EUROPEAN COMMISSION

Brussels, 29/04/2009
C/2009/3124

Dear Mr President,

Thank you for transmitting the Austrian Bundesrat's contribution to 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}.

In line with the Commission's decision to encourage National Parliaments to react to its proposals to improve the process of policy formulation, we welcome this opportunity to respond to your comments. I enclose the Commission's response. I hope you will find this a valuable contribution to your own deliberations.

I look forward to developing our policy dialogue further in the future.

Yours sincerely

Margot WALLSTRÖM
Vice-President of the European Commission

Herrn Harald Reisenberger
Präsident des Bundesrates
A-1017 WIEN

EUROPEAN COMMISSION

Bruxelles, April 2009

COMMENTS OF THE EUROPEAN COMMISSION ON AN OPINION FROM THE AUSTRIAN BUNDESRAT.

COM(2008)818 – PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON STANDARDS OF QUALITY AND SAFETY OF HUMAN ORGANS INTENDED FOR TRANSPLANTATION

The Commission would like to thank the Austrian Bundesrat 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 takes note of the concerns of the Austrian Bundesrat in relation to Article 152(4) (a) of the Treaty. The legal base of the proposal is in fact Article 152 and in particular, as stipulated in the citations, Article 152 (4)(a). This proposed Directive shall not prevent a Member State from maintaining or introducing more stringent protective measures, provided that they comply with its provisions and the provisions of the Treaty. Moreover, it should be mentioned that Article 152 provides for minimum harmonisation, therefore enabling Member States to keep their current legislation and organisational structures as far as they comply with the provisions of the proposed Directive and of the Treaty.

The Commission also takes note of the Parliament's comments regarding the different consent systems in the European Union. The proposed Directive takes this fully into account, in particular in Article 14, which stipulates that consent systems remain a national competence.

The aim of the proposal is not to compromise the supply of donor organs within individual Member States, nor to encourage transplant tourism. On the contrary the proposed Directive sets out the basic quality and safety requirements needed in every transplantation system. There is a need for common quality and safety standards for the procurement, transport and use of human organs at Community level. These standards would also facilitate exchanges of organs to the benefit of European patients in need of this type of therapy. Community legislation should ensure that human organs comply with acceptable standards of quality and safety. Therefore such standards will help to reassure the public that human organs procured in another Member State nonetheless carry the same basic quality and safety guarantees as those obtained in their own country.

Moreover the Commission also takes note of the concerns of the Austrian Bundesrat regarding administrative burden. In this respect the Commission would like to point out that the proposed Directive is flexible enough and that consideration is given to already existing structures. Nevertheless the Commission welcomes any possible comments. Regarding the comments made on Articles 3 and 11, the Commission would like to point

out that for reasons of consistency the definitions of serious adverse event reporting are identical to the Directives on Tissues and Cells[1].

As far as Article 7 of the proposal is concerned, the Commission would like to point out that a risk-benefit analysis is a fundamental approach to organ transplantation. The clinician plays an important role in this context by deciding whether or not organs are suitable for transplantation. Therefore this proposed Directive stipulates the information required to make this assessment. The proposal takes due account of the fact that advances in the medical field might occur and for this purpose the Annex can be updated through the comitology procedure as provided for in Article 25 (1) (a).

In addition, it should be pointed out that Article 25 of the proposal provides for comitology also for establishing traceability requirements and serious adverse event reporting. Establishment of a system to ensure that all organs can be traced from donor to recipient and vice versa is a key factor to ensure safety, but also to prevent remuneration, trade and trafficking in organs. The proposed Directive aims at ensuring that Member States put in place organ traceability systems. In addition, the proposal includes measures to capture serious adverse events related to the procurement, testing and transport of organs, as well as any serious adverse reactions observed during or after transplantation which may be connected to the procurement, testing and transport of the organ in the European Union.

The Commission hopes that these explanations are useful for the Austrian Bundesrat and remains available to provide any further information.

[1] Human Tissues and Cells are regulated by Directive 2004/23/EC, 2006/17/EC and 2006/86/EC