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REPORT

from :	Presidency
to :	Council
Subject :	EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS COUNCIL MEETING ON 8 AND 9 JUNE 2009 **Proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation (LA)** - *Progress report*

The Council is invited to take note of the attached progress report from the Presidency reflecting the state of play of the discussions at the Working Party on Public Health on a proposal for a Directive on standards of quality and safety of human organs intended for transplantation.

ANNEX

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

- Progress Report from the Presidency -

I. INTRODUCTION

1. On 8 December 2008, the Commission adopted a proposal for a Directive of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation.[1]

2. This initiative is based on the Commission's Communication on organ donation and transplantation adopted on 31 May 2007 where a number of suggestions for actions at both Community and Member State level were made in order to help increase the supply of organ donors across the European Union (EU) and ensure the quality and safety of these procedures.[2]

3. The proposal should provide a clear legal framework for organ donation and transplantation in the EU. Member States should create or designate a national competent authority to ensure compliance with EU quality and safety standards e.g. by establishing a traceability system of human organs and a reporting system for serious adverse events and reactions, or by standardising data collection on specific organ characteristics.

4. Together with this proposal, the Commission adopted a Communication *Action Plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States* defining 10 priority actions for addressing three key challenges in organ donation and transplantation in Europe: the quality and safety of organs across Europe, increasing organ availability and making transplant systems more efficient and accessible.[3]

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1 COM(2008) 818 final

2 COM(2007) 275 final

3 COM(2008) 819/3

5. Under the CZ Presidency, the Council Working Party on Public Health held , after a general discussion, a first examination of articles 1 – 7.

6. The European Parliament is expected to give its first-reading opinion at the earliest during autumn 2009. However, an exchange of views took place in the Committee on the Environment, Public Health and Food Safety on 30 March 2009, for the purposes of which the rapporteur Frieda Brepoels prepared a working document summarizing the proposal's main aims and focusing more in detail on issues such as flexibility, national authorities and European organ exchange organisations, the relationship with other legislation, the scope of the Directive, definitions, living donors, registers and traceability.[4]

7. The European Economic and Social Committee is also preparing an opinion on the proposal.

II. STATE OF PLAY

8. In general, the delegations welcomed the proposal and agreed that there was a need for legislation covering the area of quality and safety for human organs intended for transplantation. Only one delegation expressed its doubts about the need to legislate in this field, considering the Action Plan to be a more convenient instrument.

9. Nevertheless, a number of delegations entered scrutiny reservations and expressed a number of concerns about the increased administrative burden or the possibility to maintain current functioning structures at the national level. The need to avoid overlap with the activities of international organisations, such as the WHO and the Council of Europe, as well as to build on the already existing structures, was emphasized. Some delegations also pointed to at the unclear link between this proposal and the proposal for a Directive on the application of patient's rights in cross-border healthcare[5].

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[4] PE421.367v01-00

[5] COM (2008) 414 final

10. The parliamentary scrutiny and linguistic reservations from some delegations were noted.

11. During two detailed discussions, the majority of concerns and comments related to the content of definitions (Article 3) and the content of and relation between Articles 5 (Procurement organisations), 6 (Organ procurement) and 7 (Organ and Donor Characterisation).

12. The content and unclear binding nature of the Annex was also mentioned and it was agreed that its status within the proposal requires further discussion.

13. As regards definitions, the delegations mostly commented on the following:

- authorisation, procurement organisation, transplantation centre: several delegations opposed the potential introduction of a new authorisation procedure. During the discussion the need to clarify the relation between providers, or hospitals, and procurement teams was made clear;

- organ, serious adverse event, serious adverse reaction: it was mentioned that, though several modifications were suggested, these definitions should remain the same as in the Directive on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[6].

Delegations pointed out that all the definitions need to be looked at, together with respective articles.

14. Many delegations had questions and reservations on Articles 4 -7, emphasizing that their mutual relation needed to be clarified. The comments and concerns were, in particular, as follows:

- as regards national quality programmes (Article 4): concerns were expressed about the necessity to introduce new programmes as well as about their binding nature. Some delegations demanded greater flexibility for standards. Questions were raised about existence of international standards; the Commission mentioned work done by the Council of Europe which should be respected.

[6] OJ L 102, 7.4.2004, p. 48

- as regards procurement organizations (Article 5) and organ procurement (Article 6): the discussion revealed interpretation problems as regards the exact meaning of a procurement organization (is it a coordination body, hospital, procurement team?). It was mentioned that the procurement procedure should be as clear as possible, based on a minimum set of rules. Several delegations proposed to make a clear difference between Article 5 and 6 so that Article 5 would cover only organizations coordinating procurement and Article 6 the actual surgical procurement.

  In Article 6 several delegations opposed detailed specification of standards for operating theatres, preferring a rather general reference to a safe surgical procedure. The detailed reference to national and international regulations, standards and guidelines was also considered inappropriate.

- as regards organ and donor characterization (Article 7): it was proposed that Article 7 should cover everything regarding the donor.

  The term "qualified laboratory" was also discussed, "qualified" being an unclear concept. It was generally agreed that it should be a laboratory which is capable of performing all necessary tests properly and in good time, without the need to have a specific authorisation or qualification.

III. CONCLUSIONS

15. The Presidency has examined the first seven articles of the proposal and invites the incoming Presidency to build on the progress made and continue with the examination of the proposal.