EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Brussels,
SANCO C6

KEY STAKE HOLDERS MEETING
ON ORGAN DONATION AND TRANSPLANTATION

BRUSSELS 19 FEBRUARY 2008
9:00 – 16.30

SUMMARY REPORT

The key Stakeholders meeting on organ donation and transplantation was held in Brussels on 19 February 2008 and chaired by Maya Matthews, (DG SANCO C/6). Fourteen European level organizations were represented by 19 experts.[1]

1. WELCOME AND INTRODUCTORY REMARKS

The Chair welcomed the participants to this first EC key stakeholders meeting in the field of organ donation and transplantation and commented on the growing interest by stakeholders and the media in this field.

The aim of the meeting was to introduce the stakeholders to the draft EC working documents on organ donation and transplantation and to have a frank and open exchange of views. The chairwoman underlined the fact that these working documents do not represent the official position of the European Commission or its services and should not prejudge the form or content of any future proposals by the European Commission.

2. PRESENTATION OF THE COMMISSION ACTIONS ON ORGAN DONATION AND TRANSPLANTATION.

Eduardo Fernandez Zincke, (SANCO C/6) gave an overview of EU polices to date in the field of organ donation and transplantation. This was followed by a presentation on the Commission's working documents on organ donation and transplantation that propose an an action plan for strengthened cooperation with Member States and a legislative framework for quality and safety in relation to the donation, procurement, testing, transport, preservation, transplantation and characterisation of human organs.

3. WORKING DOCUMENT ON AN ACTION PLAN ON ORGAN DONATION AND TRANSPLANTATION.

The Commission presented the five key objectives of the draft working document:

[1] ANNEX 1: List of Participants

- Increase organ availability
- Promote the implementation of programmes of living donation
- Increase public awareness
- Make transplant system more efficient and accessible
- Improve quality and safety

This report summarises the exchange of views on each of the key objectives.

3.1. Objective 1: Member States should reach the full potential of deceased donation

Most participants agreed that increasing organ availability was a very important goal as there is a huge gap between the numbers of organs needed for transplantation and the numbers of organs available. However, some participants remarked that the term **"full potential"** needed clarification**.** Questions were raised by some participants concerning the two different methodologies used to count 'donor potential' (the European system of donor per million population versus the American system of donor converter). A discussion followed on the advantages and disadvantages of compulsory donor reporting and voluntary reporting.

The profile of the **donor coordinator** or **transplant coordinator** differs from country to country but the general concept of a dedicated person based in a hospital with overall responsibility for the donation and transplantation process was supported. The concept of 'area donor coordinators ' was also mentioned as another level of support that could contribute to increased transplantation rates.

Most participants agreed that donor coordinator training at EU level should be promoted.

The use of **expanded donors** as a means to increase organ availability was discussed and this issue raised many sensitive questions about definitions of expanded donors (age, disease status) and whether this conflicted with the goals of quality programmes. The access to transplantation for patients with rare diseases was also raised and it was felt that more data collection and exchange of information was needed on this matter.

3.2. Objective 2: Member States should promote the implementation of programmes of living donation following best practices

There was a lively discussion on the lack of consensus among European countries on legal and ethical dimensions of living donation. Participants voiced a common concern to protect living donors and were in agreement on the creation of a legally binding registry for living donation. Another suggestion was the creation of a 'safety package' for each living donor (for example, long term health care, life insurance, job security etc.) However, it must be assured that donation is made on a voluntary and altruistic basis and this package does not become an incentive for donation.

3.3. Objective 3: Increase public awareness on organ donation

The discussion on public awareness centred on whether organ donation should be targeted to specific groups or should be addressed to the general public. Several participants expressed their preference for campaigns addresses to general public, others thought that targeting specific groups might backfire unless handled with great sensitivity. Discussing organ donation at a young age, in a sensitive manner was also seen as beneficial in the long run. A key issue was to discuss organ donation with ones family and awareness campaigns could help to trigger this.

Most participants felt that a European Donor Card was a good visual symbol for increased awareness across Europe but were cautious about how it could be integrated into the different transplantation systems. There was a discussion on the symbolism of registries versus their effectiveness.

One participant stated that building public confidence in the health system in general and the transplantation system in particular was best way to increase organ availability.

Another participant called for awareness raising campaigns to include a public 'thank you' to donors and their families.

3.4. Objective 4: Make transplant system more efficient and accessible

Participants felt that in order to improve efficiency and accessibility of transplant systems, one needed comparable indicators and benchmarks. More work on methodology and definition of what constitutes efficient systems was needed. Exchanging best practice from different countries was an important first step. Increasing the number of specialised courses available on transplant medicine at European level is important. The experiences of patient organisations in transplantation should also be taken into account when defining quality programmes.

It was felt that the use of structural funds to strengthen transplantation systems should be explored with specific focus on the next budgetary term (from 2013 onwards).There was a discussion on increasing accessibility for urgent and hard-to-treat patients via cross border exchanges which can be particularly useful for smaller countries but the general feeling was that the focus should be increasing organ availability within countries. Questions were raised on how patient mobility in Europe would interact with national transplantation waiting lists.

3.5. Objective 5: improve quality and safety

The Commission presented the draft working paper on a quality and safety framework on donation, procurement and testing, transport, preservation, transplantation and characterization of human organs.

Participants were generally supportive on the need for a legal framework on quality and safety and appreciated the flexible nature of the framework. Support for the chapter on living donor protection was particularly strong., suggesting the creation of a compulsory registry for living donor with the aim to avoid the trafficking of organs. Many participants remarked again on the need for long term follow up of

living donors. There was also discussion on the importance to collect data on post-transplant follow up and follow-up on living donors.

There was a question on including artificial organs under the scope of the Directive, however, according to Art. 152 of the Treaty, the legislative competence of the commission is limited to substances of human origin.

Participants welcomed the need for more coherent and systematic data collection on transplantation since currently most data sources come from the United States.

4. CONCLUSIONS AND NEXT STEPS

The meeting concluded with a *tour de table* of the participants. There was general agreement that the meeting had been informative and useful. The participants encouraged the Commission to continue their work on developing an action plan with a directive on quality and safety. The key issues that the stakeholders wanted to emphasise were:

- The need for more investment in education and research in transplantation, including the situation for patients with rare diseases
- Continue to work on quality and safety as this will build confidence in general public and lead to increase in donors
- Further attention should be given to preventing organ trafficking and the ethical and legal issues associated with the supply and demand of organs

The chair thanked the participants for their thoughtful advice and sharing their experiences with the group. She welcomed their positive outlook on the working documents and looked forward to continued collaboration.

ANNEX 1: LIST OF PARTICIPANTS

European Society of Organ Transplantation
Ferdinand Muehlbacher
Rutger J. Ploeg

HOPE European Hospital and Healthcare Federation
Pascal Garel
Karolina Hanslik

Alpha One Foundation and Alfa Europe
Mr Larry Warren

European Kidney Patients Federation (CEAPIR)
Mark Murphys

Cystic Fibrosis Europe
Birgit Dembski

European Kidney Health Alliance
Josep Maria Grinyo Boira

European Organisation for Rare Diseases
Flaminia Macchia

European Transplant Coordinator Association
Francesco Procaccio
Luboslav Bena

Donor Action Foundation
Leo Roels

European Federation of Pharmaceutical Industries and Associations
Christopher Giot
Celine Van Doosselaere

ELPAT (Organ Transplantation: Ethical, Legal and Psychological Aspects)
Willem Weimar
Leonieke Kranenburg

Organ Exchange Organization Secretariat (OEOS)
Sue Falvey

European Transplant Network
Dr Presmyl Fryda

European Heart and Lung Transplant Federation
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Eduardo Fernandez-Zincke
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