MARGOT WALLSTRÖM
VICE-PRESIDENT OF THE EUROPEAN COMMISSION

B-1049 BRUSSELS

Brussels, 03/07/2009
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Dear President,

The Commission would like to thank the Belgian Senate for its opinion on the 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).

The Commission is pleased that the Belgian Senate fundamentally supports the Commission's intention to lay down basic quality and safety requirements for the donation of organs for transplantation purposes in order to ensure a high level of protection for patients in the EU.

The Commission strongly shares the view of the Belgian Senate namely that the major challenge facing organ donation and transplantation is the growing waiting lists and the limited number of available donors. The Commission would like to reassure the Senate that the intention of the proposed Directive is to be flexible enough in order to take into account the particularities of the various transplantation systems. Regarding the issue of "expanded donors" it should be pointed out that the proposal does not aim at regulating the use of marginal and expanded donors. Member States can continue using marginal donors as long as the transplant teams concerned make the proper risk-benefit assessment by collecting the information required in the Annex of the proposal. Therefore, the information requested is not an exclusion criterion per se.

As can be deduced from the definitions provided in Article 3 of the proposal, "procurement organisation" (Article 3(j)) and "transplantation centre"(Article 3(q)) are given the same definition. This approach aims at being flexible enough in order not to jeopardise systems that function well while at the same time allowing Member States to maintain their existing organisation structures.

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The Commission would like to draw the attention of the Belgian Senate to Article 19 on registers and reports. The Commission shares the view of the Belgian Senate regarding the importance of data record keeping as a means of assessing the efficacy of the system. This is one of the goals pursued by Article 19 of the proposed Directive. The responsibility of collecting data lies with the Competent Authorities. Nevertheless, the way they do it depends on the organisation of the national transplantation systems and is a national competence. The Commission has no mandate to regulate the funding of transplantation organisations and structures as this falls under the responsibility of the Member States according to Article 152 of the EC Treaty.

As the Belgian Senate rightly points out organ allocation is not covered by this Proposal. The Commission is currently examining whether this question is included in the scope of the proposal for a directive on the application of patients rights in cross-border healthcare.

The Commission takes note of the comments regarding the different consent systems in the European Union. The Commission would like to draw the Senate's attention to Article 14 of the proposal, which stipulates that consent systems remain a national responsibility. The proposal therefore does not aim at regulating consent systems.

The Commission also takes note of the concerns of the Belgian Senate regarding respect to "the principle of solidarity". However, as indicated above, organ allocation is not covered by this Proposal. The Commission is currently examining whether this question is included in the scope of the proposal for a directive on the application of patients rights in cross-border healthcare.

The Commission does not have the competence through this Proposal to create a pan-European organ exchange organisation. Nevertheless, the Commission aims through the Action Plan to strengthen co-operation between Member States and the various regional organisations in place. In particular, the Commission will promote EU wide agreements on aspects of transplantation medicine.

Yours sincerely,

Margot WALLSTRÖM
Vice-President of the European Commission