Replies of the Italian Senate to the COSAC Questionnaire on subsidiarity compliance check on the proposal on standards of quality and safety of human organs intended for transplantation

To COSAC Secretariat (secretariat@cosac.eu).

Procedures:
1. Which parliamentary committees were involved in the subsidiarity check and how?
The European Affairs Committee gave with an advisory remit and the Health Committee as the Committee having jurisdiction over the subject matter.

2. Was the plenary involved?
No.

3. At which level the final decision was taken and who signed it?
The European Affairs Committee issued an opinion on 4 February 2009, within the 8 weeks time, but no formal decision has been made by the Senate as yet. Senate Rules of procedure state that if the Committee having jurisdiction over the subject matter (the Health Committee in this case) does not issue its "final" decision within 15 days counting from the date when the opinion of the European Affairs Committee is issued, then the opinion of the European Affairs Committee should be considered the final decision of the Senate. In such case, the European Affairs Committee shall take another vote on the opinion, but only to "upgrade" it to. The vote is taken by simple majority, with the presence of the majority of members (15 out of 29).
All opinions issued by Senate committees scrutinising EU business are signed by the rapporteurs.

4. Which administrative services of your parliament were involved and how (please specify)?
The European Affairs Office followed the scrutiny of the proposal and prepared documentation on it. The Secretariats of EU Affairs Committee and Health Committee were involved too.

5. Did your government provide any information on the compliance of the Proposal with the principle of subsidiarity?
No.

6. In case of a bicameral parliament, did you coordinate the subsidiarity check with the other chamber?
No.

7. Did you consult your regional parliaments with legislative powers?
No.

8. Did you consult any non-governmental organisations, interest groups, external experts or other stakeholders?
No.

9. What was the chronology of events?

The European Affairs Committee started consideration on 21 January 2009 and issued an opinion on 3 February 2009.
Consideration in the Health Committee started on 3 February 2009.

10. Did you cooperate with other national parliaments in the process? If so, by what means?
No.

11. Did you publicise your findings? If so, by what means?
Yes. As usual, a summary report of the sittings was published on the Senate website the day following the Committee meetings. The papers adopted and the opinion issued are attached to the reports of the sittings.

12. Has your parliament introduced any procedural changes with regard to subsidiarity check mechanism since September 2008? If so, please specify how.
No.

Findings:
13. Did you find any breach of the principle of subsidiarity?
15. Did you find the Commission's justification with regard to the principle of subsidiarity satisfactory?

On the issue of compliance with the subsidiarity principle, the European Affairs Committee stated the following:
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";

14. Did you adopt a reasoned opinion on the Proposal? (If so, please enclose a copy)
Yes. A copy is attached.

16. Did you encounter any specific difficulties during this subsidiarity check?
No.

17. Any other comments?
The Committee's consideration of the proposal has shown that an opinion issued by a Senate committee may not always be considered a "reasoned opinion" under to the Protocol on subsidiarity. All opinions issued include compliance assessment with the subsidiarity and

proportionality principles, and also an assessment of the substance of the proposal. It is very difficult to issue a neat opinion on just one of these aspects without considering the other.

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.