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COMMUNICATION FROM THE COMMISSION

**Action plan on Organ Donation and Transplantation (2009-2015): Strengthened
Cooperation between Member States**

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Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States

1. INTRODUCTION

On 31 May 2007, the Commission adopted a Communication on organ donation and transplantation¹. This Communication and the Impact Assessment² accompanying made a number of suggestions for actions at Community and Member State levels designed to help increase the supply of organ donors across the EU and ensure the quality and safety of these procedures.

The Communication proposed a dual mechanism of action: an Action Plan enhancing active coordination and cooperation between Member States complemented by a legal instrument containing the basic quality and safety principles.

Following the adoption of this first Communication, the Commission started a process of consultation with national experts and key stakeholders with the focus on the quality and safety requirements of human organ donation and transplantation and key priority areas for the proposed action plan. This consultation process enabled the Commission to identify 10 priority actions, which are grouped under three challenges:

- Increasing organ availability
- Enhancing the efficiency and accessibility of transplantation systems
- Improving quality and safety.

2. STRENGTHENED COOPERATION ON ORGAN DONATION AND TRANSPLANTATION

Article 152(4)(a) of the Treaty provides for the possibility of the EC to adopt harmonising measures to ensure organ safety and quality. The same Article (152(2)) also states that Community action should complement national policies directed towards improving public health. The Community has to encourage cooperation between Member States in the areas referred to in this article and, if necessary, lend support to their actions. In this respect, Member States have to liaise with the Commission and coordinate their policies and programmes. Working in tandem with the Member States, the Commission may take any initiatives that might be useful or necessary to promote such coordination.

In the field of organ donation and transplantation in particular, there is huge potential for sharing experience and expertise among EU Member States. This Action Plan aims at reinforcing the cooperation between Member States, through the identification and development of common objectives and guidelines, jointly-agreed indicators and benchmarks, regular reporting, and identification and sharing of best practices.

¹ SEC(2007) 704 – SEC(2007) 705.

² Impact Assessment accompanying the Communication from the Commission to the European Parliament and the Council. Organ donation and transplantation: policy actions at EU level http://ec.europa.eu/health/ph_threats/human_substance/documents/organs_impact_en.pdf

Actions at Community level will complement Member States' efforts to improve the quality and safety of organ donation and transplantation, combat the organ shortage problem and make transplantation systems more efficient. Through the utilization of Community tools, especially the Health Programme 2008-2013, the Commission will provide assistance to the Member States.

3. PRIORITY ACTIONS FOR ORGAN DONATION AND TRANSPLANTATION

In recent years, the Commission has put considerable effort, under different Community programmes, into supporting initiatives in the area of organ transplantation. A large number of projects have been co-funded³, the results of which have generated a considerable amount of information and knowledge. It is very important that further work under the existing programmes should be continued and where necessary extended, involving not only the Member States but also other relevant stakeholders.

Having gathered the information, knowledge and expertise generated in the field of organ donation and transplantation, the Commission has identified a detailed list of priority actions. These objectives and priority actions are dispatched under the mentioned 3 challenges. In turn, the Action Plan divides each priority action into various actions enumerated in Annex.

Each Member State will decide what action and measures need to be taken in order to achieve the desired objectives; these will be included in their Sets of National Priority Actions, which should serve as a platform for discussion, exchange of expertise, and identification of best practices in the framework of this Action Plan. The Sets of National Priority Actions should be country-specific and tailored to the specific situation of each Member State.

3.1. Priority Actions for increasing organ availability

Currently, the demand for organs exceeds the number of available organs in all Member States and this demand for organs is increasing faster than organ donation rates. There are currently more than 56 000 patients waiting for a suitable donor organ within the European Union⁴.

There are large differences in practices and results among Member States. Exchanging information and best practices will help countries with low organ availability to improve their availability rates. Implementation of elements of the Spanish Model in Italy, for example, has been very successful in increasing organ donation rates, which demonstrated that changes to the organisation of organ donation and procurement can substantially increase and sustain organ donation rates.

3.1.1. Increasing deceased donations to their full potential

Improvements in the complex process from donor identification to the transplantation of an organ have been shown to have a large impact on organ donation rates⁵. The success of some Member States in increasing organ availability has been largely down to the organisation of the process, which shows that some ways of organising the organ donation process might be better suited to achieving high availability of organs than others⁶. The combination of an efficient system for organ donor identification, detection and procurement has been identified

³ A description of the projects is available in the Impact assessment attached to this Communication.

⁴ Council of Europe (2007).

⁵ See, for example, Roels et al. (2002) and Simini (2000).

⁶ ALLIANCE-O (2007b).

as one of the keys to increasing the deceased donation. In particular, the presence of a key donation person at hospital level (transplant donor coordinator), whose main responsibility is to develop a proactive donor detection programme, is the most important step towards optimising organ donation and improving donor detection rates⁷.

Member States should therefore aim to incorporate in their Sets of National Priority Actions the objective of gradually appointing **Transplant Donor Coordinators (Priority Action 1)** in all hospitals where there is potential for organ donation. The Commission could have a coordinating and monitoring role in this respect; for that purpose Member States should be encouraged to report to the Commission the number of hospitals that have appointed a transplant donor coordinator. Building on this principal objective, the Action plan must help to establish internationally recognised standards for transplant donor coordinator programmes in the forthcoming years of the Action Plan and promote the implementation of effective training programmes for transplant donor coordinators⁸. At a later stage the Commission and the Member States should aim to establish European or international accreditation schemes for transplant coordinators.

Of equal importance is to promote **Quality Improvement Programmes for organ donation (Priority Action 2)** in every hospital where there is potential for organ donation. These programmes are primarily a self evaluation of the whole process of organ donation⁹ according to the characteristics of the hospital and the health system. These will make it possible to compare results and thus to pinpoint areas for improvement. Consequently, it will also be beneficial to promote accessibility to and training for a specific methodology in relation to these Quality Improvement Programmes.

3.1.2. Living donations as complementary to diseased donations

Being complementary to deceased donation, living donation is a real alternative to improving the availability of organs for transplantation. Member States should therefore deploy the Action Plan to **promote the exchange of best practices on living donation programmes (Priority Action 3)**.

The Action Plan therefore aims to the promotion of altruistic donation programmes and the development of registration practices regarding living donors in order to assess and guarantee their safety.

The Commission will help to develop adequate tools to facilitate the proper collection of information on the medical, psychological, financial and social consequences of a living donation – in the short and the long term. This information, coupled with the exchange of best practices on living donation programmes among the Member States, should help to develop evidence-based guidelines and consensus documents, and address the selection, evaluation and follow-up of the living donor. Registers of living donors should be established to facilitate monitoring and follow-up. All of these measures must be in compliance with the existing European legal framework on the protection of personal data consisting in particular of the Data Protection Directive 95/46/EC.

⁷ Council of Europe Recommendation (Rec (2005)11) on the role and training of professionals responsible for organ donation.

⁸ ETPOD.

⁹ Council of Europe Recommendation (Rec (2006)16) on quality improvement programmes for organ donation.

3.1.3. *Increasing public awareness*

The success of the Spanish Model has shown that investing heavily in public awareness campaigns does not always yield the expected results. Great attention must be paid to the specific information given to the media: systematic and comprehensive information should be provided about organ donation and transplantation through media outlets. Researchers have argued that the use of the mass media in Spain on the issue of organ donation has greatly influenced the creation of a positive social atmosphere around organ donation and transplantation¹⁰.

It has been proven that there is an important positive correlation between having discussed the issue of donation within the family and the willingness to actually donate organs. Since public awareness and opinion play a very important role in increasing organ donation rates, continuing education should form an essential part of all Member States' communication strategies on the issue. People should be encouraged to speak about organ donation and to communicate their wishes to their relatives. Only 41% of European citizens seem to have discussed organ donation within their families¹¹.

There is therefore a need **to improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation (Priority Action 4)**. Awareness campaigns should include information regarding the rights citizens and patients have concerning organ donation and transplantation in different Member States. The Commission can actively contribute by helping Member States to collect this kind of information.

People's mobility also underlines the need to **facilitate the identification of organ donors across Europe and cross-border donation in Europe (Priority Action 5)**. The Commission will help Member States to develop identification mechanisms.

3.2. **Priority Actions for enhancing the efficiency and accessibility of transplantation systems**

Even among EU countries with well-developed health and organ transplant services, there are still considerable differences in organ donation and transplantation activity. It is clear that some organisational systems are performing better than others. Hence, initiatives focused on identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics are promoted by the Action Plan.

3.2.1. *Supporting and guiding transplant systems*

The Action Plan calls on Member States to enhance the efficiency of transplant systems **(Priority Action 6)**. To this end, they will develop their own Sets of National Priority Actions in 2009. These will provide the basis for an overall evaluation of the success Member States have in achieving the aforementioned common objectives.

Member States should then aim to establish, in close collaboration with the Commission, a common set of indicators to monitor organ policy and a methodology to evaluate the potential in each Member State. Common definitions of both terms and methodology need to be adopted in order to evaluate the results of transplant systems. The Commission will help Member States achieve this objective in particular by issuing *ad hoc* recommendations on the basis of regular reporting. The Action Plan further encourages Member States to promote the twinning of projects and peer review programmes, which should be part of a voluntary,

¹⁰ Matesanz and Miranda (2002). Also Matesanz and Miranda (1996).

¹¹ Eurobarometer survey 2006.

mutual learning process. Peer reviews should encompass scrutiny of existing policies, programmes or institutional arrangements that have been identified as good practice in the various Sets of National Priority Actions. This could prove to be a useful tool for Member States when designing and implementing more efficient and effective policies.

3.2.2. Interchange of organs between Member States

The exchange of organs is already common practice between Member States. There are, however, significant differences between the number of organs exchanged across borders between Member States that have set up bodies and rules for the international exchange of organs, such as Eurotransplant and Scandiatransplant, and the other Member States. Participants in the Eurotransplant area exchange around 20% of all organs transplanted each year (around 3 300 organs) between each other, while only 2% of organs leave or enter the Eurotransplant area. Without such comprehensive exchange agreements Member States exchange far fewer organs, but the rate can potentially increase if there are bilateral agreements in place¹².

These differences in exchange rates indicate that the full potential of exchanging organs has not yet been reached. If there is no exchange of organs between Member States, then recipients that need an infrequent match will have very low prospects of finding an organ, while at the same time donors will not be considered because there are no compatible recipients on the waiting lists. This is of particular relevance to "difficult-to-treat" patients (paediatric, urgent or hypersensitised patients that require very specific matching) and for small Member States in general. The Action Plan thus aims to have a system or a structure for the **exchange of organs for urgent patients and difficult to treat patients (Priority Action 8)**. An IT tool to support this action could be designed with guidance from the Commission and Community funding. Moreover, the Commission will support the Member States in the development of a structured system for exchanges of surplus organs between them.

3.2.3. EU-wide agreements on aspects of transplant medicine

The Action Plan strongly supports **EU-wide agreements on various aspects of transplant medicine (Priority Action 7)**. A cooperation method is the ideal context to discuss issues of mutual concern and come up with common and shared solutions and monitoring mechanisms. For instance, Member States are advised to establish such EU-wide agreements to deal with all aspects concerning transplant medicine for extra-Community patients.

This cooperation method seems especially pertinent to identifying the main challenges of increasing patient mobility, in particular in border regions and small Member States. The Action Plan recommends that EU-wide agreements be put in place to tackle the basic rules for internal EU patient mobility in respect of transplantation, in compliance with the principle of free movement of recipient of services as provided for in the EC Treaty and in Community legislation. These agreements will facilitate the relevant procedures in practice and solve any problems surrounding the equitability of transplantation systems.

A common understanding of the priorities and strategies of future research programmes on organ donation and transplantation also needs to be fostered. The creation of a European transplant research network could be considered in the context of an EU-wide agreement setting common priorities and objectives.

¹² For example, Italy now exchanges more organs with Greece and Slovakia, with which it recently signed bilateral agreements (see IGE (2007)).

3.2.4. *Organ trafficking*

One of the potential consequences of organ scarcity is the trafficking of human organs. . Organ trafficking can be linked with trafficking in human beings for the purpose of the removal of organs which constitutes a serious violation of fundamental rights and, in particular, of human dignity and physical integrity. This practice is carried out by organised criminal groups, who track down and remove organs from donors in developing countries and hand them on to recipients within the European Union.

While it is recognised that, ideally, the best way of fighting organ trafficking is to increase the number of available organs, the Action Plan, in the meantime, urges Member States to establish EU-wide agreements on monitoring the extent of organ trafficking in Europe. Given the lack of investigative information on the issue, such agreements will help Member States – through active collaboration and exchange of information – to examine and, at a later stage, find the best ways of monitoring organ trafficking.

At the same time, the Commission will for its part continue to work together with other international organisations such as the Council of Europe and the World Health Organisation in a bid to combat organ trafficking.

3.3. Priority Actions for improving quality and safety

These actions should complement the European legal framework referred to in the Commission Communication on Organ Donation and Transplantation¹³. The future legal instrument will encompass the principles needed to establish a basic quality and safety framework across the EU, including, for example, the creation of national competent authorities and other relevant structures.

3.3.1. *Improving follow-up procedures and registers*

The Action Plan sets out to complement this legal framework by way of a compilation of information in the form of **registers facilitating the evaluation of post-transplant results (Priority Action 9)**, which will in turn help to develop good medical practices in organ donation and transplantation. Evaluating post-transplant results through common definitions of terms and methodology, as suggested in the Action Plan, could help to promote EU-wide registers, if necessary, and in compliance with the existing European legal framework on the protection of personal data consisting in particular of the Data Protection Directive 95/46/EC, or create a methodology to compare the results of existing post-transplant follow-up registers of organ recipients.

In an effort to increase the pool of organs available for transplantation, the use of expanded donors (donors that from a medical point of view can only be considered for specific recipients under specific circumstances) should also be considered. Since, in practice, published experience is not enough to establish safety limits; the Action Plan recommends common definitions of terms and a methodology to help determine acceptable levels of risk in the use of expanded donors. This compilation of information will consequently help to determine acceptable levels of risk in the use of expanded donors.

These actions will ultimately help Member States to develop and promote good medical practices on organ donation and transplantation on the basis of results.

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3.3.2. *Common accreditation system*

The Action Plan also seeks to develop a methodology that could support the EU legal framework in order for Member States to accredit programmes on organ donation, procurement and transplantation. This could help, in the long run, to build a **common accreditation system for organ donation/procurement and transplantation programmes (Priority Action 10)** at EU level and provide support for centres of excellence.

4. CONCLUSIONS AND FOLLOW UP ACTIONS

This Action Plan identified 10 priority actions order to aid Member States address the challenges in the field of organ donation and transplantation. It will promote strengthened cooperation between MS and exchange of best practices as a key element in the strategy.

This cooperation process shall be based on the identification and development of common objectives and guidelines, jointly-agreed quantitative and qualitative indicators and benchmarks and identification and sharing of best practices.

On the basis of these actions Member States should develop their own Sets of National Priority Actions. The Action plan will provide the basis for an overall evaluation of the success Member States have in achieving the aforementioned common objectives. A mid-term review (mid-term review 2012) of the actions will be carried out to evaluate the efficacy of this action plan.

ANNEX I: SPECIFIC ACTIONS PROPOSED

CHALLENGE 1: INCREASING ORGAN AVAILABILITY	
OBJECTIVE 1	
MEMBER STATES SHOULD REACH THE FULL POTENTIAL OF DECEASED DONATIONS	
Priority action 1: Promote the role of transplant donor coordinators in every hospital where there is potential for organ donation.	
Action 1.1 Incorporate in the Set of National Priority Actions the objective of gradually appointing transplant donor coordinators in hospitals. Design indicators to monitor this action.	MS action EC coordinates and monitor
Action 1.2 Promote the establishment of internationally recognised standards for transplant donor coordinator programmes.	EC Action
Action 1.3 Promote the implementation of effective training programmes for transplant donor coordinators.	MS + EC Action
Action 1.4 Promote the establishment of national or international accreditation schemes for transplant donor coordinators.	MS + EC Action
Priority action 2: Promote Quality Improvement Programmes in every hospital where there is potential for organ donation.	
Action 2.1 Incorporate in the Set of National Priority Actions the objective of gradually putting in place Quality Improvement Programmes in hospitals. Design indicators to monitor this action.	MS action EC coordinates and monitor
Action 2.2 Promote accessibility to and training on a specific methodology on Quality Improvement Programmes.	MS action EC coordinates and monitor
OBJECTIVE 2	
MEMBER STATES SHOULD PROMOTE LIVING DONATION PROGRAMMES FOLLOWING BEST PRACTICES.	
Priority Action 3: Exchange of best practices on living donation programmes among EU Member States: Support registers of living donors.	

Action 3.1 Incorporate in the Set of National Priority Actions the promotion of altruistic donation programmes for living donors, with safeguards built in concerning the protection of living donors and the prevention of organ trafficking.	MS action EC coordinates and monitor
Action 3.2 Promote the development of registers for living donors to evaluate and guarantee their health and safety.	MS + EC Action
OBJECTIVE 3 INCREASE PUBLIC AWARENESS OF ORGAN DONATION	
Priority Action 4: Improve the knowledge and communication skills of health professionals and patient support groups on organ transplantation.	
Action 4.1 Incorporate in the Set of National Priority Actions the recognition of the important role of the mass media and the need to improve the level of information to the public on these topics.	MS action EC coordinates and monitor.
Action 4.2 Promote training programmes geared towards health professionals and patient support groups on organ transplantation communication skills.	MS + EC Action
Action 4.3 Organise periodic meetings at national level (competent authorities) with journalists and opinion leaders and manage adverse publicity.	MS action EC coordinates and monitor.
Priority Action 5: Facilitate the identification of organ donors across Europe and cross-border donation in Europe.	
Action 5.1 Collect and disseminate information about citizen's rights concerning organ donation across the EU.	MS + EC Action
Action 5.2 Develop mechanisms to facilitate the identification of cross-border donors	MS + EC Action

CHALLENGE 2: ENHANCING THE EFFICIENCY AND ACCESSIBILITY OF TRANSPLANT SYSTEMS

OBJECTIVE 4

SUPPORT AND GUIDE TRANSPLANT SYSTEMS TO BE MORE EFFICIENT AND ACCESSIBLE

Priority Action 6: Enhancing the organisational models of organ donation and transplantation in the EU Member States.

Action 6.1 Include in the Set of National Priority Actions ad hoc recommendations of the committee of experts to the Member States by way of regular reporting.	MS + EC Action
Action 6.2 Promote twinning projects and peer reviews.	EC Action
Action 6.3 Assess the use of structural funds and other Community instruments for the development of transplantation systems.	EC Action
Action 6.4 Promote networks of centres of reference.	EC Action

Priority Action 7: Promote EU-wide agreements on aspects of transplantation medicine.

Action 7.1 EU-wide agreement on basic rules for internal EU patient mobility and transplantation, in compliance with Community law..	MS + EC Action
Action 7.2 EU-wide agreement on all issues concerning transplant medicine for extra-Community patients.	MS + EC Action
Action 7.3 EU-wide agreement on monitoring organ trafficking.	MS + EC Action
Action 7.4 EU-wide agreement on common priorities and strategies for future research programmes.	MS + EC Action

Priority Action 8: Facilitate the interchange of organs between national authorities.

Action 8.1 Evaluate procedures for offering surplus organs to other countries.	EC + MS action
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Action 8.2 Put procedures in place for the exchange of organs for urgent and difficult-to-treat patients.	EC + MS action
Action 8.3 Design IT tools in support of the previous actions.	EC + MS action
CHALLENGE 3: IMPROVING QUALITY AND SAFETY	
OBJECTIVE 5	
IMPROVE THE QUALITY AND SAFETY OF ORGAN DONATION AND TRANSPLANTATION	
Priority Action 9: Evaluation of post-transplant results.	
Action 9.1 Develop common definitions of terms and methodology to evaluate the results of transplantation.	EC Action
Action 9.2 Develop a register or network of registers to follow up organ recipients.	MS + EC Action
Action 9.3 Promote common definitions of terms and methodology to help determine acceptable levels of risk in the use of expanded donors.	EC Action
Action 9.3 Develop and promote good medical practices on organ donation and transplantation on the basis of results, including the use of expanded donors.	EC Action
Priority Action 10: Promote a common accreditation system for organ donation/procurement and transplantation programmes.	