**OPINION OF THE 14TH COMMITTEE**
**ON COMMUNITY ACT NO. 26**

**Proposal for a directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (COM (2008) 818 final)**

The 14th Committee, European Union Policies,

upon concluding its consideration of the Community Act above,

whereas the proposal for a directive under scrutiny deals with a context marked by stark imbalance between supply and demand and the shortage of available organs feeds the proliferation of illegal trafficking, the proposal abates such risk by establishing transplantation authorities and centres and laying down conditions for organ reception and traceability;

whereas the proposal aims to combine in a harmonious and balanced fashion the need to quickly procure organs with the need to ensure high safety and quality standards, following the guidelines of the Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union, held on 17-18 September 2003, and the Council conclusions on organ donation and transplantation of 6 December 2007;

whereas in the working paper attached to the proposal the Commission emphasizes that Article 152 of the EC Treaty, which provides the legal basis for the proposal, may be construed to reconcile a measure of the European Union in the field of organ donation and transplantation with the subsidiarity principle, in that the Union manifestly can and must implement binding measures setting high quality and security standards;

whereas the working paper shows that the European Commission, for the purposes of achieving a high level of human health protection in the field of organs intended for transplantation while complying with the proportionality principle, has chosen a specific action plan to be implemented alongside a "flexible" directive, including non-detailed framework measures providing for the adoption of national legislation dealing with the crucial aspects of organ donation and transplantation;

expresses the following comments:

a) regarding compliance with the subsidiarity principle, the Committee

1. acknowledges that, as per Article 152 of the EC Treaty, the proposal for a directive aims to ensure – through the adoption of binding measures – high

quality and safety standards for the use of organs intended for transplantation, in line with the provisions of directives 2002/98/EC and 2004/33/EC on blood and blood products, and human tissue and cells, and through a harmonisation procedure which is necessary in order to effectively regulate cross-border exchange of organs;

2. believes however that the draft directive suffers from shortcomings in terms of determination and motivation of subsidiarity and therefore it should be reworded. As is the case with directives 2002/98 and 2004/33 mentioned above, it should include a clause enabling member States to keep or introduce stricter health safety and protection measures in compliance with the provisions of Article 152.4(a) of the EC Treaty, and should also take into consideration the provisions of 152.5, whereby "measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood";

b) regarding compliance with the proportionality principle, the Committee,

in consideration of the sensitive nature of the subject, expresses appreciation for the decision of the Commission to introduce, alongside the tool of the action plan, a "flexible", non prescriptive, directive, rather than a "rigorous" directive laying down, like directive 94/33 on tissue and cells, detailed regulation of quality and safety systems to be adopted in the member States; the Committee therefore hopes that the final text of the directive will fully comply with such flexibility criteria and shall confine itself to framework provisions, stopping short of an overly detailed regulation, especially with regard to Article 4 on the "National Quality Programmes" that member States will be called to adopt;

c) regarding the substance of the proposal, the Committee,

1. recalls that Italy sets a veritable example in terms of safety standards for human organs intended for transplantation. This renders all the more necessary a reference to Article 152.4(a) of the EC Treaty, in order to enable our country to keep its regulations in place, where it is more rigorous than the standards envisaged in the directive;
2. underlines that the "bad publicity" relating to the tragic phenomenon of organ trafficking, engenders dangerous scaremongering, which translates into a psychological obstacle to donation. Following this consideration, softer and more cautious wording should be used in paragraph 5 of the introduction to the proposal for a directive. It is therefore necessary and appropriate to amend the directive, and particularly the whereases, in order to specify most clearly that donation takes place between the living and that in most cases it involves relatives by blood or the inner family, for which there obviously is no anonymity requirement;

3. urges to consider whether measures should be introduced, at national or European level, to provide organ donors with welfare measures, in terms of social security, health assistance and insurance;
4. believes that the present training of organ transplantation staff based on the mere specifics of the work, should be complemented by a system of assessment and certification, ensuring that the training process has indeed produced an improvement of knowledge and skills;
5. believes that the establishment of a "European observatory" is highly desirable, also in view of the migration flows of third-country nationals, to ensure appropriate health checks in relation to organ exchange and transplantation and timely information to member States on the presence of pathogenic agents uncommon or rare in Europe in live or deceased donors;
6. finally believes that, during scrutiny of the proposal for a directive, consideration should be given to donor's and receiver's age standards, so as to keep abreast of the changes occurred over the last few years in terms of health and average life expectancy.