The Vice-President of the European Commission
Mrs M. Wallström
B – 1049 BRUSSELS
Belgium

COURTESY TRANSLATION

date: 12 February 2009
subject: *Subsidiarity check on the proposal for a directive on standards of quality and safety of human organs intended for transplantation (COM(2008)818)*
reference: *142983.02u/YTB/FB*

Dear Mrs Wallström,

In accordance with the procedures adopted by them, the two Houses of the States General of the Kingdom of the Netherlands have checked 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) by reference to the principles of subsidiarity and proportionality. In doing so they have applied Article 5 of the EC Treaty and Protocol 30 to the Treaty of Amsterdam on the application of the principles of subsidiarity and proportionality. Both Houses of the States General would inform the European Commission that this procedure has not yet been completed.

Both Houses of the States General consider the chosen legal basis for the proposed directive to be adequate for the intended objective. They are not yet convinced, however, that the proposed measures fulfil the requirements of subsidiarity and proportionality in the EC Treaty. They will therefore defer a final assessment of this subject until they have received an adequate response from the European Commission to the comments and questions set out in the enclosure and have had the opportunity to consult stakeholders about the proposed measures.

The two Houses of the States General therefore look forward to receiving a reply from the European Commission as quickly as possible.

Yours sincerely,

Yvonne E.M.A. Timmerman-Buck
President of the Senate
of the States General

Gerdi A. Verbeet
President of the House of Representatives
of the States General

An identical letter has been sent to the presidents of the Council of the European Union and the European Parliament and to the Dutch government and the secretariat of COSAC.

QUESTIONS TO THE EUROPEAN COMMISSION FROM BOTH HOUSES OF THE STATES GENERAL OF THE KINGDOM OF THE NETHERLANDS CONCERNING THE SUBSIDIARITY AND PROPORTIONALITY OF 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)

Legal basis

The European Commission has based the proposal for a directive on Article 152 (4) (a) of the EC Treaty. It appears to both Houses of the States General of the Kingdom of the Netherlands that the chosen legal basis is adequate for the intended objective, namely to adopt standards of quality and safety of human organs intended for transplantation. This legal basis is also in keeping with Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[1] and with the legal basis of Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC of the Council.

Subsidiarity

In view of the subsidiarity requirements, action on the part of the Community is justified only if (1) the objective(s) of the proposed action cannot be sufficiently achieved by the Member States and (2) the objective(s) can be better achieved by the European Union.

The two Houses of the States General note that organ donation and transplantation have transnational aspects. All the Member States are involved in organ donation and transplantation. Around one fifth of the organs donated within the countries that participate in Eurotransplant are exchanged between the countries concerned. Seven countries (Austria, Belgium, Croatia, Germany, Luxembourg, Slovenia and the Netherlands) are at present affiliated to Eurotransplant for the exchange of organs and apply strict quality and safety rules in this connection. Countries not affiliated to Eurotransplant also exchange organs, either within Eurotransplant or otherwise. The Commission has supplied figures with this proposal showing that there is a shortage of 56,000 organs in Europe. No European country whatever has a surplus of organs.

The European Commission considers that the present European measures are necessary because (1) the differences in quality between the organs have, in its view, become too great and the measures to prevent this are insufficient, partly because not all countries participate in Eurotransplant, and (2) it is necessary to combat the high volume of organ trafficking by criminal groups. The proposed measures are thus intended to help achieve the objectives of the proposed directive, namely to increase the number of donations, provide better accessibility and more efficient transplantation systems and ensure compliance with quality and safety standards.

As regards the subsidiarity of the proposed measures, the two Houses of the States General have a number of questions and comments. It follows that they both defer making

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[1] Transposed into Dutch law in the Body Material (Safety and Quality) Act and various other laws (Parliamentary Papers 30338)

a final assessment until these questions and comments have been adequately answered by the European Commission.

1. The States General wonders whether the survey of how transplantation systems etc. operate in practice dating from some seven years ago is still sufficiently relevant to serve as a basis for the measures now proposed. They would request the European Commission to comment on this.
2. The directive and the underlying documents still provide insufficient information about the figures on which the proposal is based. Can the European Commission provide more clarity about the figures on which the proposal is based? How many organs are exchanged annually between non-Eurotransplant countries and Eurotransplant countries? Can the Commission explain how this legislation would benefit quality?
3. At present, the professional groups of transplant physicians, transplant surgeons and tissue typing experts, united in the European Society for Organ Transplantation (ESOT) (as well as at global level), are already responsible for exchanging information about best practices and adequate courses for fundamental, translational and clinically applied research. The international exchange of organs in the Netherlands takes place under the auspices of Eurotransplant, which covers an optimal geographic area as an unduly long cold ischemia time (organ too long in transit) adversely affects the quality of the organ. Improvement of the existing cooperation within Eurotransplant and in the context of the agreements within the Council of Europe would be a possibility. It should be noted in this connection that the latter agreements have the disadvantage that they cannot be compulsorily implemented (Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS N°. 186)). The States General requests the European Commission to address the question of the extent to which the above-mentioned cooperation could help to achieve the objectives of the proposal for a directive.
4. It was submitted in the previous point that Eurotransplant covers an optimal geographic area as an unduly long cold ischemia time (organ too long in transit) adversely affects the quality of the organ. Shortening the cold ischemia time is of greater importance than achieving a better match, given the present quality of immunosuppressants. This does not apply to highly sensibilised patients. As it is nowadays already possible to transplant across blood group incompatibility, organ exchanges are becoming less important. Does the European Commission agree with this analysis and, if so, how does this affect the added value of the European action proposed in the draft directive?
5. Is the Commission able to be more specific about the extent to which the quality of organs differs from country to country, in particular about the differences in quality between Eurotransplant and non-Eurotransplant countries?

6. Does the European Commission agree with the States General that the quality of organs and the safety of organ donation depend to a great extent on cultural attitudes and the level of care in the various European countries? A clear example has been given by the Dutch government[2], namely non-heart-beating organ donations and the use of marginal organs. Some European countries do not accept these organs. Mention should also be made in this connection of live organ donation (living related donors and living unrelated donors). This is a form of organ donation that achieves very good results. The statutory rules on consent for such donation differ from country to country in Europe. Can the European Commission indicate whether achievement of the objectives of the proposed directive can nonetheless be guaranteed by means of the measures now proposed and, if so, to what extent?
7. It is insufficiently clear from the directive and the related documents what effect the directive will have on the practice relating to non-heart-beating donors. This is of importance to the Netherlands as it has a relatively large number of non-heart-beating donations. Can the Commission provide more information about this?
8. Does the European Commission agree with the States General that the following factors determine to a large extent the number of organs available, namely donation demand, ideological views (affecting intrinsic motivation), organisation, logistical aspects and care providers' familiarity with the practice of organ donation. If so, how does this affect the added value of the European action proposed in the draft directive?
9. A second reason which the Commission puts forward for common action is the high volume of organ trafficking by criminal groups. The two Houses of the States General consider that this is not adequately explained in the directive and the underlying documents. Can the Commission provide further information and support this with figures?

Proportionality

The two Houses of the States General are not yet convinced that the proposed measures are proportional. Before making a definite assessment, they request the European Commission to provide further clarification and explanation in respect of the following questions:

1. With a view to the proportionality requirement the European Commission has opted for what is known as a 'flexible directive', without detailed policy measures. Can the European Commission provide more evidence than is presently given in the directive and the related impact assessment of why the directive would be more effective in achieving the objectives (increase in the number of donations, better accessibility, more efficient transplantation systems and compliance with quality and safety standards) than the present practice.
2. Nor is it sufficiently clear to either House of the States General what would happen if there were to be no new European legislation. What would be the consequences for the different countries? The Commission does not deal with this point at all in the proposal. Could the European Commission provide more clarity about this, and distinguish in particular between the effects on the Eurotransplant countries and the non-Eurotransplant countries?

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[2] Views of the Dutch government dated 10 December 2008, Parliamentary Paper 22.112, 750.

3. There is some concern in the States General that European supervision of procedures on the transfer of information about the characteristics and traceability of organs and about serious adverse events will cause delay in the process. The two Houses of the States General request the European Commission to allay this concern by providing convincing reasons.
4. It is still insufficiently clear from the directive and the related documents what the effects will be of any innovations in the field of organ donation and transplantation. Can the Commission indicate how these matters will be dealt with in the future?
5. In assessing the proposal the British government has come to the conclusion that the quality and safety regulations proposed by the Commission are more far-reaching than is clinically necessary. What is the Commission's reaction to this assessment?
6. Organ trafficking. This point has already been dealt with in point 9 under the heading 'subsidiarity'.