2010/45/EU.

[1] Such data may be stored in an electronic form, as permitted by article 10 of Directive 2010/45/EU.

It is interesting to observe that selection requirements for living organ donation include, in accordance with the new European standards, an assessment by qualified healthcare professionals regarding donor's health and medical history, as well as a psychological evaluation of the donor, if necessary. Directive's provisions also establish grounds for the exclusion of organ donation by living donors in hypotheses in which the organ donation may present serious health risks to potential recipients or to donors themselves particularly form the angle of transmitting diseases. Which is also worth noting is that no reference is made in the Directive text as to specific limits or exclusions of donors based on their spousal or genetic relationship to the potential organ recipient. Contemporary Romanian legislation makes no distinction on the mentioned criteria either; however, the future legal text transposing Directive 2010/45/EU into Romanian law may represent a good opportunity for the legislator to establish detailed rules concerning spousal or genetic relationship between the donor and the potential organ recipient

8. Concluding Remarks

The article focused on the technical and legislative difficulties brought on the Romanian Public healthcare system by the recent adoption on 7 July 2010, of Directive 2010/45/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation, which is expected to be transposed in the national law before 2013. As recorded by article 6 of the Directive, organ procurement is to be subjected to uniform rules, Member States being called to ensure that medical activities regarding organ procurement, such as donor selection and evaluation, respect the advice and the guidance of a doctor of medicine, also ensuring that design, construction and maintenance of the operating locations, in which the organ procurement takes place, are compelled to adequate standards of quality and safety. In addition, it becomes compulsory for the Member States to ensure that the relevant European Union's legislation, international and national legislation, standards and guidelines on the sterilization of medical devices are respected while performing activities related to organ procurement material and equipment. The exchange of organs between Member States establishments is an important way of increasing the number of organs available for the European patients and of ensuring a better match between donor and recipient, therefore improving the quality of the transplantation. This feature is particularly important for the optimum treatment of specific patients, such as

patients requiring urgent treatment, hypersensitive patients or pediatric patients, cases in which available organs should be able to cross borders without unnecessary problems and delays. However, in practice, transplantation is carried out by hospitals or professionals falling under different jurisdictions and there are significant differences in quality and safety requirements between Member States, an aspect that fully justifies the adoption of uniform safety standards.

Concerning the Administrative procedures to be changed, we attempted to underline the importance of creating a specialized Administrative body, uncharged with the accurate, rapid and verifiable reporting (to the European organisms inclusively) of serious adverse events and reactions related to human organs transplants, as well as that of creating national and local Administrative organs in charge of the management of serious adverse events and reactions in accordance with Directive 2010/45/EU provisions. As to the elaboration of new legislation on packaging and labeling of organs in accordance with the new European standards, the elaboration of legal rules and specific Administrative procedures for the authorization of transplantation centers or the establishment of conditions of procurement and systems of traceability of organs intended for transplantation into the human body, all these represent major themes for the Public Health Department in the next two years, since the recent experience of semi-failure in the field of healthcare reforms showed the lesson of the importance of details when public health is concerned.

9. References

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