Directorate-General for Health & Consumers

Europe for Patients

Citizens' summary on organ donation and transplantation

The issue

The recent medical advances in organ donation and transplantation have led to organ shortages across Europe. For many conditions, organ transplantation is the only life saving treatment. There are more than 56,000 patients waiting for a suitable organ donor within the European Union. In 2006 more than 5,500 patients died while on an organ waiting list. This implies that 15 to 30% of people waiting for a suitable organ die. If more organs were donated, many lives would be saved and the quality of patients lives would improve.

Faced with these challenges, the Commission adopted a Communication in May 2007 identifying the main challenges in the field.

Three priority areas of action were identified:

1) improving quality and safety of organs,
2) increasing organ availability and
3) making transplantation systems more efficient and accessible.

In order to address these challenges, the Commission came forward with two different mechanisms of action:
- An Action plan for strengthened coordination between Members States on organ donation and transplantation and
- An EU legal framework on quality and safety of human organs

Benefits

These two initiatives – the Directive and Action Plan - will assure EU patients and citizens that organs used for transplantation will be of high safety and quality standards. Transplantation systems will be strengthened thanks to greater cooperation among Member States. This means that EU patients will benefit.

Why does action have to be taken at EU level?

The Treaty expressly provides the possibility for the EC to adopt harmonising measures to ensure safety and quality of organs. A national approach could not ensure the same minimum standard of quality and safety for organs as every year a number of organs are exchanged between EU Member States.

The establishment of common binding standards of quality and safety will be the only mechanism to ensure a high level of health protection throughout the EU. Increasing the exchange of best practices between Member States and strengthening their coordination will ensure better access to treatment for all EU patients while at the same time assist in better allocation of organs to those in need. Also cooperation to introduce initiatives that facilitate information to citizens about the different donation systems in Europe will bring added value.

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What exactly will change?

Directive

The Directive provides for the creation or designation in each Member State of a national competent authority which will make sure that the quality and safety standards of the Directive are complied with.
Moreover, the Directive will guarantee the traceability of all organs (i.e. that organs can be traced back from donor to recipient) to maximise quality and safety. Living donors will also be protected by the Directive which will provide guarantees for their follow-up through registers.
Given the fact that the cross-border exchange of organs has many benefits, the Directive also puts in place quality and safety conditions in order to facilitate such exchanges.

Action Plan – Working in collaboration with Member States

In order to increase the number of available organs in each Member State the Action Plan suggests 10 priority actions. Some of these actions include sharing best practice on the use of transplant donor coordinators in hospitals and the promotion of quality improvement programmes. In Spain, the introduction of such organisational changes amongst others led to a 130% donation rate increase in a 10 year period.
The Action Plan also focuses on raising awareness of European citizens on organ donation and strengthening the role of health professionals in providing information regarding organ donation and transplantation. In addition, the importance of a mechanism to facilitate the exchange of organs for specific, difficult to treat and paediatric patients is proposed .

When is the proposal likely to come into effect?

The Action Plan with its' 10 key priority actions will enter into force in 2009. The Directive will be discussed and negotiated with the Council of Ministers and the European Parliament as this conforms to the EU co-decision procedures. It is therefore difficult to know when the Directive will come into effect.

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