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On 21 January 2009, the Council decided to consult the European Economic and Social Committee, under Article 242 of the Treaty establishing the European Community, on the


The Section for Employment, Social Affairs and Education, which was responsible for preparing the Committee’s work on the subject, adopted its opinion on 26 May 2009. The rapporteur was Mr RODRÍGUEZ GARCÍA-CARO.

At its 454th plenary session, held on 10 and 11 June 2009 (meeting of 10 June 2009), the European Economic and Social Committee adopted the following opinion by 114 votes, with one abstention.

1. Conclusions

1.1 The European Economic and Social Committee welcomes the proposal for a directive and wishes to express its satisfaction at the fact that at the instrument’s main aim is to extend the protection of EU citizens’ health, by combining safety with measures intended to improve the quality and accessibility of treatment based on organ transplantation.

1.2 The Committee firmly believes that an adequate donor recruitment policy entails the following elements: raising public awareness, creating a collective conscience, ensuring the active and disinterested involvement of the media and motivating and involving health professionals. The EESC is convinced that these elements could result in similar levels of donation in all Member States and it is on these aspects that the work of the Commission and the Member States should focus.

1.3 Organ donation in the European Union should be based on the principles of voluntary and altruistic donation, solidarity and being unpaid. Member State legislation should prevent any attempt to sell organs and must severely punish illegal trafficking in organs for the purpose of transplantation. Through joint action and coordination, the EU Member States could achieve high levels of donation, and also block attempts by organised crime to break into the field of organ transplantation.

1.4 The European Economic and Social Committee considers that a strong and organised public health authority is the best guarantee of monitoring the implementation of quality and safety standards in the field of organ transplantation. It therefore takes the view that the directive should clearly specify the need for Member States to lay down periodic inspection and monitoring measures to ensure that organ procurement and transplant centres comply with these standards.

1.5 The European Economic and Social Committee has confidence in the work of the competent national authorities referred to in the proposal for a directive. The Committee considers that a strong and organised public health authority is the best guarantee of monitoring the implementation of quality and safety standards in the field of organ transplantation. It therefore takes the view that the directive should clearly specify the need for Member States to lay down periodic inspection and monitoring measures to ensure that organ procurement and transplant centres comply with these standards.

1.6 At the same time as publishing this proposal for a directive, the Commission has presented a Communication on the Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (1). Despite not having been asked to draw up an opinion on the matter, the European Economic and Social Committee considers that, because of the issue's importance to all EU citizens, it should state its position on this action plan and will thus draw up an own-initiative opinion on the matter.

1.7 The European Economic and Social Committee considers that the specific comments made on the proposal for a directive in point 4 of this opinion will make the entire text easier to understand and more coherent, and could improve the final wording of this Community instrument. This applies in particular to the comments highlighting possible inconsistencies between articles.

1.8 Amongst the specific comments, the Committee wishes to highlight two fundamental aspects that represent a clear retrograde step in relation to Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (2). In this regard, the rapporteur wishes to point out the lack of any article similar to Article 7 on inspections and control measures and to Article 10 on registers of tissue establishments. In the Committee’s view, both articles should be reflected equally in the proposal for a directive, because they will improve its wording.

2. Introduction to the proposal for a directive

2.1 Article 152(4a) of the Treaty establishing the European Community lays down that the Council, acting in accordance with the procedure referred to in Article 251 and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this article through adopting measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives.


2.3 In May 2007, the Commission adopted a communication on the donation and transplant of organs, focusing on subsequent measures to be discussed in the framework of quality and safety in the donation and transplant of organs and the promotion of cooperation between Member States. The European Economic and Social Committee did not produce an opinion on this communication.

2.4 The Council conclusions of 6 December 2007 recognised the importance of having stringent safety and quality standards for organs to ensure a high level of patient protection.

2.5 The Commission has presented, at the same time, both this proposal for a directive and the communication entitled Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States, on which the EESC has not been asked to draw up an opinion.

2.6 Lastly, the rapporteur also wishes to highlight the European Parliament resolution of 23 April 2008, on ‘Organ donation and transplantation: policy actions at EU level’ (5). The European Economic and Social Committee wishes to state its clear support for this resolution.

2.7 The aim of the proposal for a directive is to set standards that will help ensure the quality and safety of organs of human origin intended for transplantation to the human body, applicable to the process of donation, procurement, testing, characterisation, preservation, transport and transplantation of organs of human origin.

3. General comments

3.1 The Committee welcomes the proposal for a directive on standards of quality and safety of human organs intended for transplantation, notwithstanding the general and specific comments made in this document. The rapporteur fully agrees with the Council and the European Parliament in that the ultimate aim of the directive should be to ensure the protection of human health. It is therefore crucial to attain the highest levels of quality and safety throughout the process leading to an organ transplant.

3.2 An organ cannot be transplanted without a living or deceased donor from whom the organ can be removed. The European Economic and Social Committee therefore considers that the most important aspect of the entire process is to ensure the existence of donors. This is the main aspect on which the EU’s efforts should focus. Raising awareness, creating a collective conscience, ensuring the active and disinterested involvement of the media and motivating and involving healthcare professionals are key factors in achieving high levels of donation.

3.3 The Committee therefore fully supports the European Parliament in its initiative to establish an international donor day. The Commission and the Member States should establish that day as a means of promoting donation amongst Europeans and should thus be given the support and experience of civil society, through the different associations and organisations representing transplant patients.

3.4 The EESC wishes to state its agreement with the principle that donations should be voluntary, altruistic and unpaid, as set out in the proposal for a directive. All Member States should ensure that their legislation contains no legal loopholes allowing organs to be sold or allocated to patients on the basis of less than scientific criteria.

3.5 Donation is the basic and crucial starting point of the process, which ends with an organ being implanted in a patient. Raising awareness and understanding are cornerstones of the transplant process. Consent for the removal of organs from individuals who have died should thus be respected in legal terms but simplified at the operational level, to ensure that as many donations as possible are made. The existence of legal, cultural, ethical, religious, historical, social and other factors should not be used as grounds for opposing donation, as these could result in an undesired shortage of organs. The potential shortage of organs for reasons that are not strictly scientific or related to demographics should not be counter-balanced by importing organs from other States where people are more aware of organ transplantation and demonstrate greater solidarity towards this process.

3.6 The European Economic and Social Committee considers that raising awareness about organ donation and motivating health professionals in this field is equally important. Health professionals’ scientific and technical knowledge is not only important to promoting the process of donation and transplantation; it is also crucial to encouraging health professionals to act as intermediaries in the task of procuring organs, improving their communication skills which will enable them to facilitate the donation process.
3.7 In this regard, a sufficiently qualified and experienced figure in this field in certain Member States – Spain in particular – is the intra-hospital transplant coordinator, whose purpose is to secure as many organs for transplant as possible by monitoring potential donors and raising the awareness of the health professionals in those hospital units that are most likely to receive these potential donors. The Intra-hospital transplant coordinator supervises, promotes and coordinates the donation, removal, transport and availability of organs for transplant. The European Economic and Social Committee considers that hospitals in the EU must have health professionals carrying out this role and thus calls on the Commission and the Member States to promote the appointment of these coordinators in European hospitals, as efficiently as possible.

3.8 The Committee supports the creation of national quality programmes in all Member States as a means of ensuring compliance with the quality and safety standards set out in the directive. The EESC is also of the view that appointing national authorities to implement the requirements set by the directive is also crucial. Laying the foundations for a strong national organisation inevitably requires implementing national quality programmes, appointing national authorities that carry out their tasks effectively and lastly the close involvement of the public in an aspect of individual and collective health that is constantly increasing in scale and having an ever-greater effect on society.

3.9 It is the Member State health authorities that are primarily responsible for ensuring quality and safety in the transplant process. Adopting quality and safety standards in the donation and transplant process and common standards for the structural, material and personal requirements that organ procurement and transplant centres should have is a clear priority for ensuring a high degree of efficiency and safety in this type of surgical procedure. The competent Member State authorities should, therefore, establish detailed periodic inspection and monitoring programmes for these centres, to ensure that they comply fully with the quality and safety standards for human organs intended for transplant.

4. Specific comments

4.1 With regard to article 1:

The proposal for a directive states that its aim is to guarantee ‘high’ levels of quality and safety for organs and ‘high’ levels of health protection. The European Economic and Social Committee considers that merely seeking to ensure a ‘high level’ is not adequate, because in practical terms, this is too vague. In the field of transplants the aim must be excellence; a level at which errors have no place. The rapporteur therefore proposes that the word ‘high’ be removed from the article’s wording and that the paragraph be reworded as follows: ‘to ensure the necessary standards of quality and safety for organs of human origin intended for transplantation to the human body, in order to ensure the highest level of human health protection.’

4.2 With regard to Article 3(j):

This article’s definition of ‘procurement organisation’ covers centres, units, teams and bodies. The Committee considers that the definition is vague and the term used does not tally with the definition provided in point (q) of the same article. Whilst the latter point refers to ‘transplantation centres’, it would more consistent to use the term ‘procurement centre’ and not ‘procurement organisation’. Similarly, the word ‘body’, which features in both points, should be deleted, as both organ removal and implantation are carried out by professionals forming part of teams or units working in health centres belonging to public or private bodies. It is these centres, units and teams that receive authorisation from the competent authority to carry out these activities. Therefore, and in line with this comment, Article 5, which covers procurement centres, should be amended to reflect this.

4.3 With regard to Article 3(r):

With regard to this point, which is concerned with the definition of traceability, it is proposed that the term ‘procurement organisation’ be replaced by ‘procurement centre’, in line with the previous comment.

4.4 With regard to definitions not included in Article 3:

Article 2 of the proposal states that the directive applies to the different stages of the organ transplant process; All of the stages listed are set out in Article 3, except for testing and transport. The Committee considers that the stages described in the article should be clearly defined, particularly given that Article 8 of the directive is dedicated to organ transport.

4.5 With regard to article 6:

This article, which deals with organ procurement, makes a very brief reference to requirements for the operating theatres in which organs are procured. The requirements set out in paragraphs a) and b) are so self-evident and minor that the EESC recommends deleting them and including a reference to an appendix or subsequent document that provides an exhaustive list of the minimum structural, equipment and staffing requirements for operating theatres in which organ removals take place, from both living and deceased donors.

4.6 The Committee also wishes to express its surprise at the lack of an article on inspection and monitoring measures similar to the measure set out in Article 7 of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. Article 18 of the proposal for a directive makes a brief reference to the competent authorities of the Member States ensuring that procurement organisations and transplantations centres are controlled and audited. In the EESC’s view, the proposal should include a new article along the lines of the article referred to above.
4.7 With regard to Article 7 of the proposal:

4.7.1 The first sub-paragraph states that the tests required for organ characterisation shall be carried out by a qualified laboratory. The Committee wishes to point out that the word 'qualified' does not appear in the definitions provided in Article 3. In the EESC's view, the laboratory should be authorised, accredited or hold a licence to carry out activities of this nature, in line with the definition contained in Article 3(a), as referred to above. In any event, it might also be worth defining at the European Union level the conditions under which laboratories are qualified to characterise a donor, an organ or a recipient.

4.7.2 Sub-paragraph 2 of the same article confuses the matter even further, because in addition to qualified laboratories, it includes organisations and bodies in the process of characterising organs and donors. In the rapporteur's mother-tongue [Spanish], it makes sense that there should be qualified laboratories but the proposal's reference to including bodies and organisations on an equal footing with laboratories is hard to fathom. The EESC reiterates that the text must be consistent in order to prevent confusion.

4.8 With regard to article 9:

4.8.1 The words 'accreditation', 'designation', 'authorisation' and 'licence' should be deleted from sub-paragraph 2, because they are covered by the definition of authorisation set out in Article 3(a). It is also the Committee's view that when referring to a 'transplant centre', the authorisation should specify the type of transplant that the centre is authorised to carry out. This specific reference would be more discriminating than the word 'activities' used in the text.

4.8.2 Sub-paragraph 3(b) includes a word that is not defined in Article 3 or included in the scope of Article 2. This is the word 'storage'. The EESC considers that unless there is good reason for the contrary, this is a mistake, because the word used in the proposal's scope and definitions is 'preservation'. We urge that the text be corrected to reflect this.

4.8.3 Lastly, the Committee believes it to be important that national requirements for the authorisation of transplant centres are available on request by any State but considers that it would be more flexible and efficient for this information to be available without first having to submit a request. The Commission could hold this information, provided by the different competent authorities and make this available to any other competent Member State authority.

4.9 With regard to article 11:

With regard to the adverse reactions likely to apply to one or more stages of the donation and transplant process and as stated in comment 4.4, the EESC considers that the text includes a stage that does not feature in the directive's scope – testing – and omits two stages that are described and which could have adverse effects – characterisation and preservation. In the Committee's view, the text should be corrected to reflect this.

4.10 With regard to article 15:

As regards the protection of living donors, the article sets out Member States' obligations to ensure that these individuals are fully aware of all the circumstances surrounding their disinterested action and the steps to be taken to protect their health. For the sake of consistency with the article's heading, the Committee proposes deleting part of the last line of the second sub-paragraph, which refers to third persons, leaving it as follows: 'may provide for the exclusion of persons whose donation could present a serious risk to themselves'.

4.11 With regard to Article 19(2):

This sub-paragraph grants the Commission and the Member States access to the registers of organ procurement and transplant centres in other Member States that request them. The European Economic and Social Committee considers this article to be a retrograde step in relation to the wording of Article 10 of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. In the Committee's view, the wording of the directive referred to above should be used in this matter, especially as regards setting up national public national registers of procurement and transplant centres and as regards establishing an EU-level network encompassing all national registers.

Brussels, 10 June 2009.

The President
of the European Economic and Social Committee
Mario SEPI