EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Health Law and International

Brussels,
SANCO C6/EFZ/ps D(2008)360266

STAKE HOLDERS MEETING
ON ORGAN DONATION AND TRANSPLANTATION

BRUSSELS 23 MAY 2008
9:00 – 16.30

SUMMARY REPORT

The Stakeholders meeting on organ donation and transplantation was held in Brussels on 23 May 2008 and chaired by Maya Matthews, DG SANCO C/6. The participants had responded to an open invitation posted on the DG SANCO website. The meeting grouped 32 organizations (list attached) covering a range of national and European stakeholders from patient groups, industry, professional organisations and national ministries of health.

1. WELCOME AND INTRODUCTORY REMARKS

The Chair welcomed the participants to the meeting and stressed that the aim of the meeting was to focus the discussion on the potential impacts of the Commission's policy proposals in the field of organ donation and transplantation.

2. THIS WAS FOLLOWED BY A TOUR DE TABLE WITH PARTICIPANTS INTRODUCING THEIR RESPECTIVE ORGANISATIONS. ACTIONS ON ORGAN DONATION AND TRANSPLANTATION

Dr Eduardo Fernandez Zincke (SANCO C/6) gave an overview of EU polices to date in the field of organ donation and transplantation. He made a brief presentation on the Commission's working documents on organ donation and transplantation:

- an action plan for strengthened cooperation with Member States
- a legislative framework for quality and safety in relation to the donation, procurement, testing, transport, preservation, transplantation and characterisation of human organs

He also detailed several steps of the EU's legislative process, including the timeframe for the adoption of the Organ Package and the importance of the 1 Dec 2007 Council Conclusions and the European Parliament resolution of April 2008.

The Commission underlined that changes would still be introduced into the working documents and invited the stakeholders to send their comments in writing to the Commission by end June 2008.

3. IMPACT ASSESSMENT

The Commission presented the impact assessment process in the European Commission and how it is used at evaluate the impacts of a policy proposal in order to assess whether it is a useful initiative and should be adopted at EU level. Every Impact Assessment should first define the problem, define the policy objectives and provide several policy options. The health, social and economic, impacts of each of these options is then assessed and a preferred policy option is chosen. The Impact Assessment report is presented to the Impact Assessment Board for approval. This is intended to take place in July 2008.

In this case, four policy options were presented to the stakeholders:

1. No new EU policies – status quo
2. EU Action Plan for strengthened MS cooperation only
3. EU Action Plan for strengthened MS cooperation with a flexible legislative framework on quality and safety standards
4. EU Action Plan for strengthened MS cooperation with a stringent legislative framework on quality and safety standards based on the Tissues and Cells Directive (EC/ 2004/23

Jan Tiessen, from Rand Europe, presented the research Rand Europe had undertaken to support the Commission in the development of the Impact Assessment. He noted the difficulty in finding data on specific aspects of the policies such as cost data and welcomed any data on organ donation and transplantation that participants had. The presentation illustrated the complex nature of organ donation and transplantation and how the Action Plan and the legislative framework were linked and mutually re-enforced the each other. After much analysis and the modelling of different outcomes (scenarios), RAND Europe's preferred option was number 3.

A debate ensued on the underlying assumption that had been taken into account when modelling future changes in organ donation rates.

4. GENERAL DISCUSSION ON DRAFT IMPACT ASSESSMENT REPORT.

Several general points were raised in the discussion that followed the presentation. One major concern was the lack of reliable data and that there was an element of guess work rather than scientific research underlying the impact assessment. The need for post-transplant research and following living donors through a registry was stressed as a mean of monitoring and filling the data gap. The need to address rare diseases and whether these policies would increase the ability of patients with rare diseases to receive transplants was raised. This was also mentioned in the context of health inequalities and how these policies would address the disparities in organ transplant rates across Europe. In fact, it was suggested to show data per organ transplanted by country. There was also a discussion on the usefulness of using data in terms of donor per million population rather than conversion rates - the potential number of donations successfully transformed into transplants.

Numerous participants mentioned that EU action in organ donation and transplantation should build on existing MS and stakeholder initiatives. The new proposals should not act as disincentives to hospitals to continue to provide organs for transplantation. The Commission reassured the stakeholders that this was an important issue which would be taken into account. One of the aims of the policy proposals was to increase organ availability.

There was also a discussion on the use of targets and benchmarking and how useful these were. One of the major bottlenecks in organ donation was family refusal and how would this be addressed in the EC proposals. The Commission responded that many of the proposed actions in the Action Plan, such as promoting the use of transplant coordinators and the carrying out of public awareness campaigns that build public confidence in the transplant system could address family refusals.

5. DISCUSSION ON SPECIFIC IMPACTS

The afternoon was devoted to a discussion on the specific impacts presented in the draft impact assessment study.

5.1. Health impacts

Most participants agreed that health impacts would be positive and that options 3 and 4 would provide the biggest heath impact because MS would be obliged to set quality and safety standards. In MS with well developed transplant systems, the health impact may not be as big. There was some concern that a new system of quality and safety might be jeopardise some existing systems. Therefore the more flexible Option 3 would be preferred because it is less prescriptive and more process based.
Another participant pointed out that the analysis of the health impacts of different organs such be specified because of the big differences in risk. The risk to the living donor could also be considered.

The participants seemed to agree on the benefits of cross-border exchanges, even for larger countries, and stronger positive wording was subsequently asked on this point..

5.2. Economic impacts

There was a discussion on the methodology used in the impact study for costs. The cost of immune-suppression medication post transplant should be factored in. Others mentioned the cost of second opinions and the costs for the living donor post operation. One participant suggested that a a global figure for savings was insufficient, that an estimate of costs and savings per patient would be much more explicit. It was clear that more data is needed to really assess the economic impacts that the proposals would have. Furthermore, we need to look at employment prospects for transplant patients as well.

5.3. Social impacts

These seemed difficult to measure and RAND asked for input from the participants. One of them suggested considering the effects on families waiting for transplants. Another promised data on the positive impact for donor families.

The debate ensued on the benefits of public campaigns and on the opportunity of having a EU-wide one. It was also suggested that an initiative should be made to promote the employment prospects of transplant patients.

It was suggested that the cross-border exchanges could also give rise to a general feeling of European solidarity.

6. CONCLUSIONS AND NEXT STEPS

The meeting concluded with a *tour de table* of the participants, who were asked to explain what they thought was the most important element that the impact assessment should contain. There was general agreement that there was a need to act at EU level and the impact assessment should illustrate this point. Several participants felt it was important to stress the cost-effectiveness of organ donation with more data on the economic impacts and the need for more training of surgeons and transplant professionals. There was also concern that the Impact assessment did not address organ trafficking or organ tourism. Finally, some participants welcomed more discussion on data collection, targets and benchmarking.

The chair thanked the participants for their input and welcomed their positive outlook on the working documents.

Stakeholders meeting on organ donation and transplantation
Brussels, 23 May 2008

PARTICIPANTS' LIST

Organisations
The Swedish Transplantation Society
European Directorate for the Quality of Medicines and HealthCare
Dutch Health Council
National Health Service
Burson Marsteller
European Association for the Study of the Liver
Chinese Ministry of Health
The European Social Insurance Platform
Association Interrégionale Italienne des Transplantations
SANCO. 02 Strategy and analysis
Genzyme Health Policy Europe
Ministry of Health, Welfare and Sport (Nl)
UK Transplant
Association Interrégionale Italienne des Transplantations
European Hospital and Healthcare Federation
EKD (Protestant Church of Germany)
Deutsche Stiftung Organtransplanation (DSO)
Representation of the Free State of Bavaria to the European Union
German Transplant Association (DTG)
German Federal Health Ministry
Austrian Federal Ministry of Health, Family and Youth (BMGFJ)
Agence de la biomédecine
European Organisation for Rare Diseases
Scientific Development & Bioethics Division, Department of Health,UK
Donor Action Foundation
German Hospital Federation Health Policy Department
Heart centre, University Hospital Linköping (SE)
RAND
Bristol-Myers Squibb
EDPS
Representation of the Free State of Bavaria to the European Union
Liaison agency Flanders-Europe
Swedish Council for Organ and Tissue Donation