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REPUBLIC OF AUSTRIA
Bundesrat [Federal Council]
The President

Vienna, 04/02/09

Ref. 27000.0040/6-L2.,1/2009

Dear Mr Barroso,

At its meeting of 3 February 2009, the EU Committee issued the following communication following its discussion of the EU 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):

'Communication to the European Commission

On 3 February 2009 the EU Committee of the Federal Council discussed in open session 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 final). On the basis of information provided by the competent Federal ministries and the opinions of the Länder, the Federal Chamber of Labour, the Austrian Chamber of Commerce and the Austrian Federal Institute for Health, the following conclusions were arrived at:

1. With any projects involving cross-border organ trade or transplants, it will have to be borne in mind that Member States have different systems regarding the consent requirements that apply to the deceased or their relatives (objection-based versus consent-based approach), and that this may have a major impact on the availability of donor organs. As regards the attendant ethical issues, the EU should be extremely wary of trying to standardise regulations.

2. The proposed rules can be reconciled with Article 152(1) and (5) of the Treaty only if a high level of health protection continues to be ensured in the implementation of all Community policies and if Community action in this field continues to fully respect the responsibilities of the Member States for the organisation of health services and medical care.

3. The proposed item of legislation must therefore in no way compromise the guaranteed supply of donor organs within the individual Member States. At all events, this would be prejudiced if Member States with effective systems and legal frameworks were in any way forced to 'export' organs to other Member States with ineffective systems or inadequate legal frameworks. These could cause the system as a whole to collapse, as the willingness of many people to agree to an organ donation might rapidly evaporate if there were the slightest concern that Community rules might jeopardize the local supply of donor organs.

4. Nor should the proposed legislation in any way encourage organ transplant tourism, which is typically disadvantageous for the host country. Indeed, it should prevent this. This could be reinforced by means of a stated objective or a recital making express provision for demand for donor organs to be met within the individual Member States. Experts also agree that short journeys definitely make for much better transplantation results.

5. Finally, the legislation being proposed must not lead to a greater administrative burden – it must mesh neatly with, and build on, existing Europe-wide cooperation structures, information exchange mechanisms and quality assurance arrangements. This will mean having to re-work a number of the provisions of Chapters IV and V (the 'equivalence requirement', for instance) in close cooperation with experts and practitioners.

6. In Articles 3 and 11, the definition of a serious adverse event that requires reporting is insufficient and should be re-worked in collaboration with medical experts.

7. In Article 7, the 'donor characterisation' requirements are far too detailed from a technical point of view. Given the changes that advances in the medical field can be expected to bring about, the level at which legislation is promulgated also requires consideration. There might be a case for leaving this to, say, the 'Eurotransplant' system and the national institutions that work together under that scheme.

8. Article 25 authorises the Commission to lay down additional procedures. This does not appear to be necessary and is at odds with the principle of subsidiarity. Experience has shown that these types of procedure are best left to cooperating national organisations themselves, which can lay down and mutually harmonise state-of-the-art procedures.'

The EU Committee also unanimously decided to publish this communication as an EU Committee Communiqué pursuant to Section 34(6) of the Rules of Procedure of the Federal Council.

Yours sincerely,

(Harald Reisenberger)