Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation

[X1DIRECTIVE 2010/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 7 July 2010]

on standards of quality and safety of human organs intended for transplantation

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(4) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee(1),

After consulting the Committee of the Regions,

Having regard to the opinion of the European Data Protection Supervisor(2),

Acting in accordance with the ordinary legislative procedure(3),

Whereas:

(1) Over the past 50 years organ transplantation has become an established worldwide practice, bringing immense benefits to hundreds of thousands of patients. The use of human organs (hereinafter 'organs') for transplantation has steadily increased during the last two decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, while for end-stage failure of organs such as the liver, lung and heart it is the only available treatment.

(2) Risks are, however, associated with the use of organs in transplantation. The extensive therapeutic use of organs for transplantation demands that their quality and safety should be such as to minimise any risks associated with the transmission of diseases. Well organised national and international transplantation systems and use of the best available expertise, technology and innovative medical treatment can significantly reduce the associated risks of transplanted organs for recipients.

(3) In addition the availability of organs used for therapeutic purposes is dependent on citizens of the Union being prepared to donate them. In order to safeguard public health and to prevent the transmission of diseases by these organs, precautionary measures should be taken during their procurement, transport and use.

(4) Every year organs are exchanged between Member States. The exchange of organs is an important way of increasing the number of organs available and ensuring a better match between donor and recipient and therefore improving the quality of the transplantation. This is particularly important for the optimum treatment of specific patients such as patients requiring urgent treatment, hypersensitised patients or paediatric patients.

Available organs should be able to cross borders without unnecessary problems and delays.

(5) However, 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.

(6) There is therefore a need for common quality and safety standards for the procurement, transport and use of organs at Union level. Such standards would facilitate exchanges of organs to the benefit of thousands of European patients in need of this type of therapy each year. Union legislation should ensure that organs comply with recognised standards of quality and safety. Such standards would help to reassure the public that organs procured in another Member State carry the same basic quality and safety guarantees as those obtained in their own country.

(7) Unacceptable practices in organ donation and transplantation include trafficking in organs, sometimes linked to trafficking in persons for the purpose of the removal of organs, which constitutes a serious violation of fundamental rights and, in particular, of human dignity and physical integrity. This Directive, although having as its first objective the safety and quality of organs, contributes indirectly to combating organ trafficking through the establishment of competent authorities, the authorisation of transplantation centres, the establishment of conditions of procurement and systems of traceability.

(8) According to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the measures adopted pursuant to Article 168(4)(a) thereof shall not affect national provisions on the medical use of organs, nor therefore the surgical act of transplantation itself. However, in view of the objective of reducing the associated risks of the transplanted organs, it is necessary to include in the scope of this Directive certain provisions concerning transplantation and, in particular, provisions aimed at addressing those unintended and unexpected situations occurring during the transplantation that might affect the quality and safety of organs.

(9) In order to reduce the risks and maximise the benefits of transplantation, Member States need to operate an effective framework for quality and safety. That framework should be implemented and maintained throughout the entire chain from donation to transplantation or disposal, and should cover the healthcare personnel and organisation, premises, equipment, materials, documentation and record-keeping involved. The framework for quality and safety should include auditing where necessary. Member States should be able to delegate the performance of activities provided for under the framework for quality and safety to specific bodies deemed appropriate under national provisions, including European organ exchange organisations.

(10) Competent authorities should supervise compliance with the conditions of procurement through the authorisation of procurement organisations. Such organisations should have in place proper organisation, suitably qualified or trained and competent personnel and adequate facilities and material.

(11) The risk-benefit ratio is a fundamental aspect of organ transplantation. Owing to the shortage of organs and the inherent life-threatening nature of diseases leading to the need for organs for transplantation, the overall benefits of organ transplantation are high and more risks are accepted than with blood or most tissues and cell-based treatments. The clinician plays an important role in this context by deciding whether or not organs are suitable for transplantation. This Directive sets out the information required to make that assessment.

(12) Pre-transplant evaluation of potential donors is an essential part of organ transplantation. That evaluation has to provide enough information for the transplantation centre to undertake a proper risk-benefit analysis. It is necessary to identify and document the risks and characteristics of the organ in order to allow its allocation to a suitable recipient. Information from a potential donor's medical history, physical examination and complementary tests should be collected for the adequate characterisation of the organ and the donor. To obtain an accurate, reliable and objective history, the medical team should perform an interview with the living donor or, where necessary and appropriate, with the relatives of the deceased donor, during which the team should properly inform them about the potential risks and consequences of donation and transplantation. Such an interview is particularly important due to the time constraints in the process of deceased donation which reduce the ability to rule out potentially serious transmissible diseases.

(13) The shortage of organs available for transplantation and the time constraints in the process of organ donation and transplantation make it necessary to take into account those situations in which the transplantation team lacks some of the information required for organ and donor characterisation as set out in Part A of the Annex, which specifies a mandatory minimum data set. In those particular cases, the medical team should assess the particular risk posed to the potential recipient by the lack of information and by not proceeding with transplantation of the organ in question. Where a complete characterisation of an organ, according to Part A of the Annex, is not possible in time or due to particular circumstances, the organ may be considered for transplantation where non-transplantation might pose a greater risk to the potential recipient. Part B of the Annex, referring to a complementary data set, should allow a more detailed organ and donor characterisation to be made.

(14) Effective rules for the transportation of organs should be provided that optimise ischaemic times and reduce organ damage. While maintaining medical confidentiality, the organ container should be clearly labelled and accompanied by the necessary documentation.

(15) The transplantation system should ensure traceability of organs from donation to reception and should have the capacity to raise the alert if there is any unexpected complication. A system should therefore be put in place to detect and investigate serious adverse events and reactions for the protection of vital interest of the individuals concerned.

(16) An organ donor is also very often a tissue donor. Quality and safety requirements for organs should complement and be linked with the existing Union system for

tissues and cells laid down in Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[(4)]. This does not mean that systems for organs and for tissues and cells should necessarily be electronically linked. An unexpected adverse reaction in an organ donor or recipient should be traced by the competent authority and reported through the notification system for serious adverse events and reactions for tissues and cells as provided for in that Directive.

(17) Healthcare personnel directly involved in the donation, testing, characterisation, procurement, preservation, transport and transplantation of organs should be suitably qualified or trained and competent. The importance of donor coordinators, appointed at hospital level, has been acknowledged by the Council of Europe. The role of the donor coordinator or coordination team should be recognised as key to improving not only the effectiveness of the process of donation and transplantation, but also the quality and safety of the organs to be transplanted.

(18) As a general principle, organ exchange with third countries should be supervised by the competent authority. Organ exchange with third countries should be allowed only where standards equivalent to those provided for in this Directive are met. However, the important role played by existing European organ exchange organisations in the exchange of organs between the Member States and third countries participating in such organisations should be taken into account.

(19) Altruism is an important factor in organ donations. To ensure the quality and safety of organs, organ transplantation programmes should be founded on the principles of voluntary and unpaid donation. This is essential because the violation of these principles might be associated with unacceptable risks. Where donation is not voluntary and/or is undertaken with a view to financial gain, the quality of the process of donation could be jeopardised because improving the quality of life or saving the life of a person is not the main and/or the unique objective. Even if the process is developed in accordance with appropriate quality standards, a clinical history obtained from either a potential living donor or the relatives of a potential deceased donor who are seeking financial gain or are subjected to any kind of coercion might not be sufficiently accurate in terms of conditions and/or diseases potentially transmissible from donor to recipient. This could give rise to a safety problem for potential recipients since the medical team would have a limited capability for performing an appropriate risk assessment. The Charter of Fundamental Rights of the European Union should be recalled, notably the principle set out in Article 3(2)(c) thereof. That principle 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. 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.

(20) Other internationally recognised principles guiding practices in organ donation and transplantation include, inter alia, 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. They should be recalled and be taken into account in the context of the Commission's Action Plan on Organ Donation and Transplantation.

(21) Several models of consent to donation coexist in the Union, including opting-in systems in which consent to organ donation has to be explicitly obtained, and opting-out systems in which donation can take place unless there is evidence of any objection to donation. In order to enable individuals to express their wishes in this regard, some Member States have developed specific registries where citizens record them. This Directive is without prejudice to the broad diversity of the systems of consent already in place in the Member States. In addition, by means of its Action plan on Organ Donation and Transplantation the Commission aims to increase public awareness of organ donation and in particular to develop mechanisms to facilitate the identification of organ donors across Europe.

(22) 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[(5)] 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 organisational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access and against all other unlawful forms of processing. It should be ensured 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. Moreover, the competent authority may also consult the national data protection supervisory authority in relation to developing a framework for the transfer of data on organs to and from third countries. As a general principle, the identity of the recipient(s) should not be disclosed to the donor or the donor's family or vice versa, without prejudice to legislation in force in Member States which, under specific conditions, might allow such information to be made available to donors or donors' families and organ recipients.

(23) Living donation coexists with deceased donation in most Member States. Living donation has evolved over the years in such a way that good results can be obtained even where there is no genetic relationship between donor and recipient. Living donors should be adequately evaluated to determine their suitability for donation in order to minimise the risk of transmission of diseases to the recipients. 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. Complications may be medical, surgical, social, financial or psychological. The level of risk depends, in particular, on the type of organ to be donated. Therefore, living donations need to be performed in a manner that minimises the physical, psychological and social risk to the individual donor and the recipient and does not jeopardise the public's trust in the healthcare community. The potential living donor has to be able to take an independent decision on the basis of all the relevant information and should be informed in advance as to the purpose and nature of the donation, the consequences and risks. In this context, and to guarantee respect for the principles governing donation, the highest possible protection of living donors should be ensured. 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. Complete information, a proper evaluation and an adequate follow-up are internationally recognised measures aimed at protecting the living donors and also contribute to ensuring the quality and safety of organs.

(24) The competent authorities of the Member States should have a key role to play in ensuring the quality and safety of organs during the entire chain from donation to transplantation and in evaluating their quality and safety throughout patients' recovery and during the subsequent follow-up. For that purpose, besides the system for reporting serious adverse events and reactions, the collection of relevant post-transplantation data is needed for a more comprehensive evaluation of the quality and safety of organs intended for transplantation. Sharing such information between Member States would facilitate further improvement of donation and transplantation across the Union. As emphasised by the Recommendation Rec(2006)15 of the Committee of Ministers of the Council of Europe to Member States on the background, functions and responsibilities of a National Transplant Organisation (NTO), it is preferable to have a single non-profit making body which is officially recognised with overall responsibility for donation, allocation, traceability and accountability. However, depending especially on the division of competences within the Member States, a combination of local, regional, national and/or international bodies may work together to coordinate donation, allocation and/or transplantation, provided that the framework in place ensures accountability, cooperation and efficiency.

(25) Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that these penalties are implemented. Those penalties should be effective, proportionate and dissuasive.

(26) The Commission should be empowered to adopt delegated acts in accordance with Article 290 TFEU in order to adapt the Annex. The Commission should supplement or amend the minimum data set specified in Part A of the Annex only in exceptional situations where it is justified by a serious risk to human health, and supplement or amend the complementary data set specified in Part B of the Annex in order to adapt it to scientific progress and international work carried out in the field of quality and safety of organs intended for transplantation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level.

(27) The exchange of organs between Member States requires that uniform rules on the procedures for the transmission of information on organs and donor characterisation, as well as for ensuring the traceability of organs and for reporting serious adverse events and reactions, should be adopted by the Commission, in order to ensure the highest standards of quality and safety of the organs exchanged. According to Article 291 TFEU, rules and general principles concerning mechanisms for the control by Member States of the Commission's exercise of implementing powers are to be laid down in advance by a regulation adopted in accordance with the ordinary legislative procedure. Pending the adoption of that new regulation, Council Decision 1999/468/EC of 28 June

1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[(6)] continues to apply, with the exception of the regulatory procedure with scrutiny, which is not applicable.

(28) Since the objectives of this Directive, namely laying down quality and safety standards for organs intended for transplantation to the human body, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

Editorial Information

X1 Substituted by Corrigendum to Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (Official Journal of the European Union L 207 of 6 August 2010).

(**1**) OJ C 306, 16.12.2009, p. 64.

(**2**) OJ C 192, 15.8.2009, p. 6.

(**3**) Position of the European Parliament of 19 May 2010 (not yet published in the Official Journal) and decision of the Council of 29 June 2010.

(**4**) OJ L 102, 7.4.2004, p. 48.

(**5**) OJ L 281, 23.11.1995, p. 31.

(**6**) OJ L 184, 17.7.1999, p. 23.