

## **Some selected comments<sup>1</sup> on the draft working papers**

**A. on a quality and safety legal framework on donation, procurement, testing, transport, preservation, transplantation and characterisation of human organs**

**B. on an action plan on organ donation and transplantation (2009-2015)**

on behalf of

- the secretariat of COMECE – Commission of the Bishops’ Conferences of the European Community
- the Brussels office of the Protestant Church in Germany (EKD)
- the “Kommissariat der Deutschen Bischöfe”, Catholic Bureau in Berlin

2 June 2008

---

<sup>1</sup> We should like to underline that these are comments on some of the issues raised in the Commission draft working documents and that we may wish to add further comments in the future.

## **Preliminary comments:**

1. The need for more organs in order to help suffering patients to receive life-saving organ transplantation is evident and adequate measures to address it meet our strong support. We share the view of the European Commission that increasing public awareness regarding the severe organ shortage in Europe is likely to be one of the most effective mechanisms to remedy that situation. In this respect it is worth noting that the Churches with their wide “constituencies” in all EU countries have been addressing this issue and have been accompanying people in the process of their decision to become organ donors; there have already been numerous actions on the part of the Churches in many EU member states.
2. While finding an answer to the severe organ shortage in Europe is extremely important, we should like to underline that the free choice to donate or not to donate an organ needs to be respected and protected as well. Both decisions can be ethically responsible. No one is obliged to donate his or her organs or shall be pressured or feel compelled to do so.
3. Organ donation is a gift based on solidarity and love. Donated organs may not be treated as a commodity of the Common Market, and this should be clarified by avoiding any language from the commercial sector. Example: On page 2 of the draft working document regarding the action plan (second paragraph), one should therefore speak of “rising need” (instead of rising “demand”). A wording like “import/export” concerning organs (point 2.2 of the draft working paper on a legal framework) should be avoided (rather e.g. “cross-border exchange”).
4. The principle of non-commercialisation of the human body and its parts is explicitly stated in Art.3 §2 of the EU Charter on Fundamental Rights. The Commission Communication should incorporate this principle in relation to organ trafficking as well as to the donation of one’s own organs.
5. When it comes to living donors particular safeguards need to be put in place. Living donors are in a vulnerable position being in danger of exploitation. Emotional pressure or financial incentives may unduly influence potential living donors. Therefore donations from living donors should not be encouraged and only be possible for the benefit of close relatives. This would take into account the special emotional suffering in cases of dire need of a loved one.
6. The application of the expanded donor criteria in order to increase the number of donated organs has the potential of creating new ethical problems in the field of organ distribution.
7. There is a link between organ shortage and organ trafficking. In order to fight against organ trafficking in the poorer parts of the world, a long-term strategy should be adopted so as to abolish the social inequalities lying at the root of such practices. In order to combat the practice of organ selling for money (especially in countries of the developing world), mechanisms of traceability should be put in place in order to avoid that these organs enter the European Union.

**A. Some concrete proposals on the Draft Working Paper on a quality and safety legal framework on donation, procurement, testing, transport, preservation, transplantation and characterisation of human organs**

(The proposed amendments are printed in bold and italics, proposals for deletions are indicated by barring the relevant words; explanations are given in italics only.)

- **1.3:** There are risks however associated with the use of organs in transplantation such as the transmission of diseases and it is therefore *indispensable* ~~beneficial~~ to have a safety and quality system in place to avoid potential risks and trace recipients if necessary

- **1.24:** As a matter of principle *and in order to ensure the principle of non-commercialisation of the human body*, organ transplantation programmes *have to* ~~should~~ be founded on the philosophy of voluntary and unpaid donation, altruism of the donor and solidarity between donor and recipient while ensuring anonymity of the deceased donor and the recipient(s). *The donation of an organ is a gift from one human being to another; therefore the organ must not be treated as a mere commodity of the Common Market.*

*Organ donation is a gift based on solidarity and love, it cannot be compared to and even less be treated as a mere commodity of the Common market. The principle of non-commercialisation of the human body, enshrined in Article 3 (2) of the Charter on Fundamental Rights, does apply. This is particularly crucial to protect living donors.*

- **1.26 b [NEW]:** *This framework acknowledges the vulnerable position of living donors resulting from the extreme emotional situation they find themselves confronted with and the danger of psychological pressure or financial incentives aimed at persuading him or her to become a living donor. The living donor, therefore, needs special protection.*

~~- 1.27: In order to expand the donor pool it is important to explore the increase in donations from living donors.~~ *Living donors of organs will face risks associated both with testing to ascertain their suitability as a donor and the procedure to obtain the organ. Complications may include medical, surgical, social, financial or psychological problems. This risk very much depends on the type of organ to be donated. It has to be recognized that living donations needs to be performed in a manner that minimizes the physical, psychological and social risk to the individual donor and does not jeopardize the public trust on the healthcare community. The donation decision should be performed in an environment that enables the potential living donor to decide in an autonomous manner.*

*The promotion of living donations is not envisaged in the legislative framework of the European Commission. The main focus of the Commission's efforts should be on tapping the full potential of organ donations from deceased donors. The Commission should avoid creating situations or incentives for the misuse of the emotionally unstable or financially vulnerable position of potential living donors.*

- **1.28:** The clinical use of organs of human origin for transplantation is constrained by limited availability. Therefore it *is necessary* ~~would be desirable~~ that the criteria for allocating these organs are defined in a transparent *and non-discriminatory* manner, on the basis of an objective evaluation ~~based on medical need and other factors~~.

*Either the framework does not say anything on the allocation system and leaves this entirely up to the Member States, or it insists that the system must be non-discriminatory.*

**- 2.1 GENERAL PROVISIONS**

Rationale of the chapter of general provisions

This chapter establishes the objective and the scope of the quality and safety framework *based on Article 152 (4) and (5) EC Treaty*. The objective based on Article 152 of the Treaty is to ensure high quality and safety standards for human organs and a high level of protection of human health. The

scope should cover the whole process from donation to transplantation, respecting at the same time the responsibility of Member States for the organisation and delivery of health services and medical care.

*It is important to distinguish clearly between quality and safety requirements which should be dealt with in the legislative measure, and other EC-activities related to the goals of Article 152 EC-Treaty.*

### **2.1.1 Objective**

This EU quality and safety framework lays down standards of quality and safety for human organs intended for transplantation. (footnote: "A recital clarifying that quality and safety standards shall take fully into account the context of shortage of organs should be included. ***This recital should clarify that in the case of doubt, quality and safety are prevailing.***")

### **2.1.4. Implementation**

This EU quality and safety framework should not prevent a Member State from maintaining or introducing ***higher and*** more stringent protective measures that comply with the provisions of the Treaty.

## **2.3: DONOR PROTECTION**

Rationale for the chapter of donor protection

This chapter tries to address a number of complex and sensitive issues as far as is permitted by the legal basis of Article 152, which is limited to quality and safety.

Donation ~~should~~ ***has to*** be voluntary and altruistic with legal and ethical contexts clearly defined, ***not only*** ~~both~~ for ethical and public health reasons, ***but also for legal reasons.***

Data from donors and recipients ***have to*** ~~should~~ be protected, ***at the same time ensuring*** ~~provided that~~ traceability is ~~ensured~~. Anonymity should ***be*** aimed at; ***exceptions may be granted*** ~~except~~ in the case of a living donor with a close relationship to the recipient.

Organ retrieval is only allowed if ***valid*** ~~some form of~~ consent according ***to the specific and varying national requirements*** is available. This is also reflected in international guidelines; according to the additional protocol to the Convention of Biomedicine of the Council of Europe concerning Transplantation of Organs and Tissues of Human Origin. Member States should ensure that there is a legal basis for ensuring valid consent or objection to organ donation.

The protection of the living donor is specifically addressed in this chapter.

### **2.3.1.: Principles governing organ donation**

0. ***Organ donation out of financial motivation is unethical. It degrades the gift of an organ to a mere commodity and constitutes a violation of human dignity. It would also be in conflict with article 3 § 2 of the EU Charter of Fundamental Rights which stipulates "the prohibition on making the human body and its parts as such a source of financial gain". Therefore, Member States have to*** ~~should~~ ensure, ***that organs are donated only in a*** voluntary and unpaid ~~donations of human organs-manner.~~

1. Member States should take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human organs comply with guidelines or legislative provisions laid down by the Member States. ***In order to ensure the principle of non-commercialisation,*** ~~Such~~ guidelines or legislative provisions should include ~~appropriate restrictions or prohibitions~~ on advertising the need for, or availability of, human organs with a view to offering or seeking financial gain or comparable advantage.

**1.b(NEW): Member States need to ensure that organ donation is made altruistically and voluntarily, without any payment; compensation for the organ donation may only cover expenses such as reasonable travelling expenses, loss of earning and childminding costs occurred, thereby excluding any financial incentives for a potential donor.**

*Any practice of advertising the need for human organs with a view to offering or seeking financial gain or comparable advantage would be in breach of Art.3 §2 of the EU Charter on Fundamental Rights. It would also facilitate channels of organ trafficking. Therefore there may be no payment for organ donation.*

#### **1.3.4. Protection of the living donors**

**0. [NEW:] In contrast to deceased donors, living donors are in a much more vulnerable position being in danger of exploitation. Emotional pressure or financial incentives may unduly influence living donors in their decision to donate. Therefore donations of living donors should not be encouraged. In any case they shall be restricted to narrowly defined cases of donations among close relatives.**

1. The living donor should be given ~~appropriate,~~ **comprehensive, unbiased, non-directive** and independent information as to the purpose and nature of the donation, and to the consequences and risks. The information ~~must should~~ be supplied in advance and should be as accurate as possible, **in order to ensure informed consent.**

**1.b [NEW] While finding an answer to the severe organ shortage in Europe is extremely important, the free choice to donate or not to donate an organ needs to be respected and protected as well. Both decisions can be ethically responsible. No one is obliged to donate his or her organs or shall be pressured or feel compelled to do so.**

*The free choice of a potential organ donor needs to be respected and protected, an aspect which the Commission Communication does not acknowledge in a sufficiently outspoken manner.*

2. Living donors, **willing to donate an organ to a close relative**, must be ~~selected~~ **chosen** on the basis of their health and medical history, including psychological evaluation if deemed necessary, and the donations should be undertaken by qualified and trained professionals. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves.

## **B. Draft Working Paper on an action plan on organ donation and transplantation (2009-2015)**

### **Selected observations on some of the objectives**

#### **Goal 1: Increasing organ availability**

The need for more organs in order to help more suffering people to receive often life-saving organ transplantation is out of question.

However, the principle of non-commercialisation of the human body, as stated in Art. 3 § 2 of the EU Charter on Fundamental Rights, also needs to be respected. Organ trafficking as well as organ donation out of financial motivation is unethical and degrades the gift of an organ to a mere commodity. Both constitute violations of the human dignity and must be prohibited.

While finding an answer to the severe organ shortage in Europe is extremely important, the European Commission should underline – as did the European Parliament – that the free choice to donate or not to donate an organ needs to be respected and protected as well. Both decisions can be ethically responsible. No one is obliged to donate his or her organs or shall be pressured or feel compelled to do so.

It is essential that information on organ donation be made in a non-directive manner, respecting the freedom of people to donate or not to donate. In order to foster a climate of trust, comprehensive information should be made available to the public, including on the concrete procedure of organ procurement, addressing also the issue of multiple organ donation and additional tissue donation.

#### **Objective 2: Implementation of programmes for living donations**

The action plan needs to address the particular ethical issues linked to the second objective. One such ethical dimension relates to the specific need for protection and particular safeguards that need to be put in place for the living donor.

In contrast to deceased donors, living donors are in a much more vulnerable position being in danger of exploitation. Emotional pressure of financial incentives may unduly influence living donors in their decision to donate. Therefore living donors should not be encouraged. Living donations should be restricted to narrowly defined cases of donations among close relatives. Consequently, the project of a register of living donors should be abandoned. Also, a register for living donors is prone to a large tableau of possible misuses.

#### **Objective 3: Increasing public awareness**

With regard to Priority Action 4 it needs to be underlined that the improvement of knowledge in health care professionals, the media and the general public will play an important role in increasing the willingness to donate organs. It is, however, crucial that the information on organ donations and – transplantation spread for that purpose is comprehensive, unbiased and non-directive. Furthermore, it needs to be concrete and address also fears and possible misuse as well as the possibility to address the latter.

#### **Proposal for a New Priority Action 4 a:**

#### **Call on Organizations of civil society, Churches and religious communities**

A very effective way of increasing organ availability is by increasing public information also at the local and regional level. The European Commission should call on the Member States and on organizations of civil society as well as on Churches and religious communities to take part in this effort to raise public awareness of the possibility of organ donation whilst taking into account the national cultural particularities in each member state.