Parliament of the Czech Republic
CHAMBER OF DEPUTIES
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RESOLUTION

of the Committee for European Affairs
from its 46th session held on 22 January 2009

on the Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation [16521/08, COM(2008) 818 final]

The Committee for European Affairs after hearing the report of MUDr. Markéta Hellerová and after hearing the report of the rapporteur, Mr Jozef Kochan, and after deliberating the matter

a p p r o v e s the position annexed to this resolution.

Josef Šenfeld	Jozef Kochan	Jan Bauer
Committee Verifier	Committee Rapporteur	Committee Vice-Chairman

Annex to Resolution No. 373

DOCUMENT 16521/08

Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation

COM(2008) 818 final, 16521/08
Interinstitutional file 2008/0238/COD

- **Legal basis:**
  Article 152(4) of the EC Treaty

- **Date of transmission to the Council of the EU:**
  8 December 2008

- **Date of transmission to the Chamber of Deputies via the Committee for European Affairs:**
  11 December 2008

- **Date of deliberation in the Committee for European Affairs:**
  18 December 2008 (first round)

- **Procedure:**
  Co-decision

- **Preliminary position of the Government [pursuant to Article 109a(1) of the Rules of Procedure of the Chamber of Deputies]:**
  Dated 19 December 2008, delivered to the Committee for European Affairs on 7 January 2009 via the ISAP system.

- **Conformity with the principle of susbsidiarity:**
  The proposal complies with the principle of subsidiarity.

- **Background and subject:**

At this time, organ transplantation is the most effective procedure in end stage renal failure and the only treatment available for end stage failure of organs such as the liver, lungs, and heart.[1] Even at this time, however, the main problem shared by all European countries is a lack of organs. The differing approaches and standards used in each of the Member States for organs and donors are also a problem.

The Commission has decided to respond in a number of ways to the fast pace of development of this medical treatment and to the differences between each of the Member

[1]In Europe, almost 40,000 patients are on waiting lists. The mortality rate of patients waiting for a heart, liver or lung transplant is usually in the range of 15 – 30 percent.

States. First it adopted the *Communication on organ donation and transplantation of 31 May 2007,*[2] in which it assessed what activities should be undertaken at the Community and Member State level to help increase the number of organ donors in the whole EU and ensure the quality and safety of these procedures.

Based on this Communication, it was decided that new Community legislation on organ donation and transplantation would be adopted along with an action plan for the same area. However, since the very beginning, some of the Member States have been of the opinion that it would be more appropriate to adopt the action plan first, evaluate its functionality, and only then, if appropriate, agree to the legislative proposal. It is planned that the first evaluation of the proposed action plan accompanying this proposal for the directive will be performed sometime in 2012.

Article 152(4)(a) of the EC Treaty makes it possible to address the problems with the mentioned legislation at the Community level. This provision gives the European Parliament and the Council the authority to adopt through co-decision according to Article 251 of the EC Treaty harmonised healthcare measures setting high standards of quality and safety for organs and substances of human origin. On this basis, the Community has, among other things, adopted guidelines on quality and safety standards for blood in 2003 and on quality and safety standards for tissues and cells in 2004.

The first of these legal instruments is *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.*[3]

The purpose of adopting the mentioned directive was to ensure a higher level of protection of donation, procurement, testing, preservation, storage, and distribution of human tissues and cells intended for human applications and for the preparation of products for use on humans. For this reason, this directive sets the standards for each one of the steps in the human tissues and cells application process. [4]

The main objective of the set of directives[5] on standards of quality and safety for blood was to contribute to the general trustworthiness of the quality of donated blood and blood components, to achieve self-sufficiency at the Community level, and to increase trustworthiness in the safety of transfusion chains between Member States.

As blood and blood components, human tissues and cells and organs or tissues and cells of animal origin are governed by other provisions, they are explicitly excluded from the scope of the proposed legislation. It is necessary, however, to mention the existence of these

[2] SEC(2007) 705.

[3] Transposition period until 7 April 2006

[4] There exist two additional technical implementing directives to this directive: Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells; and Commission Directive 2006/86/ES of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.

[5] Blood and blood derivatives are at this time governed by Directives 2002/98/EC, 2004/33/EC, 2005/61/EC and 2005/62/EC.

provisions also for the reason that they use the same legal basis as the proposed directive and make use of a similar structure, which can help in particular in checking compliance with the principles of subsidiarity and proportionality.

Another initiative by the Community in this area is the *Action Plan on Organ Donation and Transplantation (2009 – 2015): Strengthened Cooperation between Member States*, which has been mentioned numerous times. This document, however, is being addressed by the European Affairs Committee as a separate point and, as such, is being analysed separately.

- **Content and impact:**

The objective of the proposed directive is to ensure that human organs used for transplantation in the EU comply with the same quality and safety requirements during all the phases of the process.[6] To ensure that this objective is met, the directive imposes the obligation on the Member States to establish or appoint a national authority to ensure compliance with the requirements of the directive and to establish a system for the authorisation of programmes of organ procurement and transplantation based on common quality and safety criteria.[7]

The discussed legislative proposal also deals with the protection of organ donors. It does so because most donors are often also tissue and cell donors – these donors would then be granted certain guarantees in the area of tissues or blood and other guarantees in connection with organ donation. The provisions to protect the living donor include the due evaluation of the health of the donor and comprehensive information about the risk prior to donation, the introduction of registers for living donors to follow up their health, and measures to ensure the altruistic and voluntary donation of organs by living donors. This provision is also tied to the action plan, which has a supplementary function in the creation of these instruments.

The proposed directive further imposes on the Member States the obligation to introduce national quality programmes laying down standard operating procedures and the rules ensuring traceability of organs from donation to transplantation or disposal. In the area of organ transport, the Member States shall ensure the fulfilment of requirements both on the entities involved in the transport of the organs and on the organ container used for the transport.

The directive should also serve to facilitate both cooperation between Member States and cross-border exchanges. Such cooperation should take place mainly between bodies established on the basis of this directive to take responsibility for its implementation. A register of procurement organisations and transplantation centres will also be established and reports on their activities drawn up.

The presented legislative proposal also contains provisions governing the exchange of organs with third countries and allowing Member States to establish written agreements with European organ exchange organisations, granting to them the competencies that would otherwise be the competencies of the national authority responsible for administering the directive.

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[6] Thus, the matter concerns not only use, but also donation, procurement, testing, transport, and preservation.

[7] Recommendation Rec(2004)19 of the Committee of Ministers of the Council of Europe to the Member States on criteria for the authorisation of organ transplantation facilities.

Position of the Czech Republic

In the Czech Republic, the national transplantation system is at a good level and complies with most of the provisions of the presented proposal. The Transplantation Coordination Centre, established by the Ministry of Health on the basis of the *Transplantation Act,*[8] already exists in the Czech Republic as an organisational unit of the state. In fact, it is planned for the Transplantation Coordination Centre to become the authorised body for the area of organ donation and transplantation as mentioned in the directive.

Although in the framework of its Presidency the Czech Republic is not openly counting on concluding all negotiations, its ambition is to make as much progress in them as possible. Therefore, discussion of the presented proposal has already been put on the agenda of the Working group on public health.

Subsidiarity checks on acts of European law

For the period of Czech Presidency of Council of the European Union, the Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation was chosen for a subsidiarity check. The subsidiarity check on this proposal was decided at the Meeting of the COSAC Chairpersons on 7 July 2008. This decision was then confirmed at the XL Conference of Community and European Affairs Committees of Parliaments of the European Union, which was held in Paris on 3 – 4 November 2008.

The European Commission adopted the presented proposal on 8 December 2008, the date on which the eight-week deadline for national parliaments to perform the check began to run. This deadline ends on 9 February 2009.

The legal basis contained in the establishing Treaties for adopting this directive, as described hereinabove, is sufficient and allows for the adoption of the proposal for the directive.

- **Anticipated timeframe for deliberation in the EU bodies:**

In the European Parliament, the document under discussion was forwarded to the Environment, Public Health and Food Safety Committee; Legal Affairs Committee; and the Civil Liberties, Justice and Home Affairs Committee. So far, none of the mentioned committees have included the document in their meeting agendas.

[8] Act No. 285/2002 Coll., of 30 May 2002, on organ and tissue donation, procurement and transplantation and on changes to certain acts.

- **Conclusion:**

  The Committee for European Affairs

1. **takes into account** the Proposal for a Directive of the European Parliament and of the Council on the standards of quality and safety of human organs intended for transplantation;

2. **states** that the presented proposal is not in breach with the principles of subsidiarity and proportionality at this time;

3. **requests the Government** to inform the Committee of subsequent developments of the deliberation of this proposal;

4. **resolves** to forward this document, together with its resolution and Government's position, to the Healthcare Committee for information.

Josef Šenfeld	Jozef Kochan	Jan Bauer
Committee Verifier	Committee Rapporteur	Committee Vice-Chairman