

The EU Standards Directive on human organ transplantation: a Maltese Law evaluation

Kevin Aquilina

Abstract

This paper discusses European Union 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. At the outset, the organ transplantation directive is introduced in the light of Maltese Medical Law regulating organ donation and transplantation. Next, the European Union's legislative authority for adopting this Directive is set out. The salient innovative and pioneering features of the organ transplantation Directive are then briefly explained. As this Directive has to be transposed by Malta not later than 27 August 2012, the implications for transposition are considered so as to assist the Maltese authorities at identifying those measures which have to be addressed by them in the Directive's transposition and subsequent implementation. This is because transposition requires not only the adoption of the Directive's provisions into Maltese Law but also the taking of several other measures by the State of Malta and the competent authority to be designated for the implementation of the Directive at national level. The paper then considers certain unaddressed and unresolved matters in the Directive and concludes by making recommendations for adoption by the State of Malta in the transposition and implementation of the Directive on organ donation and transplantation stages into Maltese Law.

Keywords

Human organ donation and transplantation; human organ disposal; standards of quality and safety; procurement, transport and use of human organs; transposition of European Union Directive 2010/45/EU

Kevin Aquilina LL.D., PhD(Lond) (LSE)
Department of Media, Communications and Technology Law,
Faculty of Laws, University of Malta, Msida, Malta
Email: kevin.aquilina@um.edu.mt

Introduction

The European Parliament and Council of the European Union have, on 7 July 2010, adopted Directive 2010/45/EU on 'standards of quality and safety of human organs intended for transplantation.' This is the very first directive at E.U. level to deal with procurement, transport and use of human organs and is a welcome addition to E.U. Medical Law. It is therefore a pioneering directive in the field of organ donation and transplantation. Nevertheless, this is not the first E.U. directive to deal with donation of human body materials. Indeed, the E.U. has already in the past addressed this issue with regard to donation of blood, human tissue and human cells.¹ Such donations, in so far as Maltese Law is concerned, are regulated by the Human Blood and Transplants Act, 2006² which transposes relevant E.U. directives on human blood and transplants into Maltese Law with effect from 15 September 2006. On the other hand, the 2010 organ transplantation directive has to be transposed by Malta not later than 27 August 2012.

Moreover, Maltese Law does not contain provisions regulating in detail the medical law subject of organ transplantation except for a provision in the Criminal Code dealing with the prohibition of trafficking of persons for the purpose of organ removal, both in the case of adults and minors.³ This provision is of recent origin dating back to 2002.⁴ The Human Blood and Transplants Act, 2006 - notwithstanding the use of the term 'transplants' - does not regulate organ transplantation. There is thus a gap in Maltese Medical Law in so far as the subject-matter of Directive 2010/45/EU is concerned. This lacuna will, nonetheless, thanks to E.U. Medical Law, be filled up by 27 August 2012 unless Malta acts proactively before that date.

The legal basis for the adoption of the directive

Directive 2010/45/EU is made in conformity with the provisions of Article 168(4) of the Treaty on the Functioning of the European Union. This Article mandates in paragraph 1 that 'Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.' More specifically, paragraph 4(a) thereof empowers the European Parliament and the Council to adopt 'measures

setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures.’ Finally, paragraph 7 thereof provides that ‘Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.’

The salient provisions of Directive 2010/45/EU

The Directive’s subject-matter is to ‘ensure standards of quality and safety for human organs intended for transplantation to the human body’⁵ and applies to the ‘donation, testing, characterisation, procurement, preservation, transport and transplantation of organs.’⁶ Its main thrust is to establish a framework for quality and safety of human organs intended for transplantation which covers all the stages involved, that is, from donation to transplantation or disposal. The Directive regulates in great detail transplantation, i.e., the ‘process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient.’⁷ The Directive allows such a donation both from a living or a dead person and allows for the possibility of multiple donations to diverse recipients.

To achieve its scope, the Directive requires Member States to establish a framework for quality and safety for organ transplantation or disposal. Disposal is defined as ‘the final placement of an organ where it is not used for transplantation.’⁸ Such a framework provides for the adoption and implementation of operating procedures for, *inter alia*, donor identity verification. Operating procedures are the ‘written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome.’⁹ It further regulates procurement organisations, that is, 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, and is authorised to do so by the competent authority under the regulatory framework in the Member State concerned.’¹⁰ Only procurement organisations can take care of organ procurement. This serves to deter illegal trafficking of organs. Member States have to provide information to the Commission on the authorisation of procurement organisations.

An organ is defined by the Directive as a ‘differentiated part of the human body, formed by different tissues that maintain its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ 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 vascularisation.’¹¹ The definition thus comprises a human body organ and a

part thereof. Animal organs are therefore excluded. Although no example of such organs is provided in the Directive’s interpretation provision, the recitals do. For instance, the very first recital states that ‘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.’¹² Furthermore, organs have to be distinguished from human tissue and blood which, although such body materials can still be donated, do not fall within the purview of the definition of a human organ.

The Directive mandates that organ procurement is performed in strict compliance with the advice and the guidance of a medical doctor, that procurement is performed in operating theatres ‘designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.’¹³ Procured material and equipment have to comply with ‘relevant Union, international and national standards and guidelines on the sterilisation of medical devices.’¹⁴

Organ and donor characterisation are distinguished in the Directive. They relate to the collection of the relevant information on the characteristics of the organ or donor needed to respectively evaluate its suitability or his/her suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation. All procured organs and donors need to be characterised before transplantation. An Annex to the Directive sets out the minimum and complementary data which have to be compiled for the purposes of the Directive. Nonetheless, in certain life threatening emergencies, the required data might not be available; in which case if, from a risk-benefit analysis, it transpires that the expected benefits of the transplantation outweigh the risks posed by the missing information, then the Directive allows the organ transplantation to be effected. It remains the duty of the medical team to ‘obtain all necessary information from living donors’ and such donors are to provide the medical team with the information such team need to understand the consequences of donation.¹⁵ Similar information has to be obtained by the medical team from relatives of the deceased donors or from other persons. The Directive is, nevertheless, silent as to what powers the medical team ought to have to obtain such information. Furthermore, the characterisation has to be performed ‘by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.’¹⁶ It is up to Member States to regulate these matters. Even healthcare professionals have to be suitably qualified or trained and competent to perform the duties set out in the Directive.

The Directive regulates in quite some detail the actual transport of organs and transplantation centres, that is, ‘a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the competent authority under the regulatory framework in the Member State concerned.’¹⁷ The duties of transplantation centres are also set out in the Directive. Traceability, that is, ‘the ability to locate and identify the organ

at each stage in the chain from donation to transplantation or disposal¹⁸ requires that Member States have in place a donor and recipient identification system.

Another required system is the reporting system intended to investigate, register and transmit relevant and necessary information concerning serious adverse events or reactions observed during or after transplantation. Reporting is a characteristic feature of the Directive and Member States are obliged to report to the European Commission before 27 August 2013 and every three years thereafter and the Commission, in turn, has to report, in turn, to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions on the Directive's implementation.¹⁹

The Directive sets out the principles governing organ donation. Donation has to be voluntary and unpaid though living donors can receive compensation limitedly to 'making good the expenses and loss of income related to the donation.'²⁰ It is up to Member States to define the allowable conditions for the granting of compensation, 'while avoiding there being any financial incentives or benefit for a potential donor.'²¹ Advertising organ availability is prohibited. Organ procurement has to be 'carried out on a non-profit basis.'²² Organs can only be procured subject to relevant consent in terms of national law.

The Directive requires Member States to retain a register or record of living donors that is to comply with data protection legislation. It also requires Member States to designate one or more competent authorities to carry out the tasks assigned to it by the Directive and sets out their respective duties, including keeping records and drawing up reports concerning procurement organisations and transplantation centres. Competent authorities are to 'exchange information on the experience acquired with regard to the implementation of this Directive.'²³ The Directive also contemplates organ exchange with third countries and European organ exchange organisations, that is, 'a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its members are Member States.'²⁴

The Directive's transposition implications for Malta

European Union Law requires Malta to transpose the Directive, that is, to give effect to the substance of the directive into Maltese Law. Transposition provides a bigger challenge than simply adopting the Directive's provisions into Maltese law as there are certain policy decisions which Malta still has to take. Malta will have to decide whether to adopt an opt-in or an opt-out model of consent to donation, that is, '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.'²⁵

The competent authority will have to be designated²⁶ though its powers can be delegated to another body deemed suitable under national law.²⁷ Should this be the case, Maltese Law will have to define the criteria to achieve such suitability. The competent authority has to establish criteria for the

recognition of procurement organisations²⁸ and the designation of transplantation centres.²⁹ The competent authority will have to draw up operating procedures under various provisions of the Directive³⁰ and may also enter in organ exchange agreements with its counterparts in third countries³¹ and with European organ exchange organisations.³² The competent authority has to 'issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain.'³³ Moreover, information has also to be compiled and certain information has to be submitted to the Commission on various aspects of the Directive's implementation.³⁴ Member States have to retain a register or record of living donors whilst respecting personal data³⁵ and have to establish penalties for infringement of national law transposing the Directive and making ancillary provisions thereto.³⁶

Relevant information for donor characterisation and organ characterisation has to be established³⁷ as well as national rules on donor's or donor's family's consent, authorisation or absence of any objection have to be adopted.³⁸ National law has to provide rules on consent, authorisation or absence of any objection.³⁹ Moreover, Member States are to define the conditions under which, exceptionally, donors may receive compensation.⁴⁰ Living donors and relatives of deceased donors are to be requested to provide the medical team with the necessary information. The term 'medical team' should also be defined.⁴¹ Member States have to qualify the necessary measures they will take to ensure the protection of living donors.⁴²

Member States have to regulate operating theatres in terms of design, construction, maintenance and operation in accordance with adequate standards and best medical practices.⁴³ Even laboratory personnel have to be suitably qualified or trained and competent personnel and adequate facilities and equipment certified.⁴⁴ Healthcare personnel are to be suitably qualified or trained and competent to perform their duties.⁴⁵

Unaddressed and unsolved matters in the Directive

Certain aspects concerning organ transplantation have not been addressed in the Directive, nor for that matter are regulated by Maltese Law. Take the cases of xenotransplantation, that is, inter-species organ transplantation, and the definition of death which are both permeated with profound ethical considerations. The Directive specifically addresses 'human organs.' Hence xenotransplantation is not regulated by this Directive: it does not allow the transplantation of animal organs in humans and vice-versa. Nor is such practice however outlawed.⁴⁶ Malta does not yet have a policy on this matter. As to the definition of death, a key medical concept in the realm of organ transplantation, this remains undefined in the Directive even if there is a fleeting reference thereto in Recital 20 which leaves it up to national law to define. The same applies in Malta. Brain stem death is not referred to in any provision of the Directive or in Maltese Law. Furthermore, bio-tourism remains unregulated by the Directive as there are no rules contained therein regulating the situation of patients who have to travel abroad in order to undergo treatment

unavailable or not legally permitted in their own country. Even in Maltese Law there is no such prohibition of bio-tourism. In this context one asks why has not the opportunity been taken to harmonise at EU level private international law rules regulating bio-tourism? Finally, no method of consent to donation is adopted: the Directive does not take a stand in favour of an opt-in or an opt-out method of consent leaving the matter to be regulated by national law. As Recital 21 puts it: 'This Directive is without prejudice to the broad diversity of the systems of consent already in place in the Member States.' The Bioethics Consultative Committee refers to the Transplant Support Group (Malta) who favour an opt-out system 'principally because of their strong belief that a donation should be altruistic without any pressure and after having reached a conscious decision following adequate information.'⁴⁷

Conclusion

Notwithstanding the very hard work done by the national Bioethics Consultative Committee in the field of organ donation and transplantation over the past years,⁴⁸ Maltese Law is totally lacking in so far as the regulation of standards of quality and safety of human organs intended for transplantation are concerned. This Directive - when transposed into national law - will start to regulate a branch of Maltese Medical Law which has so far not attracted the attention of the Maltese legislature notwithstanding the fact that organ donation and transplantation has been carried out in Malta for several years. Hence the matter needs to be legislatively addressed. A specific select committee which might be appointed by the House of Representatives for the purpose should be tasked to discuss medico-legal issues in their wider perspective. In this way, amongst other medical law matters, Directive 2010/45/EU and its transposition into Maltese Law should be studied in greater depth within this Select Committee. The Committee could thus well address the matters referred to above under the headings 'The Directive's transposition implications for Malta' and 'Unaddressed and unsolved matters in the Directive'. In addition, the Human Tissue and Blood Act should be amended by the addition of another part therein transposing the Directive under examination in this paper and the title of the Act should be changed to 'Human Organs, Tissue and Blood Act.' Moreover, xenotransplantation should be prohibited; death should be defined as brain stem death and bio-tourism should be regulated. A decision has to be arrived at as to an opt-in or opt-out regime. Malta should also adhere to the convention and protocol referred to in the recitals of the Directive namely 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; it should also adopt the World Health Organisation's Guiding Principles on Human Cell, Tissue and Organ Transplantation; take on board 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; and,

finally, reference should be made to the Commission's Action Plan on Organ Donation and Transplantation. This Select Committee with its extended terms of reference should be tasked with the specific duty of studying all these documents with a view to adoption, with or without reservations.

References

1. For the text of applicable E.U. legislation on blood, tissues and cells see http://ec.europa.eu/health/blood_tissues_organ/key_documents/index_en.htm.
2. Chapter 483 of the Laws of Malta.
3. Article 248C of the Criminal Code.
4. It was introduced in the Criminal Code by Act No. III of 2002.
5. Article 1.
6. Article 2.
7. Article 3(q).
8. Article 3(c).
9. Article 3(p).
10. Article 3(k).
11. Article 3(h).
12. Recital (1).
13. Article 6(2).
14. These include Directive 93/42/EEC of 14 June 1993 concerning medical devices (see http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm).
15. Article 7(3).
16. Article 7(4).
17. Article 3(r).
18. Article 3(s).
19. Article 22.
20. Article 13.
21. *Ibid.*
22. *Ibid.*
23. Article 19(1).
24. Article 3(g).
25. Recital 21.
26. Articles 3(b) and 17.
27. Article 17.
28. Article 3(k). Article 5(2) further provides that national requirements for the authorisation of procurement organisations have to be drawn up by Member States.
29. Article 3(r).
30. See Article 3(p), 4(2), 7(5), 8(1)(a), 11(2), 11(3)
31. Article 20.
32. Article 21.
33. Article 17(2)(e).
34. Article 9(4), 10(2), 10(4), 11(1), 11(4), 15(4), 17(2)(d), 18, 19, 22, 23, 29 and 31.
35. Article 15(3).
36. Article 23.
37. Article 3(f) and (i).
38. Article 4(2).
39. Articles 3(a) and 14.
40. Article 13(2).
41. Article 7(3).
42. Article 15(1).
43. Article 6(2).
44. Article 7(4).
45. Article 12.
46. In fact certain states allow it. See the Committee of Ministers of the Council of Europe Recommendation REC(2003) on xenotransplantation adopted on 19 June 2003 available at <https://wcd.coe.int/wcd/ViewDoc.jsp?id=45827&Site=COE&BackColorInternet=DBDCF2&BackColorIntranet=FDC864&BackColorLogged=FDC864>.
47. See Bioethics Consultative Committee, *Organ Donation*, available at https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/bioethics_committee/current_work.aspx.
48. The terms of reference of the Bioethics Consultative Committee are available at https://ehealth.gov.mt/HealthPortal/others/regulatory_councils/bioethics_committee/bioethics_committee_terms.aspx.