

COUNCIL OF THE EUROPEAN UNION

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NOTE

from: General Secretariat
to: Council

Subject: EMPLOYMENT, SOCIAL POLICY, HEALTH AND CONSUMER AFFAIRS
COUNCIL MEETING ON 9 AND 10 JUNE 2008

Organ donation and transplantation
- Information from the Commission
(Other business item)

With a view to the Council meeting (Employment, Social Policy, Health and Consumer affairs) on 9 and 10 June 2008, <u>Delegations</u> will find in the annex a note from the Commission on the abovementioned subject.

ORGAN DONATION AND TRANSPLANTATION

INFORMATION FROM THE COMMISSION

The Communication communication on organ donation and transplantation was adopted in May 2007. The Communication identified three priority areas of action: 1) improving quality and safety of organs, 2) increasing organ availability and 3) making transplantation systems more efficient and accessible.

In order to respond to these objectives, the Communication suggested two different mechanisms:

- An Action plan for strengthened coordination between Members States on organ donation and transplantation which would address the main policy challenges outlined in the Communication. Strengthened cooperation between Member States would be a key element in the Action Plan
- An EU legal framework (Directive) on quality and safety of human organs, which would complement the Action Plan. The Directive would introduce the basic principles and technical requirements on donation, procurement, testing preservation, transport and distribution, so as to ensure the quality and safety of human organs.

On 6 December 2007, the Council adopted conclusions in line with the Commission's Communication and invited the Commission to continue its examination of the need for an EU framework on the quality and safety of organ donation and transplantation, as well as to coordinate, promote and strengthen the cooperation between the Member States on these, on the basis of agreed objectives and priorities.

On 22 April 2008, the EP adopted by a huge majority a report on the Communication. The report welcomes the approach taken in the Commission's Communication and acknowledges the need for legislative action at European level. On several issues the resolution challenges Member States and the Commission to take more concrete and immediate action, among which action to prevent organ trafficking and "transplant tourism".

Over the last 12 months, the Commission has held four meetings with national experts, mainly focused on technical requirements for quality and safety of human organ donation and transplantation and priority areas for the proposed Action Plan.

In addition, a Key Stakeholders meeting with 16 European associations (professionals, patients and industry) met for the first time on 19 February 2008. A second consultation with stakeholders focused on the draft impact assessment of the proposals and took place on 23 May 2008, with the participation of some 30 organisations.

Both the national experts' group and the key stakeholders' group were positive and supportive of the Commission's efforts to develop a broad Action Plan, with Member States' cooperation, as well as an EU framework.

The proposed Directive and Action plan are expected to be adopted by the Commission during the second half of 2008.