Organ donation and transplantation: policy actions at EU level

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PURPOSE : to propose a set of EU policy actions on organ donation and transplantation.

CONTENT : organ donation and transplantation is a complex and sensitive issue, with an important ethical dimension. Policies on organ donation vary across the Member States depending on cultural, legal, administrative and organisational issues.

The excellent results of transplants, in terms of life years gained and in terms of improved quality of life have multiplied the indications of these therapies. There are, however, risks associated with organ donation particularly the risk of disease transmission. On the other hand, the shortage of donors affects transplantation programmes. Nearly 40 000 patients are now on waiting lists in Europe. Mortality rates while waiting for a heart, liver or lung transplant range from 15-30%. There are large differences in the deceased and living organ donor rate within the EU. These differences cannot be easily explained. Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it would appear that some organisational models are performing better than others. A further concern associated with organ donation is the trafficking of human organs by criminal gangs, who track down and remove organs in developing countries and hand them on to recipients within the European Union.

In short, therefore, the challenges facing organ donation are:

- **Transplant risks**: the risk of diseases being transmitted to the recipients such as HIV, hepatitis B and C, bacteria, fungi, parasites and different types of cancers.
- **Organ shortages**: The severe shortage of organ donors remains the main challenge facing EU Member States. Every day nearly ten patients die waiting for an organ in European societies.
- **Organ trafficking**: While current estimations indicate that organ trafficking remains relatively modest in Europe, the issue is nevertheless of serious political and ethical concern.

In recent years, the Commission has put considerable effort into supporting organ transplantation under various Community programmes. A large number of projects have been funded, the result of which have generated a considerable amount of information. In June 2006 the Commission launched an open consultation on organ donation and transplantation. Based on the outcome of this consultation, the Commission now proposes that new initiatives be taken, at a Community level, that seek to alleviate the challenges identified. In summary, the new initiatives are as follows:

Improving safety and quality: The Commission will define the precise, balanced scope of the EU legal framework on quality and safety for human organs taking account of Member State consultations. The framework must be backed- up by inter-Member State co-operation.

Increasing organ availability: The Commission will seek to boost Member State co-operation to allow for the exchange of experience and best practices with a view to establishing the most efficient systems.

Making transplantation systems more efficient and accessible: Initiatives in this area will focus on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local needs. Member States, whose transplant systems have yet to reach their full potential, could be supported and guided in their efforts to improve patient care.

Action plan on strengthened co-operation between the Member States: Analysis of organ transplantation in the EU reveals large differences in the organ donor rate within the EU. Differences in transplantation activity have also been identified. These differences can not be easily explained and it is clear that some models are performing better than others. The Commission, will therefore, identify which models work the best and support its application throughout the EU, while respecting cultural and organisation diversity.

EU legal instruments on quality and safety of organ donation and transplantation: The Community has already adopted a Directive on the quality and safety standards for blood, tissues and cells. A possible European Directive setting quality standards for organs could also be envisioned that addresses similar topics – but which takes account of issues uniquely linked to organ donation. Such a legislative act would be based on a separate impact assessment. A future legislative act could include the following elements:

- Establishing national oversight authorities responsible for implementing the Directive.
- Setting common quality and safety standards.
- Authorising programmes on organ donation and procurement.
- Setting provisions on the effective preservation and transportation of organs.
- Setting provisions on traceability.
- Establishing a procedure for reporting serious adverse events and reactions.
- Establishing control measure and inspection procedures.
- Ensuring a complete characterisation of the organ to allow transplant team to undertake risk assessments.